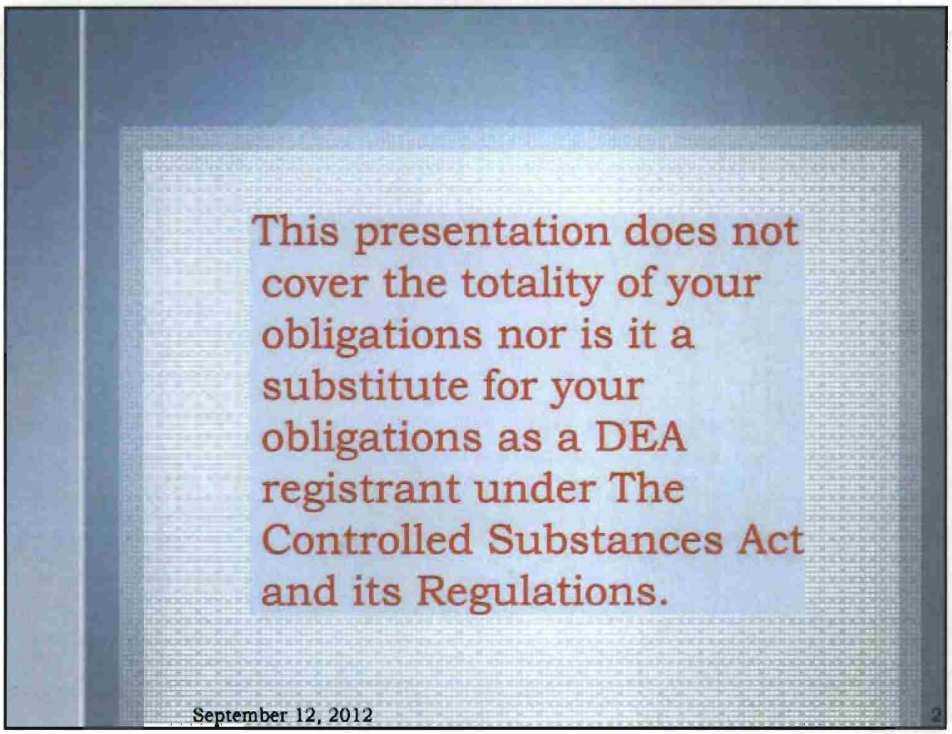
Effective Controls Against Diversion of Controlled Substances

Meeting with
Actavis Elizabeth, LLC
September 12, 2012

PowerPoint


This presentation does not cover the totality of your obligations nor is it a substitute for your obligations as a DEA registrant under The Controlled Substances Act and its Regulations.
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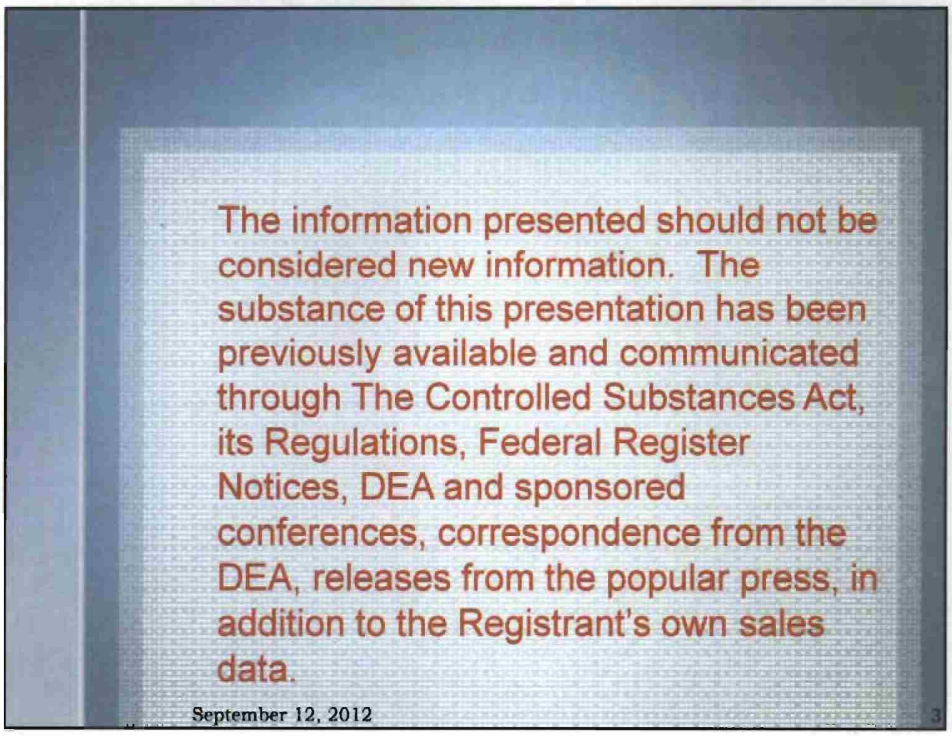
2


The information presented should not be considered new information. The substance of this presentation has been previously available and communicated through The Controlled Substances Act, its Regulations, Federal Register Notices, DEA and sponsored conferences, correspondence from the DEA, releases from the popular press, in addition to the Registrant's own sales data.
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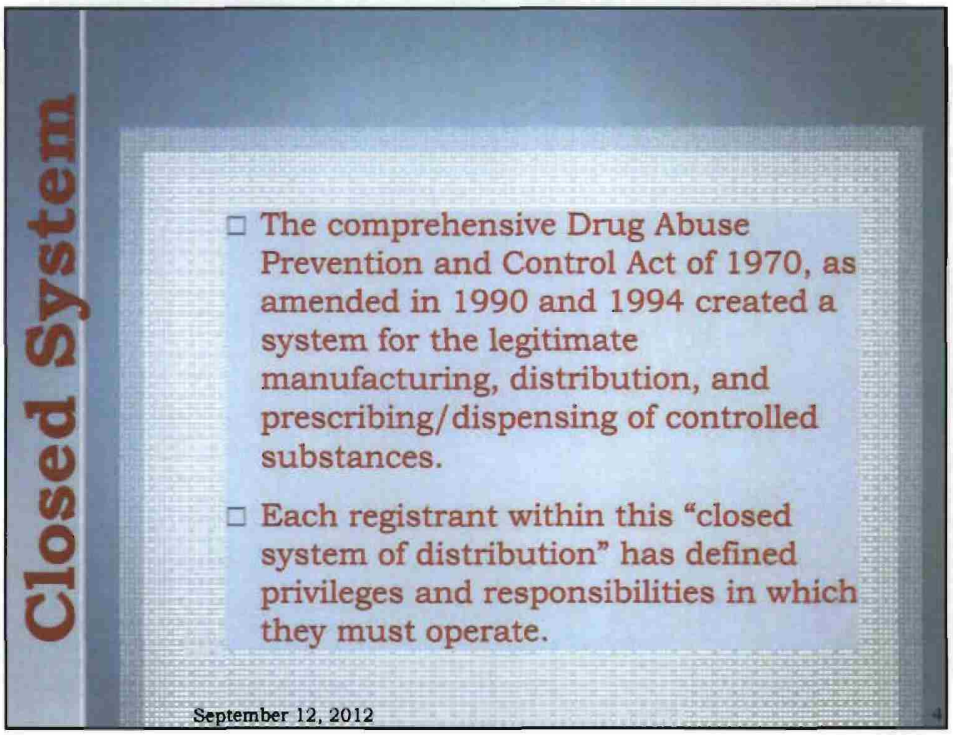
Closed System
The comprehensive Drug Abuse Prevention and Control Act of 1970, as amended in 1990 and 1994 created a system for the legitimate manufacturing, distribution, and prescribing/dispensing of controlled substances.
Each registrant within this "closed system of distribution" has defined privileges and responsibilities in which they must operate.
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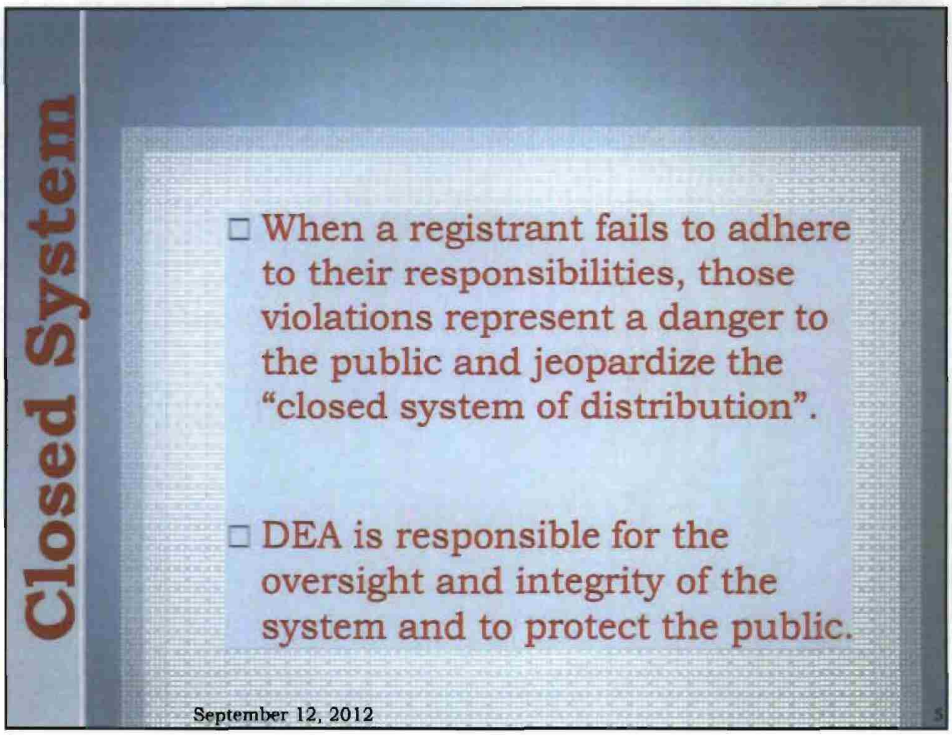
Closed System
When a registrant fails to adhere to their responsibilities, those violations represent a danger to the public and jeopardize the "closed system of distribution".
DEA is responsible for the oversight and integrity of the system and to protect the public.
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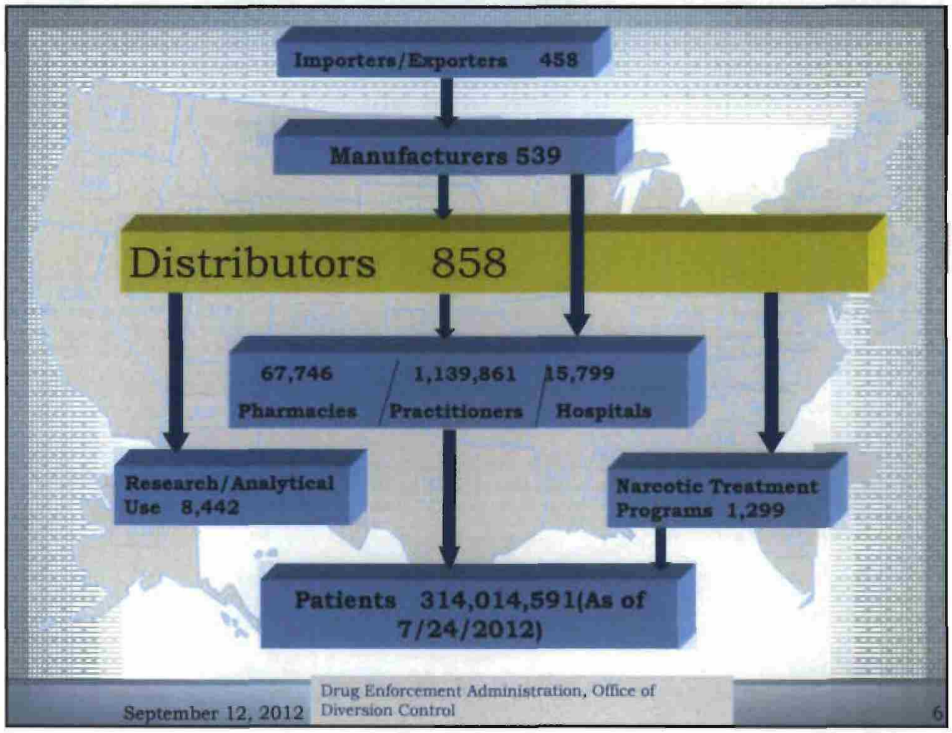
Importers/Exporters 458
Manufacturers 539
Distributors 858
67,746 Pharmacies
1,139,861 Practitioners
15,799 Hospitals
Research/Analytical Use 8,442
Narcotic Treatment Programs 1,299
Patients 314,014,591(As of 7/24/2012)
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Drug Enforcement Administration, Office of Diversion Control
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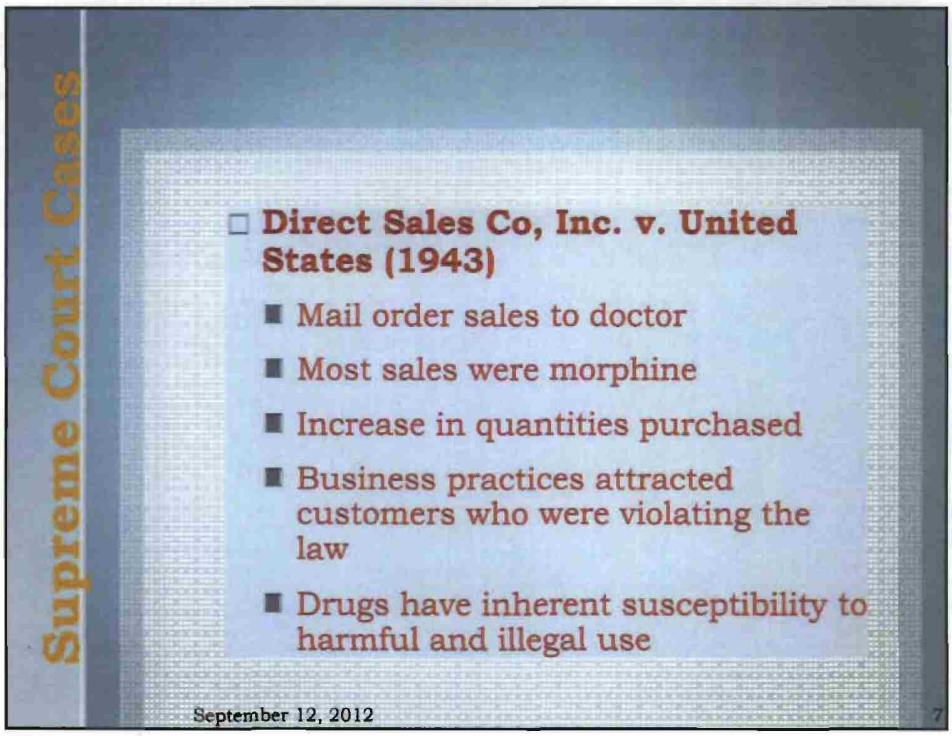
Supreme Court Cases
Direct Sales Co, Inc. v. United States (1943)
Mail order sales to doctor
Most sales were morphine
Increase in quantities purchased
Business practices attracted customers who were violating the law
Drugs have inherent susceptibility to harmful and illegal use
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Supreme Court Cases

- **United States v. Moore (1975)**
  - Usual course of professional practice
    - Patient with a Medical Complaint
    - History
    - Physical Examination
    - Nexus Between Complaint/History/Exam and Drug Prescribed

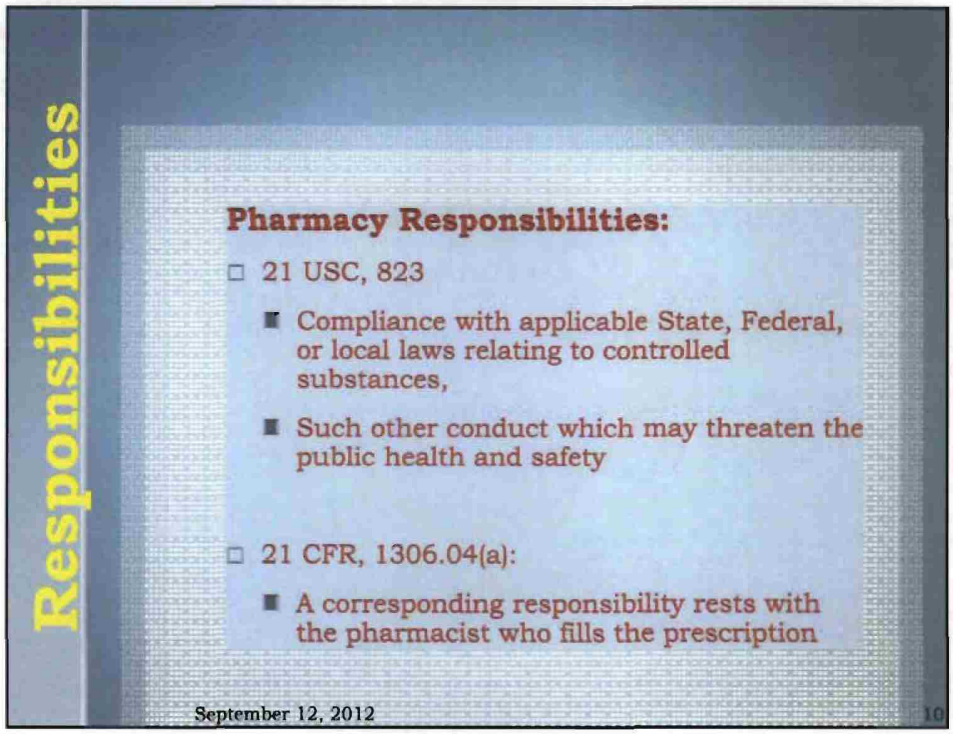
RESPONSIBITIES

Distributor Responsibilities

- 21 USC, Section 823
  - Is the registration in the public interest?

Maintenance of Effective Controls

- Against diversion of particular controlled substances into other than legitimate medical channels


Responsibilities
Pharmacy Responsibilities:
21 USC, 823
Compliance with applicable State, Federal, or local laws relating to controlled substances,
Such other conduct which may threaten the public health and safety
21 CFR, 1306.04(a):
A corresponding responsibility rests with the pharmacist who fills the prescription
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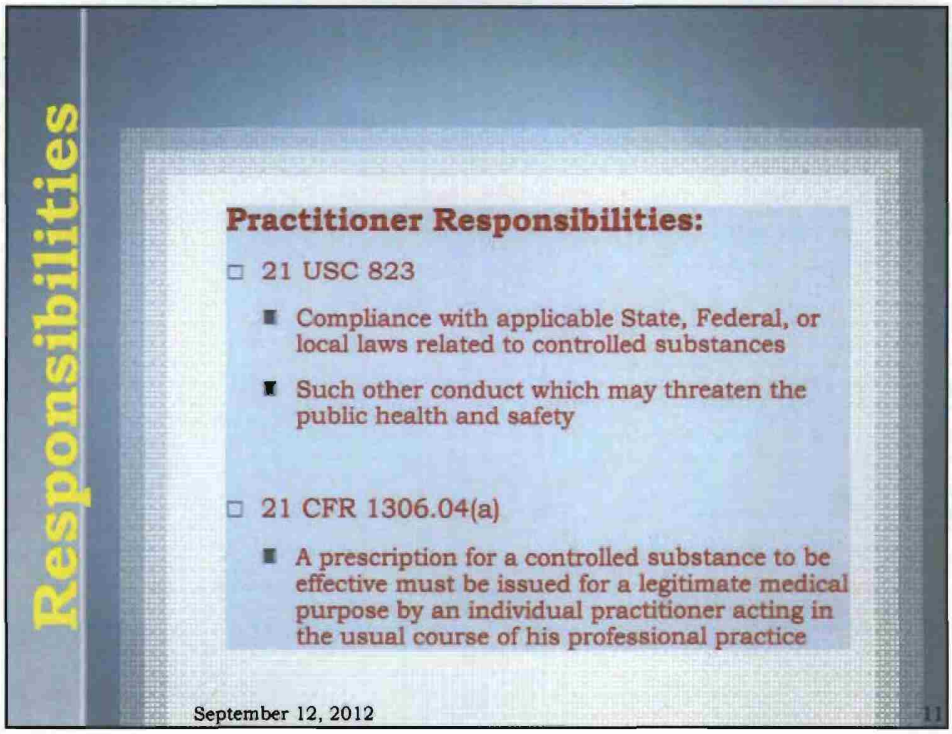
Responsibilities
Practitioner Responsibilities:
21 USC 823
Compliance with applicable State, Federal, or local laws related to controlled substances
Such other conduct which may threaten the public health and safety
21 CFR 1306.04(a)
A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice
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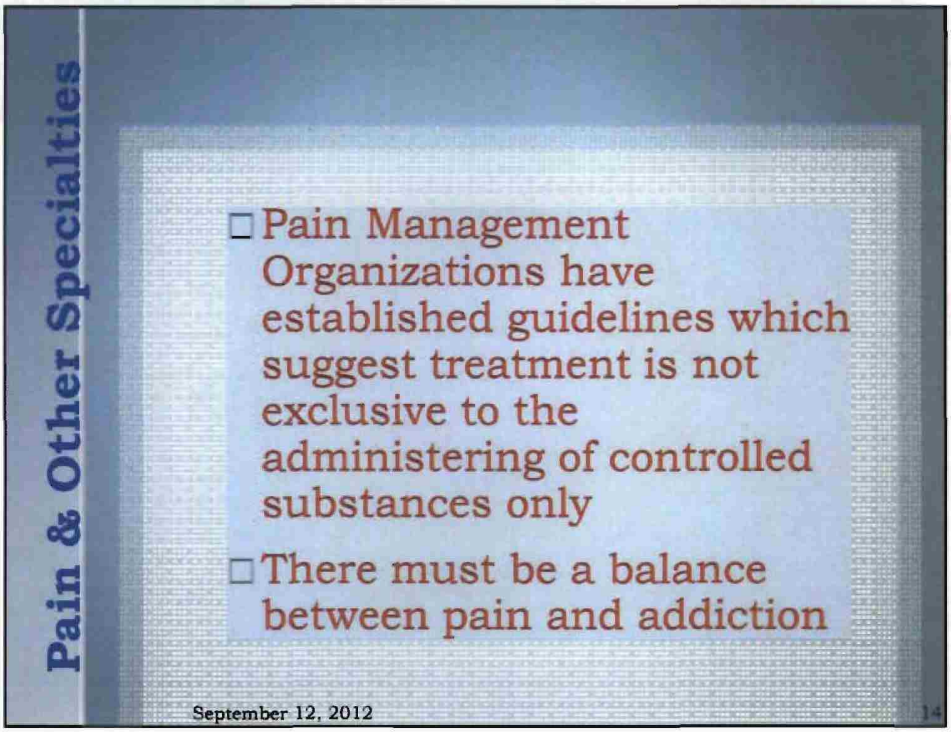
Ryan Haight Act

- MUST be approved prior to any online dispensing. ONLY a previously registered pharmacy who DEA approved with a modification of registration may be an online pharmacy
- A DEA registered pharmacy that is approved to conduct online dispensing MUST notify DEA and the state boards of pharmacy in all states in which they conduct business 30 days prior to offering a controlled substance to sell, deliver, distribute, or dispense

Ryan Haight Act

- An online pharmacy MUST comply with all state laws from which and to which they deliver, or dispense, or offer to deliver or dispense controlled substances by means of the Internet
- A VALID prescription for a controlled substance by means of the Internet MUST be for legitimate medical purpose and have at least one in-person medical examination by a practitioner authorized by DEA and respective State authorities to prescribe controlled substances in that controlled substance schedule


Pain & Other Specialties
Pain Management Organizations have established guidelines which suggest treatment is not exclusive to the administering of controlled substances only
There must be a balance between pain and addiction
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Pain & Other Specialties
Recognized Modalities for the Treatment of Pain:
Pharmacotherapy
Psychosocial Interventions
Rehabilitation Techniques
Complementary & Alternative Medicine
Implantable Devices & Surgical Interventions
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Pain & Other Specialties

- Three Pain Management Associations recommend "Opioid Guidelines"
- Guidelines provide recommended procedures and best practices for a practitioner to implement
- Not an endorsement by the DEA. A guide for you to assess your customers.

Suspicious Orders

21 CFR 1301.74

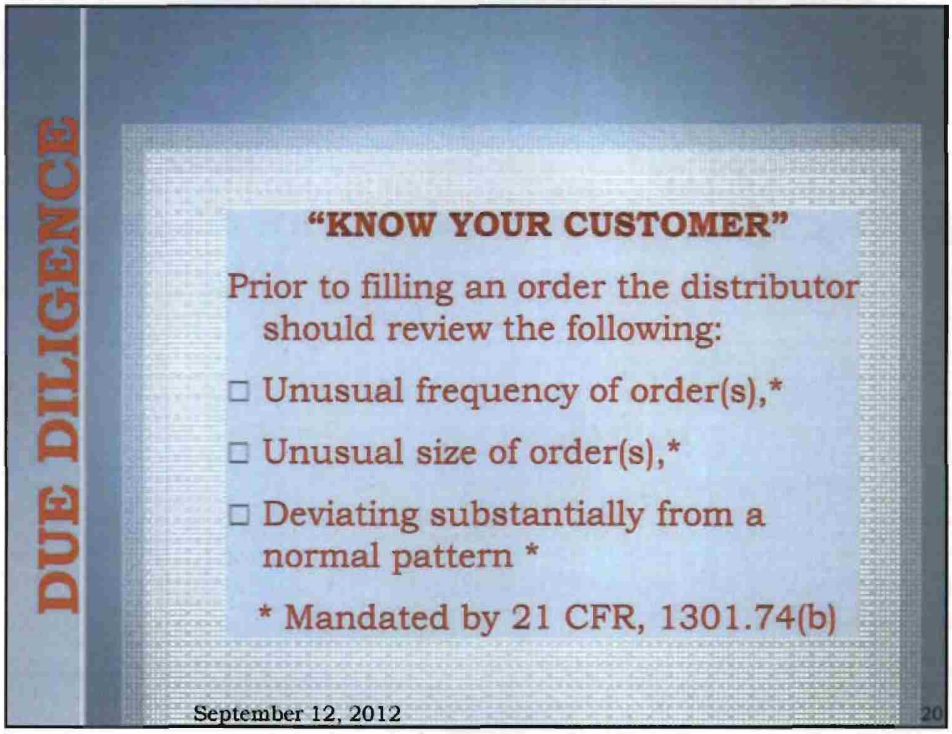
- Requires that registrants design and operate a system to identify suspicious orders
- Report suspicious orders to DEA **when discovered**

Suspicious Orders

Reporting of a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion

Suspicious Orders

- DEA cannot advise a distributor if an order is legitimate or not.
- Distributor must determine which orders are suspicious and make their OWN decision to sell or not to sell


DUE DILIGENCE
"KNOW YOUR CUSTOMER"
Prior to filling an order the distributor should review the following:
Unusual frequency of order(s),*
Unusual size of order(s),*
Deviating substantially from a normal pattern *
* Mandated by 21 CFR, 1301.74(b)
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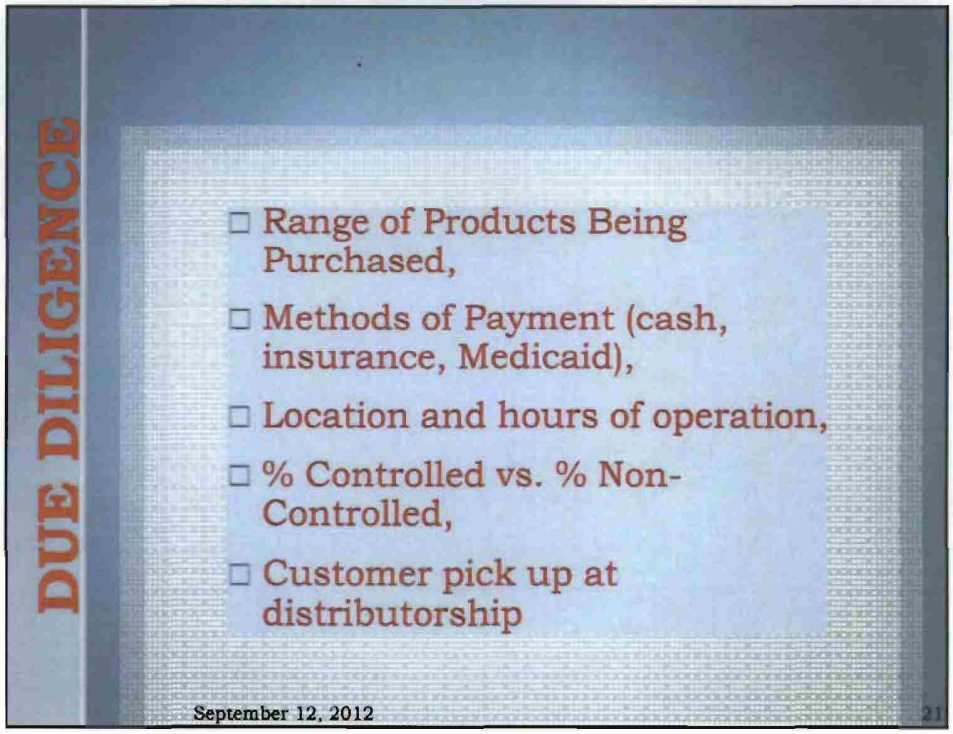
DUE DILIGENCE
Range of Products Being Purchased,
Methods of Payment (cash, insurance, Medicaid),
Location and hours of operation,
% Controlled vs. % Non-Controlled,
Customer pick up at distributorship
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DUE DILIGENCE

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Notifications

- Theft and Loss – Report immediately via on-line.
- Contact your local field office.
- ODGR – Regulatory Unit – (202) 307-7161
- ODG@USDOJ.GOV – Notification of termination of customers for cause. (No explanation required.)

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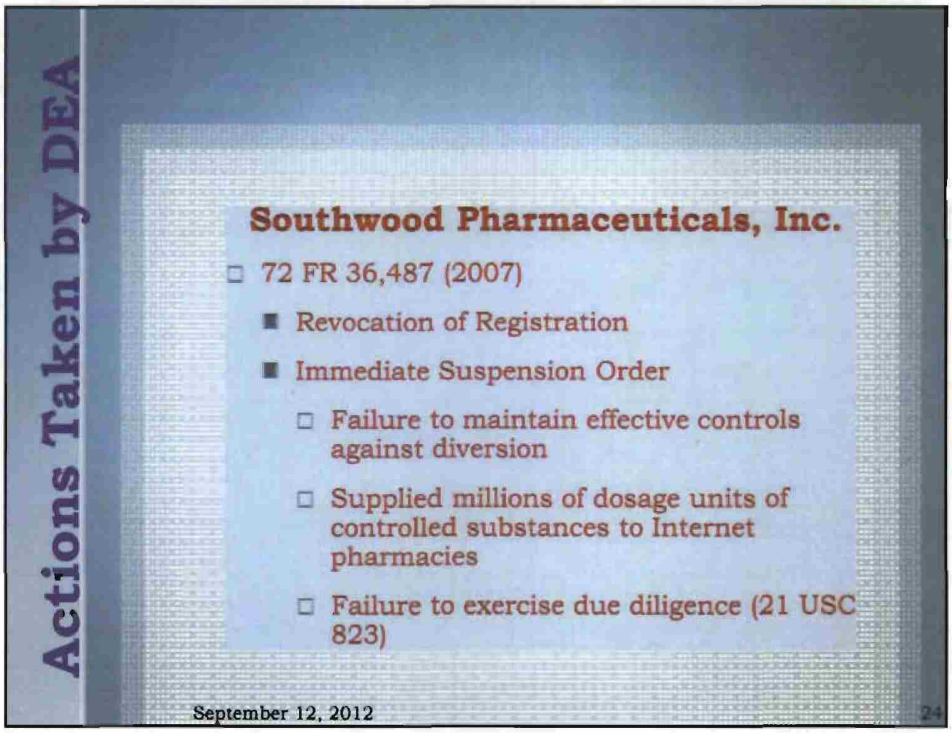
Actions Taken by DEA
Southwood Pharmaceuticals, Inc.
72 FR 36,487 (2007)
Revocation of Registration
Immediate Suspension Order
Failure to maintain effective controls against diversion
Supplied millions of dosage units of controlled substances to Internet pharmacies
Failure to exercise due diligence (21 USC 823)
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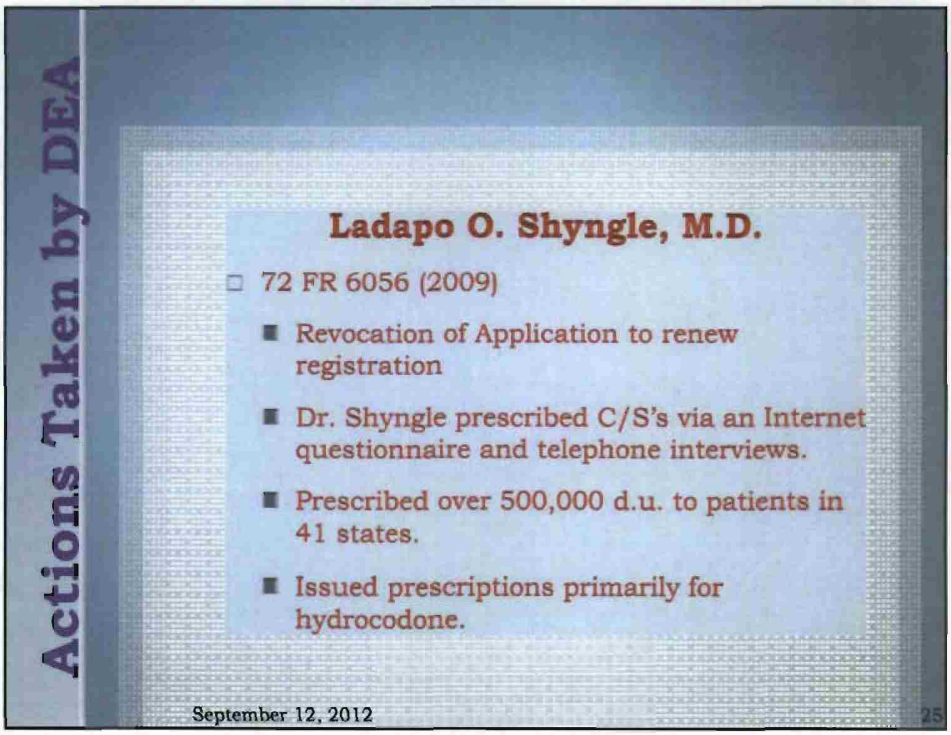
Actions Taken by DEA
Ladapo O. Shyngle, M.D.
72 FR 6056 (2009)
Revocation of Application to renew registration
Dr. Shyngle prescribed C/S's via an Internet questionnaire and telephone interviews.
Prescribed over 500,000 d.u. to patients in 41 states.
Issued prescriptions primarily for hydrocodone.
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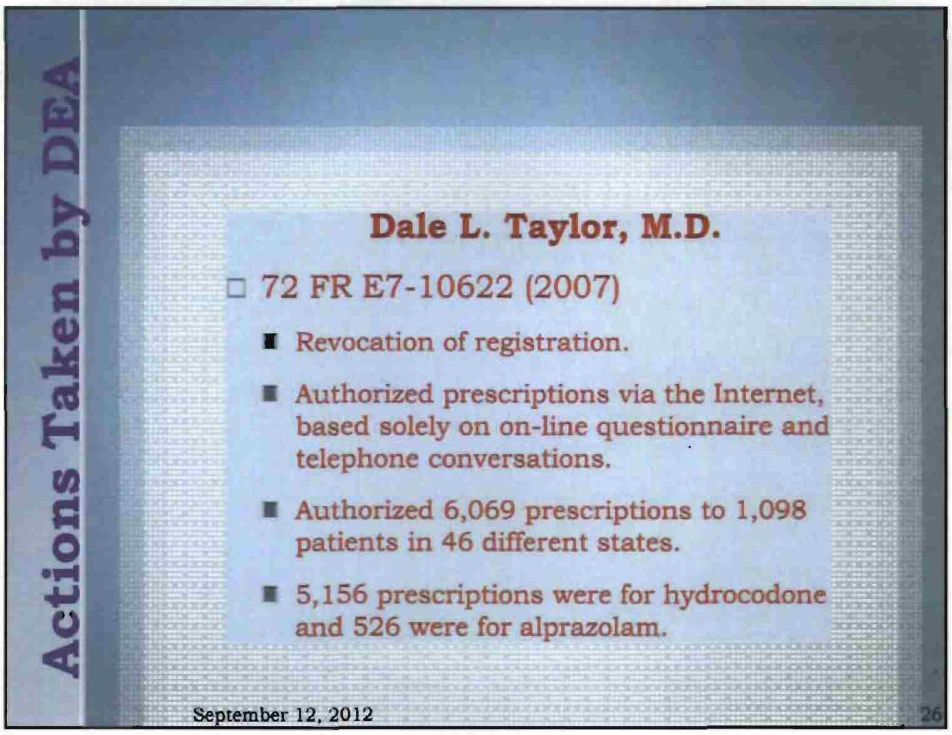
Actions Taken by DEA
Dale L. Taylor, M.D.
72 FR E7-10622 (2007)
Revocation of registration.
Authorized prescriptions via the Internet, based solely on on-line questionnaire and telephone conversations.
Authorized 6,069 prescriptions to 1,098 patients in 46 different states.
5,156 prescriptions were for hydrocodone and 526 were for alprazolam.
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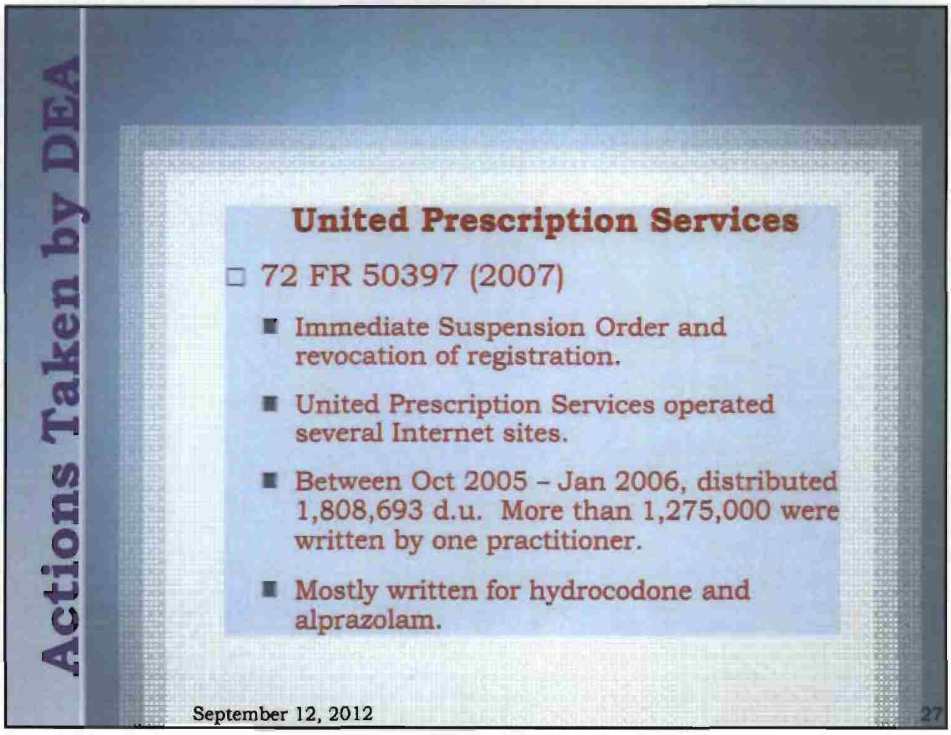
Actions Taken by DEA
United Prescription Services
72 FR 50397 (2007)
Immediate Suspension Order and revocation of registration.
United Prescription Services operated several Internet sites.
Between Oct 2005 – Jan 2006, distributed 1,808,693 d.u. More than 1,275,000 were written by one practitioner.
Mostly written for hydrocodone and alprazolam.
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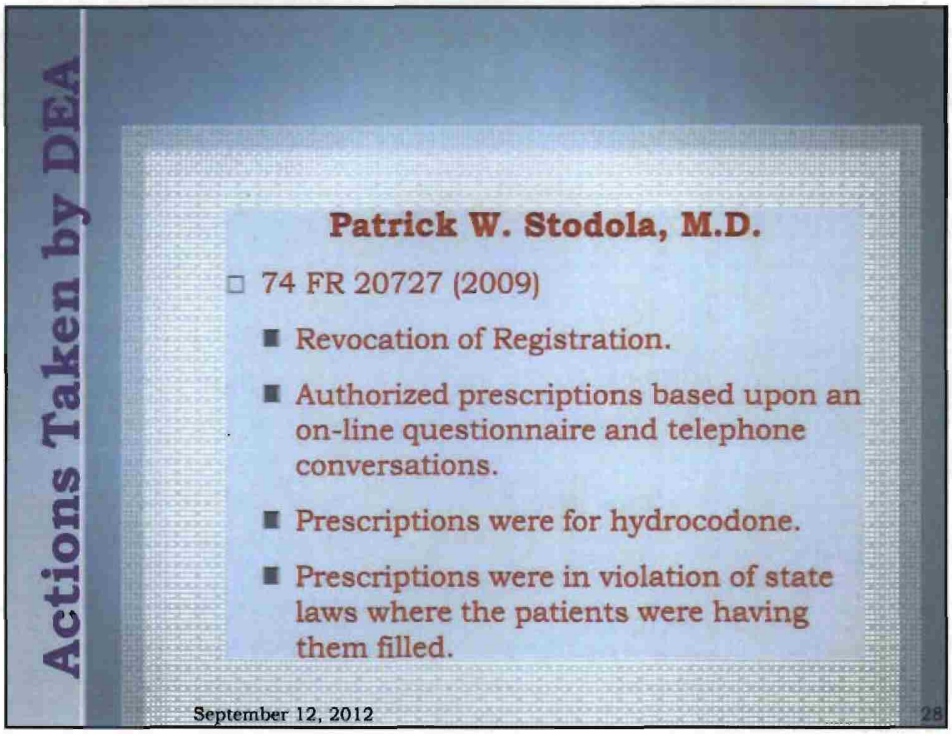
Actions Taken by DEA
Patrick W. Stodola, M.D.
74 FR 20727 (2009)
Revocation of Registration.
Authorized prescriptions based upon an on-line questionnaire and telephone conversations.
Prescriptions were for hydrocodone.
Prescriptions were in violation of state laws where the patients were having them filled.
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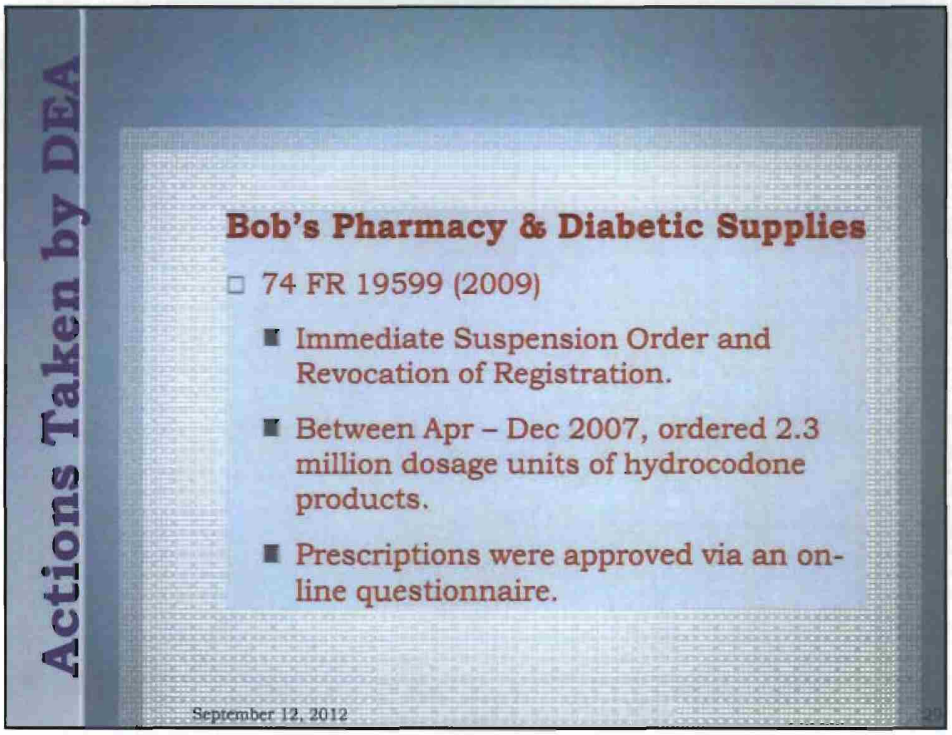
Actions Taken by DEA
Bob's Pharmacy & Diabetic Supplies
74 FR 19599 (2009)
Immediate Suspension Order and Revocation of Registration.
Between Apr – Dec 2007, ordered 2.3 million dosage units of hydrocodone products.
Prescriptions were approved via an on-line questionnaire.
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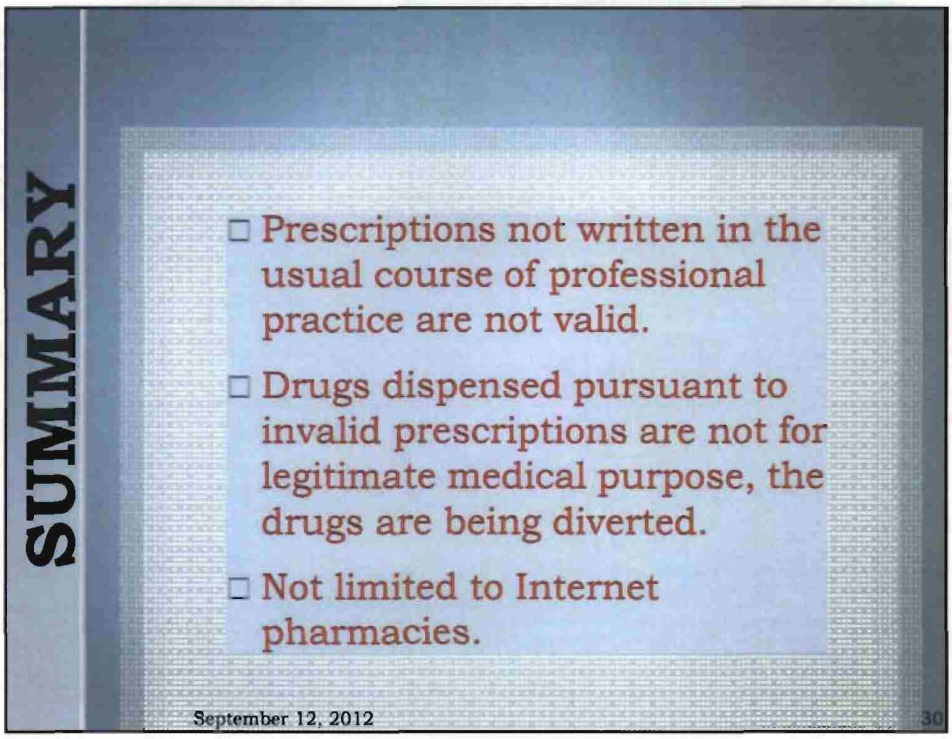
SUMMARY
Prescriptions not written in the usual course of professional practice are not valid.
Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are being diverted.
Not limited to Internet pharmacies.
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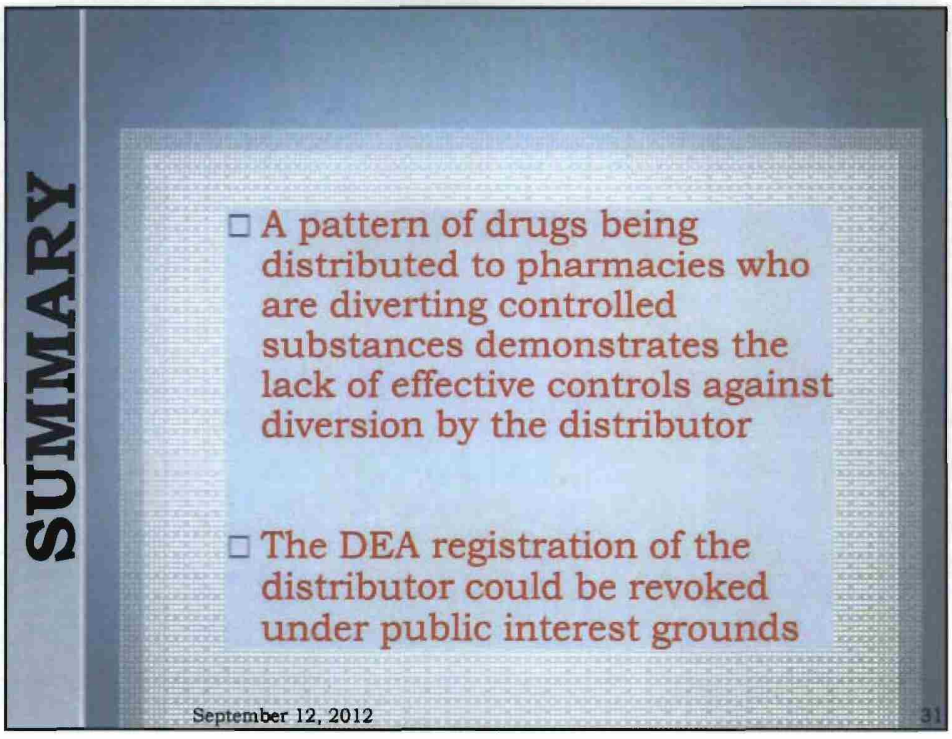
SUMMARY
A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
The DEA registration of the distributor could be revoked under public interest grounds
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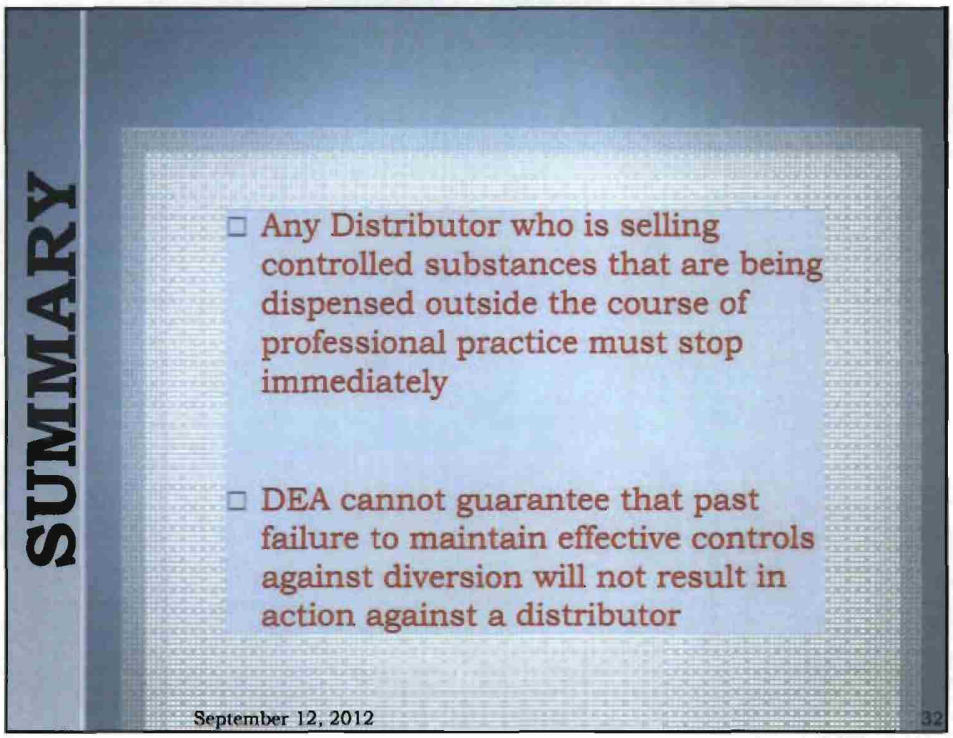
SUMMARY
Any Distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately
DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor
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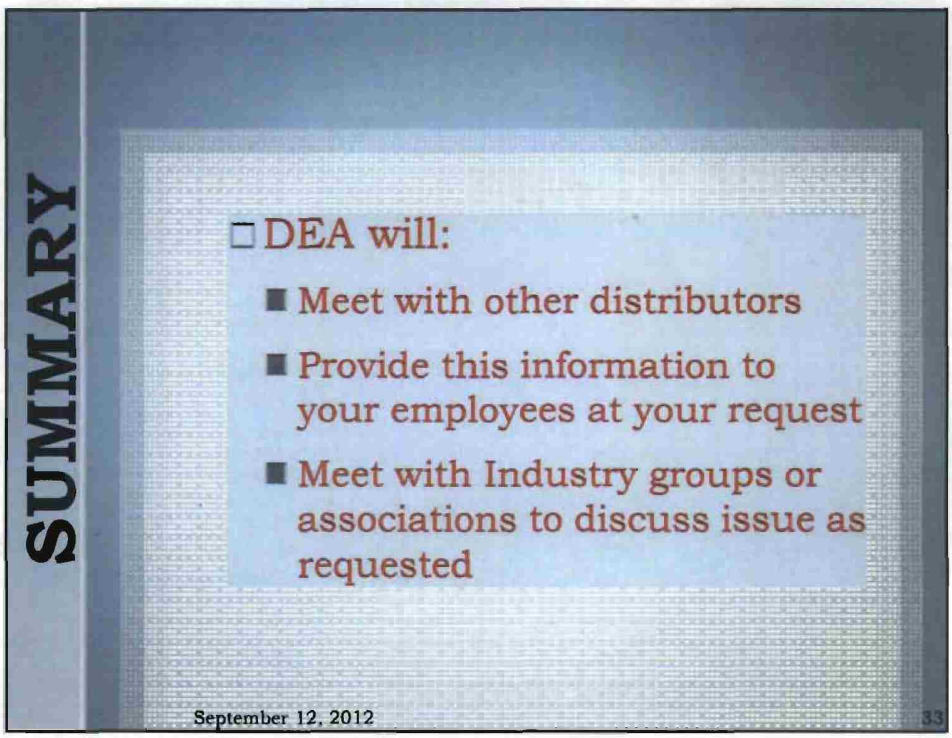
SUMMARY
DEA will:
Meet with other distributors
Provide this information to your employees at your request
Meet with Industry groups or associations to discuss issue as requested
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SUMMARY
www.deadiversion.usdoj.gov
Current Revocation Actions
Policy Changes
Validation of Registration
Links to web sites with useful information (AMA, Pain Management, Pharmacy, etc.)
Other
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Contact Information
Barbara Boockholdt, Section Chief
Regulatory Section
(202) 307-7669
Leonard Levin, Staff Coordinator
Regulatory Section
(202) 307-7984
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Direct Sales v. US

attention to the procedural delays in rate cases before that body, delays which he declared would be used to strangle financially weak water carriers, forcing them to "yield or transfer their operation to other streams." He pointed out this "would mean the death of water carriers"; that the railroads knew how to obtain delay and knew the disastrous consequences that would follow to their competitors; that railroads "seek to profit" by procedural delay; and that the diversity of their interests and extent of their revenues was so great that they could survive delays which would be unendurable for competitors.[18] The Congressman was a good observer and a sound prophet.

The judgment of the District Court enjoining enforcement of this order was correct and should be affirmed.

MR. JUSTICE DOUGLAS and MR. JUSTICE MURPHY join in this opinion.

DIRECT SALES CO. v. UNITED STATES.

CERTIORARI TO THE CIRCUIT COURT OF APPEALS FOR THE FOURTH CIRCUIT.

No. 593. Argued April 12, 1943.—Decided June 14, 1943.

A mail-order wholesale drug corporation made sales of morphine sulphate to a physician in unusually large quantities, frequently, and over an extended period. *Held*, that the evidence, from which it could be inferred that the seller not only knew the physician was selling the drug illegally but intended to coöperate with him therein, was sufficient to sustain the seller's conviction of conspiracy to violate the Harrison Narcotic Act. *United States* v. *Falcone*, 311 U. S. 205, distinguished. P. 714.

131 F. 2d 835, affirmed.

CERTIORARI, 318 U. S. 749, to review the affirmance of a conviction for conspiracy to violate the Harrison Narcotic Act. See also 44 F. Supp. 623.

[18] 86 Cong. Rec. 10181.

Mr. William B. Mahoney, with whom *Mr. Edwin J. Culligan* was on the brief, for petitioner.

Mr. Valentine Brookes, with whom *Solicitor General Fahy*, *Assistant Attorney General Berge*, *Messrs. Oscar A. Provost* and *W. Marvin Smith* and *Miss Melva M. Graney* were on the brief, for the United States.

MR. JUSTICE RUTLEDGE delivered the opinion of the Court.

Petitioner, a corporation, was convicted of conspiracy to violate the Harrison Narcotic Act.[1] It challenges the sufficiency of the evidence to sustain the conviction. Because of asserted conflict with *United States* v. *Falcone*, 311 U. S. 205, certiorari was granted.

Petitioner is a registered drug manufacturer and wholesaler.[2] It conducts a nationwide mail-order business from Buffalo, New York. The evidence relates chiefly to its transactions with one Dr. John V. Tate and his dealings with others. He was a registered physician, practicing in Calhoun Falls, South Carolina, a community of about 2,000 persons. He dispensed illegally vast quantities of morphine sulphate purchased by mail from petitioner. The indictment charged petitioner, Dr. Tate, and three others, Black, Johnson and Foster, to and through whom Tate illegally distributed the drugs, with conspiring to violate

[1] The conspiracy statute, R. S. § 5440, as amended, 18 U. S. C. § 88, provides:

"If two or more persons conspire either to commit any offense against the United States, or to defraud the United States in any manner or for any purpose, and one or more of such parties do any act to effect the object of the conspiracy, each of the parties to such conspiracy shall be fined not more than $10,000, or imprisoned not more than two years, or both."

The pertinent provisions of the Harrison Act are set out in note 3, *infra*.

[2] 38 Stat. 785, as amended, 26 U. S. C. §§ 3220, 3221.

§§ 1 and 2 of this Act,[8] over a period extending from 1933 to 1940. Foster was granted a severance, Black and Johnson pleaded guilty, and petitioner and Dr. Tate were convicted. Direct Sales alone appealed. The Circuit Court of Appeals affirmed. 131 F. 2d 835.

The parties here are at odds concerning the effect of the *Falcone* decision as applied to the facts proved in this case. The salient facts are that Direct Sales sold morphine sulphate to Dr. Tate in such quantities, so frequently and over so long a period it must have known he could not dispense the amounts received in lawful practice and was therefore distributing the drug illegally. Not only so, but it actively stimulated Tate's purchases.

He was a small-town physician practicing in a rural section. All of his business with Direct Sales was done by mail. Through its catalogues petitioner first made

[8] 38 Stat. 785, as amended, 26 U. S. C. §§ 2553, 2554. The indictment charged the conspiracy's object was to violate those portions of the Act (as amended) which provide:

"It shall be unlawful for any person required to register under the provisions of this part or section 2551 (a) to import, manufacture, produce, compound, sell, deal in, dispense, distribute, administer, or give away any of the aforesaid drugs without having registered and paid the special tax as imposed by this part, or section 2551 (a)." 26 U. S. C. § 3224.

"It shall be unlawful for any person to purchase, sell, dispense, or distribute any of the drugs mentioned in section 2550 (a) except in the original stamped package or from the original stamped package; . . ." 26 U. S. C. § 2553.

"It shall be unlawful for any person to sell, barter, exchange, or give away any of the drugs mentioned in section 2550 (a) except in pursuance of a written order of the person to whom such article is sold, bartered, exchanged, or given, on a form to be issued in blank for that purpose by the Secretary." 26 U. S. C. § 2554 (a).

"It shall be unlawful for any person to obtain by means of said order forms any of the aforesaid drugs for any purpose other than the use, sale, or distribution thereof by him in the conduct of a lawful business in said drugs or in the legitimate practice of his profession." 26 U. S. C. § 2554 (g).

contact with him prior to 1933. Originally he purchased a variety of pharmaceuticals. But gradually the character of his purchases narrowed, so that during the last two years of the period alleged for the conspiracy he ordered almost nothing but morphine sulphate. At all times during the period he purchased the major portion of his morphine sulphate from petitioner. The orders were made regularly on his official order forms. The testimony shows the average physician in the United States does not require more than 400 one-quarter grain tablets annually for legitimate use. Although Tate's initial purchases in 1933 were smaller, they gradually increased until, from November, 1937, to January, 1940, they amounted to 79,000 one-half grain tablets. In the last six months of 1939, petitioner's shipments to him averaged 5,000 to 6,000 half-grain tablets a month, enough as the Government points out to enable him to give 400 average doses every day.

These quantity sales were in line with the general mail-order character of petitioner's business. By printed catalogues circulated about three times a month, it solicits orders from retail druggists and physicians located for the most part in small towns throughout the country. Of annual sales of from $300,000 to $350,000 in the period 1936 to 1940, about fifteen per cent by revenue and two and a half per cent by volume were in narcotics. The mail-order plan enabled petitioner to sell at prices considerably lower than were charged by its larger competitors, who maintained sales forces and traveling representatives. By offering fifty per cent discounts on narcotics, it "pushed" quantity sales. Instead of listing narcotics, like morphine sulphate, in quantities not exceeding 100 tablets, as did many competitors, Direct Sales for some time listed them in 500, 1,000 and 5,000 tablet units. By this policy it attracted customers, including a dispropor-

tionately large group of physicians who had been convicted of violating the Harrison Act.

All this was not without warning, purpose or design. In 1936 the Bureau of Narcotics informed petitioner it was being used as a source of supply by convicted physicians.[4] The same agent also warned that the average physician would order no more than 200 to 400 quarter-grain tablets annually [5] and requested it to eliminate the listing of 5,000 lots. It did so, but continued the 1,000 and 500 lot listings at attractive discounts. It filled no more orders from Tate for more than 1,000 tablets, but continued to supply him for that amount at half-grain strength. On one occasion in 1939 he ordered on one form 1,000 half and 100 quarter grains. Petitioner sent him the 1,000 and advised him to reorder the 100 on a separate order form. It attached to this letter a sticker printed in red suggesting anticipation of future needs and taking advantage of discounts offered. Three days later Tate ordered 1,000 more tablets, which petitioner sent out. In 1940, at the Bureau's suggestion, Direct Sales eliminated its fifty and ten per cent discounts. But on doing so it translated its discount into its net price.

Tate distributed the drugs to and through addicts and purveyors, including Johnson, Black and Foster. Although he purchased from petitioner at less than two dol-

[4] Thus, although there were more than 1,350 wholesale drug dealers in the United States from whom physicians might order narcotics (Traffic in Opium and Other Dangerous Drugs for the Year Ended December 31, 1941, United States Treasury, Bureau of Narcotics), about 27% of the 204 doctors convicted were petitioner's customers.

[5] Testimony in the record establishes that the practice in the profession is to give one-eighth or one-fourth grain doses, and only rarely one-half grain doses. Cf. *United States* v. *Berman*, 258 U. S. 280, 289. Furthermore, there was expert testimony to the effect that codein may be, and preferably is, used for the same medical purposes as morphine sulphate. During the period from 1934 to 1940, however, the record does not show that Tate ever ordered codein from petitioner.

lars, he sold at prices ranging from four to eight dollars per 100 half-grain tablets and purveyors from him charged addicts as much as $25 per hundred.

On this evidence, the Government insists the case is in different posture from that presented in *United States* v. *Falcone*. It urges that the effort there was to connect the respondents with a conspiracy between the distillers on the basis of the aiding and abetting statute.[6] The attempt failed because the Court held the evidence did not establish the respondents knew of the distillers' conspiracy. There was no attempt to link the supplier and the distiller in a conspiracy *inter sese*. But in this case that type of problem is presented. Direct Sales was tried, and its conviction has been sustained, according to the claim, on the theory it could be convicted only if it were found that it and Tate conspired together to subvert the order form provisions of the Harrison Act. As the brief puts the Government's view, "Petitioner's guilt was not made to depend at all upon any guilt of Dr. Tate growing out of his relationship to defendants other than petitioner or upon whether these other defendants were linked with the Tate-Direct Sales conspiracy."

On the other hand, petitioner asserts this case falls squarely within the facts and the ruling in the *Falcone* case. It insists there is no more to show conspiracy between itself and Tate than there was to show conspiracy between the respondent sellers and the purchasing distillers there. At most, it urges, there were only legal sales by itself to Dr. Tate, accompanied by knowledge he was distributing goods illegally. But this, it contends, cannot amount to conspiracy on its part with him, since in the *Falcone* case the respondents sold to the distillers, knowing they would use the goods in illegal distillation.

[6] R. S. § 5323, 18 U. S. C. § 550.

Petitioner obviously misconstrues the effect of the *Falcone* decision in one respect. This is in regarding it as deciding that one who sells to another with knowledge that the buyer will use the article for an illegal purpose cannot, under any circumstances, be found guilty of conspiracy with the buyer to further his illegal end. The assumption seems to be that, under the ruling, so long as the seller does not know there is a conspiracy between the buyer and others, he cannot be guilty of conspiring with the buyer, to further the latter's illegal and known intended use, by selling goods to him.

The *Falcone* case creates no such sweeping insulation for sellers to known illicit users. That decision comes down merely to this, that one does not become a party to a conspiracy by aiding and abetting it, through sales of supplies or otherwise, unless he knows of the conspiracy; and the inference of such knowledge cannot be drawn merely from knowledge the buyer will use the goods illegally. The Government did not contend, in those circumstances, as the opinion points out, that there was a conspiracy between the buyer and the seller alone. It conceded that on the evidence neither the act of supplying itself nor the other proof was of such a character as imported an agreement or concert of action between the buyer and the seller amounting to conspiracy. This was true, notwithstanding some of the respondents could be taken to know their customers would use the purchased goods in illegal distillation.

The scope of the concession must be measured in the light of the evidence with reference to which it was made. This related to both the volume of the sales and to casual and unexplained meetings of some of the respondents with others who were convicted as conspirators. The Court found this evidence too vague and uncertain to support a finding the respondents knew of the distillers' conspiracy,

though not inadequate in some instances to sustain one that the seller knew the buyer would use the goods for illegal distilling. It must be taken also that the Government regarded the same evidence as insufficient to show the seller conspired directly with the buyer, by selling to him with knowledge of his intended illegal use.

Whether or not it was consistent in making this concession and in regarding the same evidence as sufficient to show that the sellers knew of and joined the buyers' distilling ring is not material. Nor need it be determined whether the Government conceded too much. We do not now undertake to say what the Court was not asked and therefore declined to say in the *Falcone* case, namely, that the evidence presented in that case was sufficient to sustain a finding of conspiracy between the seller and the buyer *inter sese*. For, regardless of that, the facts proved in this case show much more than the evidence did there.

The commodities sold there were articles of free commerce, sugar, cans, etc. They were not restricted as to sale by order form, registration, or other requirements. When they left the seller's stock and passed to the purchaser's hands, they were not in themselves restricted commodities, incapable of further legal use except by compliance with rigid regulations, such as apply to morphine sulphate. The difference is like that between toy pistols or hunting-rifles and machine guns. All articles of commerce may be put to illegal ends. But all do not have inherently the same susceptibility to harmful and illegal use. Nor, by the same token, do all embody the same capacity, from their very nature, for giving the seller notice the buyer will use them unlawfully. Gangsters, not hunters or small boys, comprise the normal private market for machine guns. So drug addicts furnish the normal outlet for morphine which gets outside the restricted channels of legitimate trade.

This difference is important for two purposes. One is for making certain that the seller knows the buyer's intended illegal use. The other is to show that by the sale he intends to further, promote and coöperate in it. This intent, when given effect by overt act, is the gist of conspiracy. While it is not identical with mere knowledge that another purposes unlawful action, it is not unrelated to such knowledge. Without the knowledge, the intent cannot exist. *United States* v. *Falcone, supra.*[7] Furthermore, to establish the intent, the evidence of knowledge must be clear, not equivocal. *Ibid.* This, because charges of conspiracy are not to be made out by piling inference upon inference, thus fashioning what, in that case, was called a dragnet to draw in all substantive crimes.

The difference between sugar, cans, and other articles of normal trade, on the one hand, and narcotic drugs, machine guns and such restricted commodities, on the other, arising from the latters' inherent capacity for harm and from the very fact they are restricted, makes a difference in the quantity of proof required to show knowledge that the buyer will utilize the article unlawfully. Additional facts, such as quantity sales, high-pressure sales methods, abnormal increases in the size of the buyer's purchases, etc., which would be wholly innocuous or not more than ground for suspicion in relation to unrestricted goods, may furnish conclusive evidence, in respect to restricted articles, that the seller knows the buyer has an illegal object and enterprise. Knowledge, equivocal and uncertain as to one, becomes sure as to the other. So far as knowl-

[7] Although this principle was there applied to aiding and abetting a conspiracy among others, it has at least equal force in a situation where the charge is conspiring with another to further his unlawful conduct, without reference to any conspiracy between him and third persons.

edge is the foundation of intent, the latter thereby also becomes the more secure.

The difference in the commodities has a further bearing upon the existence and the proof of intent. There may be circumstances in which the evidence of knowledge is clear, yet the further step of finding the required intent cannot be taken. Concededly, not every instance of sale of restricted goods, harmful as are opiates, in which the seller knows the buyer intends to use them unlawfully, will support a charge of conspiracy.[8] But this is not to say that a seller of harmful restricted goods has license to sell in unlimited quantities, to stimulate such sales by all the high-pressure methods, legal if not always appropriate, in the sale of free commodities; and thereby bring about subversion of the order forms, which otherwise would protect him, and violation of the Act's other restrictions. Such a view would assume that the market for opiates may be developed as any other market. But that is not true. Mass advertising and bargain-counter discounts are not appropriate to commodities so surrounded with restrictions. They do not create new legal demand and new classes of legitimate patrons, as they do for sugar, tobacco and other free commodities. Beyond narrow limits, the normal legal market for opiates is not capable of being extended by such methods. The primary effect is rather to create black markets for dope and to increase illegal demand and consumption.

[8] This may be true, for instance, of single or casual transactions, not amounting to a course of business, regular, sustained and prolonged, and involving nothing more on the seller's part than indifference to the buyer's illegal purpose and passive acquiescence in his desire to purchase, for whatever end. A considerable degree of carelessness coupled with casual transactions is tolerable outside the boundary of conspiracy. There may be also a fairly broad latitude of immunity for a more continuous course of sales, made either with strong suspicion of the buyer's wrongful use or with knowledge, but without stimulation or active incitement to purchase.

When the evidence discloses such a system, working in prolonged coöperation with a physician's unlawful purpose to supply him with his stock in trade for his illicit enterprise, there is no legal obstacle to finding that the supplier not only knows and acquiesces, but joins both mind and hand with him to make its accomplishment possible. The step from knowledge to intent and agreement may be taken. There is more than suspicion, more than knowledge, acquiescence, carelessness, indifference, lack of concern. There is informed and interested coöperation, stimulation, instigation. And there is also a "stake in the venture" which, even if it may not be essential, is not irrelevant to the question of conspiracy.[9] Petitioner's stake here was in making the profits which it knew could come only from its encouragement of Tate's illicit operations. In such a posture the case does not fall doubtfully outside either the shadowy border between lawful coöperation and criminal association or the no less elusive line which separates conspiracy from overlapping forms of criminal coöperation.

Unless, therefore, petitioner has been exempted arbitrarily by the statute's terms, the evidence clearly was sufficient to sustain its conviction for conspiring with Tate. Its position here comes down ultimately to the view alluded to above that the statute has, in fact, thus immunized its action. In effect this means the only restriction imposed upon it, apart from other provisions not now material, such as those affecting registration, was the requirement it should receive from purchasing physicians a signed order form for each sale. That done, in its view, its full duty to the law was fulfilled, it acquired a complete immunity, and what the physician had done

[9] Cf. *United States* v. *Falcone*, 109 F. 2d 579, 581 (C. C. A.); and compare *Backun* v. *United States*, 112 F. 2d 635, 637 (C. C. A.); *United States* v. *Harrison*, 121 F. 2d 930, 933 (C. C. A.); *United States* v. *Pecoraro*, 115 F. 2d 245, 246 (C. C. A.).

or might do with the drugs became of no further concern to itself. Such a view would legalize an express written agreement between a registered wholesaler and a physician for the former to supply him with all his requirements for drugs for both legal and illegal distribution, conditioned only upon his using the required order forms. The statute contains no such exemption in explicit terms. Nor was one implied.[10]

This being true, it can make no difference the agreement was a tacit understanding, created by a long course of conduct and executed in the same way.[11] Not the form or manner in which the understanding is made, but the fact of its existence and the further one of making it effective by overt conduct are the crucial matters. The proof, by the very nature of the crime, must be circumstantial[12] and therefore inferential to an extent varying with the conditions under which the crime may be committed. But this does not mean either that the evidence may be equivocal or that petitioner is exempt from its effects when it is not so, merely because in the absence of excesses such as were committed and in other circumstances the order form would have given it protection. It follows the mere fact that none of petitioner's representatives ever met Dr. Tate face to face or held personal communion with him is immaterial. Conspiracies, in short, can be committed by mail and by mail-order houses. This is true, notwithstanding the overt acts consist solely of sales, which but for their volume, frequency and prolonged

[10] Cf. *Gebardi* v. *United States*, 287 U. S. 112; see also 81 U. of Pa. L. Rev. 474.

[11] *Glasser* v. *United States*, 315 U. S. 60, 80; *United States* v. *Manton*, 107 F. 2d 834, 839 (C. C. A.); *United States* v. *Harrison*, 121 F. 2d 930, 934 (C. C. A.); cf. *Eastern States Retail Lumber Dealers' Assn.* v. *United States*, 234 U. S. 600; *Interstate Circuit* v. *United States*, 306 U. S. 208.

[12] *Ibid.*

repetition, coupled with the seller's unlawful intent to further the buyer's project, would be wholly lawful transactions.

Accordingly, the judgment is

Affirmed.

OWENS, EXECUTRIX, v. UNION PACIFIC RAILROAD CO.

CERTIORARI TO THE CIRCUIT COURT OF APPEALS FOR THE NINTH CIRCUIT.

No. 580. Argued April 7, 1943.—Decided June 14, 1943.

1. Upon the facts of this case under the Federal Employers' Liability Act, it can not be said that, as a matter of law, there was an assumption of risk by the decedent; his conduct amounted, at most, to contributory negligence, which may reduce the damages but does not bar recovery. P. 724.
2. It is unnecessary in this case to determine whether the 1939 amendment of the Federal Employers' Liability Act, abolishing the defense of assumption of risk, applies where the accident occurred before, but the suit is brought after, that enactment. P. 725.

129 F. 2d 1013, reversed.

CERTIORARI, 317 U. S. 623, to review the reversal of a judgment for the plaintiff in an action under the Federal Employers' Liability Act.

Mr. Frank C. Hanley for petitioner.

Mr. L. R. Hamblen, with whom *Mr. Roy F. Shields* was on the brief, for respondent.

MR. JUSTICE RUTLEDGE delivered the opinion of the Court.

Petitioner is the widow of an employee of respondent. In 1941 she brought this suit under the Federal Employers' Liability Act, 45 U. S. C. §§ 51–59. Her hus-

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US v. Moore

UNITED STATES *v.* MOORE

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 74-759. Argued October 7, 1975—Decided December 9, 1975

Respondent, a licensed physician registered under the Controlled Substances Act (CSA), 21 U. S. C. § 801 *et seq.*, was convicted of knowing and unlawful distribution and dispensation of methadone (a controlled substance or addictive drug used in the treatment of heroin addicts) in violation of 21 U. S. C. § 841 (a)(1), which makes it unlawful for "any person" knowingly or intentionally to distribute or dispense a controlled substance, except as authorized by the CSA. The evidence disclosed that respondent prescribed large quantities of methadone for patients without giving them adequate physical examinations or specific instructions for its use and charged fees according to the quantity of methadone prescribed rather than fees for medical services rendered. The Court of Appeals, however, reversed the conviction on the grounds that respondent was exempted from prosecution under § 841 by virtue of his status as a registrant and that a registrant can be prosecuted only under §§ 842 and 843, which prescribe less severe penalties than § 841. *Held:* Registered physicians can be prosecuted under § 841 when, as here, their activities fall outside the usual course of professional practice. Pp. 131–145.

(a) Only the lawful acts of registrants under the CSA are exempted from prosecution under § 841. That section by its terms reaches "any person" and does not exempt (as it could have) "all registrants" or "all persons registered under the Act." The language of the qualified authorization of § 822 (b), which authorizes registrants to possess, distribute, or dispense controlled substances to the extent authorized by their registration and in conformity with other CSA provisions, and which was added merely to ensure that persons engaged in lawful activities could not be prosecuted, cannot be fairly read to support the view that all activities of registered physicians are beyond the reach of § 841 simply because of their status. Pp. 131–133.

(b) There is no indication in the operative language of §§ 841–843 that Congress intended to establish two mutually exclusive

penalty systems, with nonregistrants to be punished under § 841 and registrants under §§ 842 and 843, the fact that the term "registrants" is used in some subsections of §§ 842 and 843 but not in § 841 being of limited significance. Moreover, the legislative history indicates that Congress was concerned with the nature of the drug transaction, rather than with the defendant's status. Pp. 133–135.

(c) It is immaterial whether respondent also could have been prosecuted for the relatively minor offense of violating § 829 with respect to the issuing of prescriptions, since there is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for violating § 829 is thereby exempted from prosecution under § 841 for the significantly greater offense of acting as a drug "pusher." Pp. 135–138.

(d) The scheme of the CSA, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his "professional practice." Pp. 138–143.

(e) Congress was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients, but it did not intend to exempt from serious criminal penalties those acts by physicians that go beyond the limits of approved professional practice. Pp. 143–145.

(f) Where the statutory purpose is clear, the canon of strict construction of criminal statutes favoring the accused will be satisfied if the words of the statute are "given their fair meaning in accord with the manifest intent of the lawmakers." *United States* v. *Brown*, 333 U. S. 18, 25–26. P. 145.

164 U. S. App. D. C. 319, 505 F. 2d 426, reversed and remanded.

POWELL, J., delivered the opinion for a unanimous Court.

Paul L. Friedman argued the cause for the United States. With him on the briefs were *Solicitor General Bork, Assistant Attorney General Thornburgh, Acting Assistant Attorney General Keeney,* and *Sidney M. Glazer.*

Raymond W. Bergan argued the cause for respond-

ent. With him on the brief were *Edward Bennett Williams* and *Harold Ungar*.

MR. JUSTICE POWELL delivered the opinion of the Court.

The issue in this case is whether persons who are registered under the Controlled Substances Act (CSA or Act), 84 Stat. 1242, 21 U. S. C. § 801 *et seq.*, can be prosecuted under § 841 for dispensing or distributing controlled substances. The United States Court of Appeals for the District of Columbia Circuit reversed the conviction of respondent, a licensed physician registered under the Act, on the ground that he was exempted from prosecution under § 841 by virtue of his status as a registrant. We reverse and hold that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice.

I

Dr. Moore was charged, in a 639-count indictment, with the knowing and unlawful distribution and dispensation of methadone (Dolophine), a Schedule II controlled substance,[1] in violation of 21 U. S. C. § 841 (a)(1). That subsection provides:

> "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—
>
> "(1) to manufacture, distribute, or dispense, or

[1] A substance listed in Schedule II has "a high potential for abuse," "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions," and is a drug the abuse of which "may lead to severe psychological or physical dependence." 21 U. S. C. § 812 (b)(2). Methadone is listed as a Schedule II drug in § 812 (c), Schedule II (b)(11).

possess with intent to manufacture, distribute, or dispense, a controlled substance . . . ."

The indictment covered a 5½-month period from late August 1971 to early February 1972. It was reduced before trial to 40 counts, and the jury convicted respondent on 22 counts. He was sentenced to concurrent terms of five to 15 years' imprisonment on 14 counts, and to concurrent terms of 10 to 30 years on the remaining eight counts. The second set of sentences was to be consecutive with the first. Fines totaling $150,000 were also imposed.[2]

Methadone is an addictive drug used in the treatment of heroin addicts. If taken without controls it can, like heroin, create euphoric "highs," but if properly administered it eliminates the addict's craving for heroin without providing a "high." The two principal methods of treating heroin addicts with methadone are "detoxification" and "maintenance." Under a maintenance program, the addict is given a fixed dose once a day for an indefinite period to keep him from using heroin. In detoxification the addict is given a large dose of methadone during the first few days of treatment to keep him free of withdrawal symptoms. Then the dose is gradually reduced until total abstinence is reached.

Maintenance is the more controversial method of treatment. During the period covered by the indictment, registration under § 822, in itself, did not entitle a physician to conduct a maintenance program. In addition to a § 822 registration, the physician who wished to conduct such a program was required to

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[2] In addition, Dr. Moore's license to practice medicine was revoked pursuant to D. C. Code Ann. § 2–131 (1973), which authorizes revocation upon the conviction of "any felony." An appeal from the conviction acts "as a supersedeas to the judgment . . . revoking his license . . . ."

obtain authorization from the Food and Drug Administration for investigation of a new drug. Dr. Moore's authorization by the FDA was revoked in the summer of 1971, and he does not claim that he was conducting an authorized maintenance program. Instead, his defense at trial was that he had devised a new method of detoxification based on the work of a British practitioner. He testified that he prescribed large quantities of methadone to achieve a "blockade" condition, in which the addict was so saturated with methadone that heroin would have no effect, and to instill a strong psychological desire for detoxification. The Government's position is that the evidence established that Dr. Moore's conduct was inconsistent with all accepted methods of treating addicts, that in fact he operated as a "pusher."

Respondent concedes in his brief that he did not observe generally accepted medical practices. He conducted a large-scale operation. Between September 1971 and mid-February 1972 three District of Columbia pharmacies filled 11,169 prescriptions written by Dr. Moore. These covered some 800,000 methadone tablets. On 54 days during that period respondent wrote over 100 prescriptions a day. In billing his patients he used a "sliding-fee scale" pegged solely to the quantity prescribed, rather than to the medical services performed. The fees ranged from $15 for a 50-pill prescription to $50 for 150 pills. In five and one-half months Dr. Moore's receipts totaled at least $260,000.

When a patient entered the office he was given only the most perfunctory examination. Typically this included a request to see the patient's needle marks (which in more than one instance were simulated) and an unsupervised urinalysis (the results of which were regularly ignored). A prescription was then written for the amount requested by the patient. On return visits—for

which appointments were never scheduled—no physical examination was performed and the patient again received a prescription for whatever quantity he requested. Accurate records were not kept, and in some cases the quantity prescribed was not recorded. There was no supervision of the administration of the drug. Dr. Moore's instructions consisted entirely of a label on the drugs reading: "Take as directed for detoxification." Some patients used the tablets to get "high"; others sold them or gave them to friends or relatives. Several patients testified that their use of methadone increased dramatically while they were under respondent's care.[3]

The Court of Appeals, with one judge dissenting, assumed that respondent acted wrongfully but held that he could not be prosecuted under § 841.[4] 164 U. S.

[3] One patient testified that he was taking approximately two to three pills per day when he started visiting Dr. Moore. By the end of his visits he was taking 30 to 35 pills a day. App. 43. Another patient increased his intake from five to 10 pills a day to almost 70. *Id.*, at 53–54. A third addict, relying on Dr. Moore for drugs, increased his intake from seven pills a day to over 100. Tr. 310.

[4] Section 841 (a) provides, in full:

"Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

"(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

"(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance."

"Dispense" is defined in § 802 (10) to mean "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance . . . ." Section 802 (11) defines "distribute" to mean "to deliver (other than by administering or dispensing) a controlled substance." "Administer" refers to "the direct application of a controlled substance to the body of a patient . . . ." § 802 (2).

App. D. C. 319, 505 F. 2d 426 (1974). The court found that Congress intended to subject registered physicians to prosecution only under §§ 842 and 843,[5] which pre-

[5] Section 842 in relevant part provides:

"(a) Unlawful acts.

"It shall be unlawful for any person—

"(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;

"(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

"(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title;

"(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title;

"(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;

"(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter;

"(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824 (f) or 881 of this title or to remove or dispose of substances so placed under seal; or

"(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled to protection.

"(b) Manufacture.

"It shall be unlawful for any person who is a registrant to manufacture a controlled substance in Schedule I or II which is—

"(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 826 of this title; or

"(2) in excess of a quota assigned to him pursuant to section 826 of this title."

[*Footnote 5 is continued on p. 129*]

scribe less severe penalties than § 841.[6] The court reasoned:

". . . Congress intended to deal with registrants pri-

Section 843 provides:

"(a) Unlawful acts.

"It shall be unlawful for any person knowingly or intentionally—

"(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 828 of this title;

"(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

"(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

"(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter; or

"(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance.

"(b) Communication facility.

"It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this subchapter or subchapter II of this chapter. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term 'communication facility' means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication."

[6] Violations of § 841, under which respondent was convicted, carry sentences of up to 15 years, fines as high as $25,000,

> marily through a system of administrative controls, relying on modest penalty provisions to enforce those controls, and reserving the severe penalties provided for in § 841 for those seeking to avoid regulation entirely by not registering." 164 U. S. App. D. C., at 323, 505 F. 2d, at 430.

It said, further, that §§ 842 and 843 were enacted to enforce that scheme, while § 841 was reserved for prosecution of those outside the "legitimate distribution chain." Persons registered under the Act were "authorized by [the] subchapter" within the meaning of § 841 and thus were thought to be immunized against prosecution under that section.[7]

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or both. § 841 (b). Knowing violators of § 842 are subject at most to imprisonment for one year, a fine of $25,000, or both. There also may be a civil penalty of $25,000 for violation of § 842. § 842 (c). The penalties for violation of § 843 are imprisonment for not more than four years, a fine of not more than $30,000, or both. § 843 (c). All three sections impose higher penalties for violations after the first conviction.

[7] The decision below stands alone. At the time it was issued it conflicted with the rulings of four other Circuits. Courts of Appeals for the First, Fifth, and Tenth Circuits had held squarely that physicians may be prosecuted under § 841. See *United States* v. *Badia*, 490 F. 2d 296 (CA1 1973); *United States* v. *Collier*, 478 F. 2d 268 (CA5 1973); *United States* v. *Leigh*, 487 F. 2d 206 (CA5 1973); *United States* v. *Bartee*, 479 F. 2d 484 (CA10 1973); *United States* v. *Jobe*, 487 F. 2d 268 (CA10 1973). The Ninth Circuit also had affirmed the conviction of a physician under § 841 (a)(1). *United States* v. *Larson*, 507 F. 2d 385 (1974). Since the ruling in this case, two other decisions have considered the issue and expressly rejected the analysis of the Court of Appeals for the District of Columbia Circuit. See *United States* v. *Rosenberg*, 515 F. 2d 190 (CA9 1975); *United States* v. *Green*, 511 F. 2d 1062 (CA7 1975). The Sixth Circuit has implicitly agreed. It reversed the conviction of a physician and remanded the case for a new trial because the trial court had failed to instruct the jury that physicians are exempt from prosecution under § 841 (a)(1) when they dispense or prescribe controlled substances in good faith to patients in the regular course of

Respondent advances two basic arguments, contending that each requires affirmance of the Court of Appeals: (i) as that court held, registered physicians may be prosecuted only under §§ 842 and 843; and (ii) in any event, respondent cannot be prosecuted under § 841 because his conduct was "authorized by [the] subchapter" in question. We now consider each of these arguments.

II

A

Section 841 (a)(1) makes distribution and dispensing of drugs unlawful "[e]xcept as authorized by this subchapter . . . ." Relying on this language, the Court of Appeals held that a physician registered under the Act is *per se* exempted from prosecution under § 841 because of his status as a registrant. We take a different view and hold that only the lawful acts of registrants are exempted. By its terms § 841 reaches "any person." It does not exempt (as it could have) "all registrants" or "all persons registered under this Act."

The Court of Appeals relied also on § 822 (b), which provides: "Persons registered . . . under this subchapter to . . . distribute, or dispense controlled substances are authorized to possess, . . . distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." This is a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons. This limitation is emphasized by the subsection's heading "Authorized activities," which parallels the headings of §§ 841–843 "Unlawful acts." We think the statutory language cannot fairly be read to support the view that all activities of registered physi-

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professional practice. *United States* v. *Carroll,* 518 F. 2d 187 (1975).

cians are exempted from the reach of § 841 simply because of their status.

If § 822 (b) were construed to authorize all such activities, thereby exempting them from other constraints, it would constitute a sharp departure from prior laws. But there is no indication that Congress had any such intent. Physicians who stepped outside the bounds of professional practice could be prosecuted under the Harrison Act (Narcotics) of 1914, 38 Stat. 785, the predecessor of the CSA. In *Jin Fuey Moy* v. *United States,* 254 U. S. 189 (1920), the Court affirmed the conviction of a physician on facts remarkably similar to those before us (*e. g.,* no adequate physical examination, the dispensing of large quantities of drugs without specific directions for use, and fees graduated according to the amount of drugs prescribed). A similar conviction was upheld in *United States* v. *Behrman,* 258 U. S. 280 (1922), where the defendant-doctor had prescribed heroin, morphine, and cocaine to a person whom he knew to be an addict.

In enacting the CSA Congress attempted to devise a more flexible penalty structure than that used in the Harrison Act. H. R. Rep. No. 91–1444, Pt. 1, pp. 1, 4 (1970).[8] Penalties were geared to the nature of the violation, including the character of the drug involved. But the Act was intended to "strengthen," rather than to weaken, "existing law enforcement authority in the field of drug abuse." 84 Stat. 1236 (1970) (preamble). See also H. R. Rep. No. 91–1444, p. 1.

Section 822 (b) was added to the original bill at a late date [9] to "make it clear that persons registered under

[8] To this end controlled substances were classified in five categories according to their potential for abuse, their promise for treatment, and their psychological and physical effects. § 812.

[9] Section 822 (b) was added by the House Committee on Interstate and Foreign Commerce. No comparable section was in the Act when it passed the Senate on January 28, 1970.

this title are authorized to deal in or handle controlled substances." H. R. Rep. No. 91-1444, p. 38. It is unlikely that Congress would seek, in this oblique way, to carve out a major new exemption, not found in the Harrison Act, for physicians and other registrants. Rather, § 822 (b) was added merely to ensure that persons engaged in lawful activities could not be prosecuted.

B

Respondent nonetheless contends that §§ 841 and 822 (b) must be interpreted in light of a congressional intent to set up two separate and distinct penalty systems: Persons not registered under the Act are to be punished under § 841, while those who are registered are to be subject only to the sanctions of §§ 842 and 843. The latter two sections, the argument goes, establish modest penalties which are the sole sanctions in a system of strict administrative regulation of registrants.

The operative language of those sections provides no real support for the proposition that Congress intended to establish two mutually exclusive systems. It is true that the term "registrants" is used in §§ 842 and 843, and not in § 841. But this is of limited significance. All three sections provide that "[i]t shall be unlawful for any person . . . [to commit the proscribed acts]." Two of the eight subsections of § 842 (a), one of the five subsections of § 843 (a), and § 842 (b) further qualify "any person" with "who is a registrant." The other subsections of §§ 842 and 843 are not so limited. In context, "registrant" is merely a limiting term, indicating that the only "persons" who are subject to these subsections are "registrants." [10] There is no indication that "persons"

[10] This represents a commonsense recognition by Congress that only a registrant could, for example, distribute drugs "not authorized by his registration," § 842 (a)(2), or manufacture substances "not expressly authorized by his registration" or "in excess of [his]

means "nonregistrants" when introducing the other subsections.

There are other indications that § 841, and §§ 842 and 843, do not constitute two discrete systems. Section 843 (b), for example, makes it unlawful for any person to use a communication facility in committing a felony under any provision of the subchapter. But violations of both § 841 and § 843 lead to felony convictions; criminal violations of § 842 are misdemeanors.[11] §§ 842 (c)(2)(A), 802 (13); 18 U. S. C. § 1. And counsel for respondent agreed at oral argument that registrants can be prosecuted under § 841 (a)(2), which prohibits the creation, distribution, dispensing, or possession with intent to distribute or dispense of a "counterfeit substance."

The legislative history indicates that Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant. The penalties now embodied in §§ 841–843 originated in §§ 501–503 of the Controlled Dangerous Substances Act of 1969. The Report of the Senate Judiciary Committee on that bill described § 501 (the counterpart of § 841) as applying to "traffickers." S. Rep. No. 91–613, p. 8

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quota." §§ 842 (b)(1), (2). Nor would there be any reason to apply to nonregistrants the penalties for distributing drugs without complying with the labeling and order-form requirements of the Act, §§ 842 (a)(3), 843 (a)(1), for nonregistrants are barred from making any distributions whatsoever.

[11] Another subsection which can be sensibly interpreted only if it reaches nonregistrants is § 842 (a)(1), which is limited to "any person—who is subject to the requirements of part C." Part C of the Act, §§ 821–829, covers the provisions for registration and applies to "[e]very person who manufactures, distributes, or dispenses any controlled substance or who proposes" to do so. § 822 (a). Presumably, § 842 (a)(1) is so phrased in order to reach those who should have registered but failed to do so.

(1969). Section 502 provided "[a]dditional penalties . . . for those involved in the legitimate drug trade," and "[f]urther penalties . . . for registrants" were specified in § 503. S. Rep. No. 91–613, p. 9. The House Committee Report on the bill that was to become the CSA explains: "The bill provides for control . . . of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal." H. R. Rep. No. 91–1444, p. 3. Although this language is ambiguous, the most sensible interpretation is that the penalty to be imposed for a violation was intended to turn on whether the "transaction" falls within or without legitimate channels. All persons who engage in legitimate transactions must be registered and are subject to penalties under §§ 842 and 843 for "[m]ore or less technical violations." H. R. Rep. No. 91–1444, p. 10. But "severe criminal penalties" were imposed on those, like respondent, who sold drugs, not for legitimate purposes, but "primarily for the profits to be derived therefrom." *Ibid.*

C

Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels. *Id.*, at 6; S. Rep. No. 91–613, p. 4; 116 Cong. Rec. 996 (1970) (remarks of Sen. Dodd). It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic. See *id.*, at 1663 (remarks of Sen. Hruska); *id.*, at 998 (remarks of Sen. Griffin).

Recognizing this concern the Court of Appeals suggested that Dr. Moore could be prosecuted under § 842

(a)(1) for having violated the provisions of § 829 with respect to the issuing of prescriptions.[12] Whether Dr. Moore could have been so prosecuted is not before the

[12] Section 829 provides, in part:

"(a) Schedule II substances.

"Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 353 (b) of this title. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

"(b) Schedule III and IV substances.

"Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 353 (b) of this title. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

"(c) Schedule V substances.

"No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose."

The Attorney General's regulations enacted pursuant to § 829 required:

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of

Court.[13] We note, however, that the penalties for such a violation could hardly have been deemed by Congress to be an appropriate sanction for drug trafficking by a registered physician. Indeed, the penalty for conviction under § 842 would be significantly lighter than, for example, that applicable to a registrant convicted under § 843 for using a suspended registration number.[14] Moreover, a physician who wished to traffic in drugs without threat of criminal prosecution could, if violation of § 829 were the sole basis for prosecution, simply dispense drugs directly without the formality of issuing a prescription. Direct dispensing is exempt from § 829 and thus is not reached by any subsection of § 842 or

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section 309 of the Act (21 U. S. C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 CFR § 306.04 (a) (1973) (redesignated as 21 CFR § 1306.04 (a) (1975)).

The court below suggested that a violation of the "medical purpose" requirement of § 306.04 (a) makes a prescription something other than the "written prescription" required by § 829. The dissent, which agreed that Dr. Moore could be prosecuted under § 842 (a)(1), did not rely on the regulations. It found inherent in the statutory term "prescription" a requirement that the order be issued for a valid medical purpose.

[13] On its face § 829 addresses only the form that a prescription must take. A written prescription is required for Schedule II substances. § 829 (a). Either a written or an oral prescription is adequate for drugs in Schedules III and IV. § 829 (b). The only limitation on the distribution or dispensing of Schedule V drugs is that it be "for a medical purpose." § 829 (c). The medical purpose requirement explicit in subsection (c) could be implicit in subsections (a) and (b). Regulation § 306.04 makes it explicit. But § 829 by its terms does not limit the authority of a practitioner.

[14] In addition, a doctor who dispenses a controlled substance not authorized by his registration to another registrant is also covered by § 842 and would thus be punished as severely as a doctor who sold drugs solely for financial profit to nonregistrants. § 842 (a)(2).

§ 843 so long as the technical requirements are complied with.

But we think it immaterial whether Dr. Moore also could have been prosecuted for his violation of statutory provisions relating to dispensing procedures. There is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for the relatively minor offense of violating § 829 is thereby exempted from prosecution under § 841 for the significantly greater offense of acting as a drug "pusher." [15]

III

Respondent argues that even if Congress did not intend to exempt registrants from all prosecutions under § 841, he cannot be prosecuted under that section because the specific conduct for which he was prosecuted was "authorized by [the] subchapter" and thus falls within the express exemption of the section.

The trial judge assumed that a physician's activities are authorized only if they are within the usual course of professional practice. He instructed the jury that it had to find

> "beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute

[15] Respondent argues that the proper sanction for trafficking physicians is not criminal prosecution, but deregistration or refusal to reregister. But, under respondent's analysis, at the time he was convicted neither penalty could be imposed as a sanction for the conduct in which he engaged. Registration was mandatory for practitioners with state licenses, § 823 (f), and could only be suspended or revoked if the state license was revoked or suspended, if the practitioner had "materially falsified" an application under the Act, or if he had been convicted of a drug-related felony. § 824 (a). Conviction for a misdemeanor under § 842 would be insufficient to support revocation.

> [methadone] by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." App. 123.

The Court of Appeals did not address this argument because it concluded that registrants could not be prosecuted under § 841 under any circumstances. But it suggested that if a registrant could be reached under § 841 he could not be prosecuted merely because his activities fall outside the "usual course of practice." 164 App. D. C., at 322 n. 11, 505 F. 2d, at 429 n. 11.

Under the Harrison Act physicians who departed from the usual course of medical practice were subject to the same penalties as street pushers with no claim to legitimacy. Section 2 of that Act required all persons who sold or prescribed certain drugs to register and to deliver drugs only to persons with federal order forms. The latter requirement did not apply to "the dispensing or distribution of any of the aforesaid drugs to a patient by a physician . . . registered under this Act in the course of his professional practice only." 38 Stat. 786. As noted above, Congress intended the CSA to strengthen rather than to weaken the prior drug laws. There is no indication that Congress intended to eliminate the existing limitation on the exemption given to doctors.[16] The difficulty

[16] The Narcotic Addict Treatment Act of 1974 (NATA), 88 Stat. 124, 21 U. S. C. §§ 802, 823, 824 (1970 ed., Supp. IV), modified the registration and revocation procedures provided in the CSA in order to facilitate "more expeditious" criminal prosecutions by making revocation easier.

There was no indication that Congress thought that trafficking doctors could escape felony prosecution altogether under pre-NATA law. Rather, it sought to "cure the present difficulty in such prosecutions because of the intricate and nearly impossible burden of establishing what is beyond 'the course of professional practice' for

arises because the CSA, unlike the Harrison Act, does not spell out this limitation in unambiguous terms.

Instead of expressly removing from the protection of the Act those physicians who operate beyond the bounds of professional practice, the CSA uses the concept of "registration." Section 822 (b) defines the scope of authorization under the Act in circular terms: "Persons registered . . . under this subchapter . . . are authorized [to dispense controlled substances] . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." But the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his "professional practice."

Registration of physicians and other practitioners [17] is mandatory if the applicant is authorized to dispense drugs or conduct research under the law of the State in which he practices.[18] § 823 (f). In the case of a physi-

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criminal law purposes when such a practitioner speciously claims that the practices in question were ethical and humanitarian in nature." S. Rep. No. 93-192, p. 14 (1973). Dr. Moore's conviction was cited to illustrate that successful criminal actions could be brought only "in the most aggravated of circumstances . . . after prolonged effort to make undercover penetrations." *Id.*, at 13.

[17] "Practitioner" means "a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." § 802 (20).

[18] Under § 823, registration of manufacturers and nonpractitioner distributors (such as suppliers) is discretionary with the Attorney General. He first must make a finding that registration is consistent (in the case of manufacturers of Schedule I and II drugs) or not inconsistent (in the case of manufacturers of Schedule III-V

cian this scheme contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice.[19] The federal registration, which follows automatically, extends no further. It authorizes transactions within "the legitimate distribution chain" and makes all others illegal. H. R. Rep. No. 91–1444, p. 3. Implicit in the registration of a physician is the understanding that he is authorized only to act "as a physician."

This is made explicit in § 802 (20), which provides that "practitioner" means one who is "registered . . . by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." This section defines the term "practitioner" for purposes of the Act. It also describes the type of registration contemplated by the Act. That registration is limited to the dispensing and use of drugs "in the course of professional practice or research."

Other provisions throughout the Act reflect the in-

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drugs and all distributors) with the public interest. In evaluating the public interest the Attorney General is to consider, for example, "maintenance of effective controls against diversion," compliance with applicable state and local law, prior conviction record in drug-related charges, past experience, and (in the case of manufacturers) promotion of technical advances in manufacturing and the development of new substances. Practitioners and pharmacies are automatically entitled to registration to handle drugs in Schedules II–V "if they are authorized to dispense . . . under the law of the State in which they practice." § 823 (f).

[19] The House Report described the rationale behind § 823 (f) as follows: "Practitioners . . . engaged in the distribution chain would be required to be registered, but registration would be as a matter of right where the individual or firm is engaged in *activities* involving these drugs which are authorized or permitted under State law . . . ." H. R. Rep. No. 91–1444, p. 23 (1970) (emphasis added).

tent of Congress to confine authorized medical practice within accepted limits. Section 812 (b)(2) includes in its definition of Schedule II drugs a requirement that "[t]he drug [have] a currently accepted medical use with severe restrictions." Registration under the CSA to dispense or to conduct research with Schedule I drugs, which are defined as having "no currently accepted medical use in treatment in the United States," § 812 (b)(1)(B), does not follow automatically from state registration as it does with respect to drugs in Schedules II through V, all of which have some accepted medical use. § 823 (f). The record and reporting requirements of § 827 are made inapplicable with respect to narcotic drugs in Schedules II through V when they are prescribed or administered "by a practitioner in the lawful course of his professional practice." § 827 (c)(1)(A). Section 828 (a) prohibits the distribution of Schedule I and II drugs unless pursuant to specified order forms; § 828 (e) makes it unlawful for "any person" to obtain drugs with these order forms "for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research." Section 844 (a) prohibits possession of controlled substances unless the drug was obtained "from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized . . . ." See also § 885 (a)(2).

The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of "professional practice." [20] As detailed above, he gave inadequate physical examinations or none at all.

[20] The jury was instructed that Dr. Moore could not be convicted if he merely made "an honest effort" to prescribe for detoxification in compliance with an accepted standard of medical practice. App. 124.

He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale "pusher"—not as a physician.

IV

Respondent further contended at trial that he was experimenting with a new "blockade" theory of detoxification. The jury did not believe him. Congress understandably was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories. But respondent's interpretation of the Act would go far beyond authorizing legitimate research and experimentation by physicians. It would even compel exemption from the provisions of § 841 of all "registrants," including manufacturers, wholesalers, and pharmacists—in addition to physicians.

In enacting the Comprehensive Drug Abuse Prevention and Control Act of 1970, 84 Stat. 1236, Title II of which is the CSA, Congress faced the problem directly. Because of the potential for abuse it decided that some limits on free experimentation with drugs were necessary. But it was also aware of the concern expressed by the Prettyman Commission:

> "[A] controversy has existed for fifty years over the extent to which narcotic drugs may be administered to an addict solely because he is an addict.
>
> . . . . .
>
> "The practicing physician has . . . been confused as to when he may prescribe narcotic drugs for an

> addict. Out of a fear of prosecution many physicians refuse to use narcotics in the treatment of addicts except occasionally in a withdrawal regimen lasting no longer than a few weeks. In most instances they shun addicts as patients." [21]

Congress' solution to this problem is found in § 4 of Title I of the 1970 Act, 42 U. S. C. § 257a. That section requires the Secretary of Health, Education, and Welfare, after consultation with the Attorney General and national addict treatment organizations, to "determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction . . . ." It was designed "to clarify for the medical profession . . . the extent to which they may safely go in treating narcotic addicts as patients." H. R. Rep. No. 91–1444, p. 14. Congress pointed out that "criminal prosecutions" in the past had turned on the opinions of federal prosecutors. Under the new Act, "[t]hose physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers . . . ." *Id.*, at 15. The negative implication is that physicians who go beyond approved practice remain subject to serious criminal penalties.

In the case of methadone treatment the limits of approved practice are particularly clear. As Dr. Moore admitted at trial,[22] he was authorized only to dispense methadone for detoxification purposes. His authorization by the FDA to engage in a methadone maintenance program had been revoked. Nor was respondent unfamiliar with the procedures for conducting a legitimate detoxification program. Charges arising

[21] Report of the President's Advisory Commission on Narcotic and Drug Abuse 56–57 (1963), quoted in H. R. Rep. No. 91–1444, pp. 14–15.

[22] App. 101.

out of his 1969 treatment program, which involved a combination of "long term" and "short term" detoxification, were dropped after he testified before a grand jury and agreed to abide by certain medical procedures in future methadone programs. These included obtaining a medical history of each patient, conducting a reasonably thorough physical examination, abiding by the results of urine tests, recording times and amounts of dosages, and either administering the methadone in his office or prescribing no more than a daily dosage.[23] At trial respondent admitted that he had failed to follow these procedures.[24]

V

Respondent argues finally that the statute is sufficiently ambiguous that it must be construed in his favor despite the clear intent of the Congress. It is true that "when choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite." *United States* v. *Universal C. I. T. Credit Corp.*, 344 U. S. 218, 221–222 (1952). In this case, however, the principle set forth in *United States* v. *Brown*, 333 U. S. 18, 25–26 (1948), is appropriately followed:

> "The canon in favor of strict construction [of criminal statutes] is not an inexorable command to override common sense and evident statutory purpose. . . . Nor does it demand that a statute be given the 'narrowest meaning'; it is satisfied if the words are given their fair meaning in accord with the manifest intent of the lawmakers."

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[23] *Id.*, at 97–100, 116, 136–138.

[24] *Id.*, at 97–100.

The judgment of the Court of Appeals is reversed. Because of its disposition of the case, that court did not reach the question whether respondent could be sentenced under 21 U. S. C. § 845, which provides a higher penalty for distribution of controlled substances to persons under 21 years of age. We remand for the sole purpose of considering respondent's claim that he was improperly sentenced under that section.

So ordered.

21 USC 823

U.S. Code as of: 01/06/03

Section 823. Registration requirements

Related Resources

Health Law Guide

Department of Health and Human Services Directory

Department of Justice Directory

Agriculture Discussion

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent

with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting

research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or

detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) In any case in which the practitioner is not in a group practice, the total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number.

(iv) In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 262 of title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f) of this section.

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f) of this section.

(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f) of this section. The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the

Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term ''group practice'' has the meaning given such term in section 1395nn(h)(4) of title 42.

(ii) The term ''qualifying physician'' means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

(I) During the 3-year period beginning on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs, to patients for maintenance or detoxification treatment in accordance with this

paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug. (FOOTNOTE 1)

(FOOTNOTE 1) So in original. Probably should be ''combinations of drugs.''.

(J)(i) This paragraph takes effect the date referred to in subparagraph (I), and remains in effect thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on October 17, 2000, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this chapter; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that this paragraph should not remain in effect, this paragraph ceases to be in effect 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 802(39)(A)(iv) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider -

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

Previous [Notes] Next

Stodola

NOTICES

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 07-24]

Patrick W. **Stodola**, M.D.; Revocation of Registration

Tuesday, May 5, 2009

On February 7, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Patrick W. **Stodola**, M.D. (Respondent), of Chicago, Illinois. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, AS2352653, as a practitioner, and proposed the denial of his pending application to renew his registration, on the ground that his "continued registration is inconsistent with the public interest." Show Cause Order at 1.

The Show Cause Order specifically alleged that while Respondent is licensed as a physician only in Illinois, he prescribed controlled substances, via the internet, to persons located in twenty-six other States. Id. The Order alleged that Respondent's prescribing constituted the unauthorized practice of medicine because he did not possess the licenses required to practice medicine (and prescribe) in these States, and that the prescriptions he authorized "were not issued in the usual course of professional practice as required by 21 CFR 1306.04." Id. at 1-2.

On March 14, 2007, Respondent filed a request for a hearing and the matter was placed on the docket of the Agency's Administrative Law Judges. Following prehearing procedures, a hearing was held on October 16, 2007, in Chicago, Illinois. At the hearing, both parties elicited testimony and introduced documentary evidence for the record. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law and argument.

On September 16, 2008, the ALJ issued her recommended decision (ALJ). In evaluating Respondent's experience in dispensing controlled substances and record of compliance with applicable laws, the ALJ concluded that Respondent had violated the medical practice standards adopted by multiple States which specifically require that a physician physically examine a patient before prescribing a drug to him/her. ALJ at 33-34. The ALJ further concluded that Respondent had violated the laws of numerous States by prescribing to their residents without holding the requisites licenses to practice medicine and/or dispense controlled substances. Id. at 34. While the ALJ found that Respondent has retained his Illinois medical license

and has not been convicted of a crime, she further found that Respondent has "refus[ed] to acknowledge his wrongdoing." Id. at 32 & 34. The ALJ thus "conclude[d] that Respondent is unwilling or unable to accept the responsibilities inherent in a DEA registration," and recommended that his registration be revoked and that any pending applications be denied. Id. at 35.

Respondent did not file exceptions to the ALJ's decision. [FN1] Thereafter, the record was forwarded to me for final agency action.

FN1 While the Government filed exceptions, the exceptions do not go to the merits of the proceeding.

Having considered the entire record in this matter, I adopt the ALJ's conclusions of law with respect to the public interest inquiry. I further adopt the ALJ's recommended sanction. Accordingly, I will revoke Respondent's registration and deny his pending application to renew the registration. I make the following findings.

Findings

Respondent is the holder of DEA Certificate of Registration, AS2352653, which authorizes him to dispensing controlled substances in schedules II through V as a practitioner. According to Respondent's Certificate of Registration, the expiration date of his registration was February 28, 2006. It is undisputed, however, that Respondent filed a timely renewal application. I therefore find that Respondent's registration has remained in effect pending the issuance of this Order. See 5 U.S.C. 558(c).

Respondent holds a medical license in Illinois. Tr. 85, 190-91. In his testimony, Respondent acknowledged that he is not licensed to practice medicine in any other State, id. at 85 & 191, and that he has never obtained a license to practice in any other State. Id. at 85. Moreover, Respondent does not hold a DEA registration for a location in any State other than Illinois. Id. at 191.

In early 2006, Respondent read an advertisement which had been placed by Just USA Meds [FN2] in the employment section of the Chicago Tribune's Web site. Id. at 165. Respondent called the phone number contained in the ad, and spoke with Challen Sullivan, Just USA's owner, who told him that his business "was to be a provider of medical services," but not "a dispenser or a vending machine of any particular medications." Id. at 87. Thereafter, Respondent entered into an agreement with the entity under which Just USA Meds would arrange for customers, who were seeking controlled substances, to speak with him by telephone. Id. at 14. Respondent was paid $20 per consultation and would typically issue a controlled-substance prescription for the patient upon the conclusion of the consultation. Id. The prescriptions were then sent to pharmacies which had entered into arrangements with Just USA Meds to dispense the drugs to its customers.

FN2 In this decision, Just USA Meds will also be referred to as "Just USA."

According to Respondent, a customer would contact Just USA Meds, identify himself, and provide a copy of the credit card which he intended to use to pay his bill. Id. at 91. Respondent asserted that a customer would then be interviewed by an employee of Just USA Meds, who would ask him the name of his doctor, what other drugs he was taking, and whether he would agree not to seek drugs from another source if Respondent (or the other doctors engaged by Just USA Meds) issued a prescription for him. Id. at 92. Just USA would then contact the customer's credit card company to verify whether the card was valid and to request a pre-charge for the anticipated amount of the services and drugs being provided. Id. After Just USA obtained the pre-charge, the customer would then be scheduled for a consultation with Respondent or another physician. Id. at 104.

Respondent admitted that he did not physically examine any of the persons who were referred to him by Just USA Meds. Tr. 18 (testimony of DI); id. at 84 (testimony of Respondent). [FN3] Rather, Respondent asserted that the customers were required to send in medical records including the documentation of a physical exam which had to be less than one year old. Id. at 97-98. He also maintained that persons who claimed "some sort of structural harm" were ***20728** required to forward imaging documentation such as a CT scan, MRI, or X-Ray, and that if the person did not have a physical that met the above requirement, the person was sent an eleven to twelve-page-long form, which was to be taken to a doctor in his/her community to "have the history and physical completed." Id. at 98. Relatedly, Respondent claimed that for those customers who found it inconvenient to go to a doctor's office, Just USA Meds used a company which sent a nurse to the customer's home to obtain a medical history and perform a physical. Id. at 100.

FN3 Respondent did not even physically examine those persons he prescribed to who resided in the Chicago area. See GX 34 at 24 (resident of Chicago); GX 39 at 63 (resident of Highland Park, Il.); Id. at 133 (resident of Arlington Heights, Il.); Id. at 171 (resident of Hoffman Estates, Il.).

Respondent further maintained that he kept copies of each customer's medical records. Id. Respondent did not, however, produce any of these records at the hearing.

Respondent also asserted that the phone consultations he conducted were probing and would take between twenty to thirty minutes to complete. [FN4] Id. at 105. Relatedly, he maintained that Just USA Meds "scolded [him] a couple of times in the beginning" because the consultations took too much time. Id. According to Respondent, the

FN4 The prescription records suggest that this testimony stretches the limits of credulity. According to GX 35, on February 9, 2006, Respondent would have performed approximately thirty consultations, and the following day, he would have performed approximately thirty-three consultations. Respondent would thus have spent between ten and seventeen hours a day consulting. While this is not out of

the realm of possibility, it seems most unlikely. However, because most (if not all) of Respondent's prescribings were illegal regardless of how long the consultations lasted for, it is unnecessary to determine whether this testimony is credible.

consultations were inquiries concerning the history and physical, which was in front of me, the nature and extent of the medications and therapies that they had already received, their response to any medications that they had already received, what medications other than what they were requesting they were already taking, how their condition affected them, and I usually used two or three different tests inquiring from them to find out the nature of their problem.

Id. at 104. Respondent also maintained that he asked the customer to rate their pain "on a scale of 1 to 10," whether he/she had previously "taken hydrocodone," and if so, how it affected the customer's pain level and whether the drug had caused various adverse events. Id. at 105. Respondent maintained that "those were all discussed by me each and every time," and that "[t]here were no exceptions." Id.

Relatedly, Respondent asserted that the consultations "were meaningful interviews that took as long or longer than is customarily had in a physician's office with the patient physically in front of them," and "that the interviews were comprehensive and medically appropriate." Id. at 106. According to Respondent, "probably about 90 percent of the patients who were inquiring were requesting some sort of pain relief." Id. Respondent also asserted that he would "sometimes" negotiate with the customers to "alter their request" for drugs and or "to use some other medicine." [FN5] Id.

According to various prescription records which were entered into evidence, Respondent issued in excess of three hundred controlled-substance prescriptions for Just USA, the overwhelming majority (approximately eighty-five to ninety percent) of which were for combination drugs containing hydrocodone, a schedule III controlled substance, and acetaminophen. See GXs 34, 35, & 39; 21 CFR 1308.13(e). Invariably, the prescriptions were for those formulations which contained the stronger concentrations (7.5 or 10 mg.) of hydrocodone. See GXs 34, 35, & 39.

As I have noted in numerous other decisions, these drugs are highly popular with drug abusers. See Southwood Pharmaceuticals, Inc., 72 FR 36487, 36503 (2007) (noting 2004 survey of National Institute of Drug Abuse found that "9.3 percent of twelfth graders reported using Vicodin, a brand name Schedule III controlled substance without a prescription in the previous year"); William R. Lockridge, 71 FR 77791, 77796 (2006) (noting that in 2002, the abuse of hydrocodone products resulted in more than 27,000 emergency room visits). [FN6] Respondent also issued smaller numbers of prescriptions for Didrex (benzphetamine, a schedule III controlled substance), as well as various schedule IV drugs including alprazolam, diazepam, Ambien (zolpidem) and phentermine. See GXs 34, 35, & 39; see also 21 CFR

1308.13(b)(2); Id. 1308.14(c) & (e).

FN5 The prescriptions records, however, cast doubt on the credibility of this testimony. As found above, Respondent invariably issued prescriptions for combination drugs which contained either 7.5 or 10 mg. of hydrocodone (rather than those drugs which contain only 5 mg.), and rarely issued prescriptions for such non-controlled drugs which are used to treat pain such as Tramadol and Fioricet.

The various prescription records entered into evidence show that Respondent also wrote a miniscule number of prescriptions for non-controlled drugs including Soma (carisoprodol), Tramadol, and Fioricet (a combination of butalbital, acetaminophen and caffeine).

FN6 In his testimony, Respondent asserted that drugs containing hydrocodone are not addictive or "dangerous." Tr. 158-59. As found above, combination hydrocodone drugs are among the most highly abused controlled substances. I therefore reject Respondent's testimony as self-serving.

As the prescriptions records indicate, the customers were located throughout the United States, and the overwhelming majority of them resided in States other than Illinois. See GXs 34, 35, & 39. More specifically, the records in evidence show, inter alia, that Respondent issued hydrocodone prescriptions in the following amounts: forty-eight to residents of Texas, forty to residents of California, nineteen to residents of North Carolina, thirteen to residents of both Ohio and of Virginia, ten to residents of Indiana, nine to residents of Colorado, eight to residents of both Massachusetts and Mississippi, seven to residents of Georgia, six to residents of Missouri, and four to residents of Oklahoma. [FN7] See generally GXs 34, 35, & 39.

FN7 The Government also introduced into evidence the sworn declaration of George Van Komen, M.D. GX 41. Respondent, however, objected to the admission of the exhibit on the ground that the declaration was testimonial in nature and that he was unable to cross-examine Dr. Van Komen. Tr. 58-59. The ALJ overruled Respondent's objection and admitted the declaration. Id. at 59.

I do not rely on the exhibit, however, because it is unclear whether the declaration was properly admitted. While the Government provided notice of its intent to use the Declaration in its Supplemental Prehearing Statement, the Statement does not disclose the substance of the Declaration. Moreover, the record does not establish whether a copy of the Declaration was provided to Respondent in advance of the hearing. While hearsay is admissible in these proceedings, a testimonial declaration must be timely provided to the other party in order to afford it with the opportunity to determine whether to request a subpoena of the witness.

As early as March 2006, Respondent spoke with a DEA Diversion Investigator to inquire as to why the Agency had not approved his renewal application. Tr. 87. During the conversation, the DI asked him "what [he] was doing to make a living as a

doctor." Id. Respondent told the DI that he worked at several clinics and "had some telemedicine internet practice going." Id. The DI then told Respondent "that there might be a problem with that." Id. Respondent nonetheless continued his prescribing for Just USA Meds until January 2007. Id. at 178. [FN8]

FN8 The record suggests that Respondent had additional discussions with DEA Investigators in both May and September 2006 regarding his practices. The record does not, however, establish with reasonable specificity the content of these discussions.

Throughout the hearing, Respondent maintained that his "prescribing was appropriate." Id. at 99. Furthermore, on cross-examination, Respondent acknowledged that he found evidence that Just USA Meds had used his name and registration to backdate several prescriptions which had been dispensed before he commenced working for the ***20729** entity. Id. at 170. Respondent testified that he did not authorize this use of his registration which he discovered "within the first couple of weeks" after he started working for Just USA. Id. at 169.

Respondent failed to report the incident to the Agency, asserting that Just USA had told him that "only one or two" prescriptions had been back dated. Id. at 170. Respondent admitted, however, that he "had no way of confirming" the validity of Just USA's representation that the backdating had occurred in "only one or two instances." Id.

Respondent also maintained that on multiple occasions, he engaged in due diligence to determine whether his conduct was legal. Respondent contends that shortly after he entered into his arrangement with Just USA, he was sent a document entitled "Ordering and Registration Instructions," which indicated the procedures which the "patients" were required to complete to purchase drugs which included providing a copy of an identification card, medical records, and physician reports, etc. RX 7A. Moreover, the document listed seven States that Just USA's pharmacies did not ship to including Arizona, Kentucky, Missouri, Nevada, Pennsylvania, South Carolina, and Tennessee. Id. In his testimony, Respondent maintained that Just USA had sent this document to him after he asked how he would know that he was permitted to prescribe to residents of States other than Illinois. Tr. 95. Respondent further claimed that Just USA told him that it had "already done an examination of the law, and we do not service" the above States, because they "required a face-to-face meeting between the prescribing doctor and the patient," or the State prohibited an out-of-state doctor from prescribing to its residents, or the State did not permit telemedicine. Id. at 95-96; see also id. at 184. According to Respondent, "it was good enough for me that they had ruled out certain states that it was not appropriate to go to." [FN9] Id. at 96.

FN9 Respondent subsequently stated that after he stopped working for Just USA he learned that there were two or three other States (in addition to the seven States listed in RX 7A) where his prescribing was illegal. Tr. 161.

On cross-examination, however, the Government identified multiple instances in which Respondent had issued prescriptions to patients who lived in these States. See Tr. 186-90. More specifically, the Government identified controlled prescriptions Respondent issued to residents of Arizona (GX 39 at 6), Kentucky (id. at 21), Missouri (id. at 23), Nevada (id. at 75), Pennsylvania (id. at 67), and South Carolina (id. at 182). When confronted with this evidence, Respondent did not "know how that happened" and claimed that he "wasn't aware that it happened." Id. at 194.

Respondent admitted, however, that the customer's names and addresses were in the medical records, which he claimed he had access to. Id. at 196. He also admitted that "in most instances," he did not look at where the customer lived, id., but instead relied on the employees of Just USA to screen out the customers. Id. at 200-01.

Respondent also entered into evidence an Agency document which stated that it was clarifying DEA's "policies regarding the dispensing and prescribing of controlled substances as they pertain to the internet." RX 7C. This document specifically noted the prescription requirement of Federal law, see 21 CFR 1306.04(a), and made explicit reference to the Agency's 2001 Guidance Document, Dispensing and Purchasing Controlled Substances over the Internet, 66 FR 21181. The document further stated: "As noted in the guidance document, it is unlikely that such a relationship could be established through the use of an online questionnaire completed by a consumer prior to the purchase of controlled substances." RX 7C, at 1.

The Agency's 2001 Guidance expressly stated that "[u]nder Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship." 66 FR at 21182. Continuing, the Guidance observed that "[f]or purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established: A patient has a medical complaint; A medical history has been taken; A physical examination has been performed; and Some logical connection exists between the medical complaint; the medical history, the physical examination, and the drug prescribed." Id. at 21182-83. The Guidance further stated that "[c]ompleting a questionnaire that is then reviewed by a doctor hired by the internet pharmacy could not be considered the basis for a doctor/patient relationship." Id. at 21183.

Of further relevance, the Guidance explained that "[o]nly practitioners acting in the usual course of their professional practice may prescribe controlled substances. These practitioners must be registered with DEA and licensed to prescribe controlled substances by the State(s) in which they operate." Id. at 21181 (emphasis added). [FN10]

FN10 Respondent also cites a "Flow Chart," RX 7B, which was prepared by Just USA

Meds Pharmacy and which sets forth the purported process by which customers obtained drugs as evidence of his having engaged in due diligence. The document does not set forth any legal advice and is merely cumulative of Respondent's testimony as to the procedures used by Just USA to process customer orders.

Respondent also submitted a document which contains several e-mail messages from July 27 and 28, 2006, which discuss an e-prescribing initiative introduced in Illinois, one of which originated from Mudri Associates, a DEA Consultancy. RX 7E. Respondent asserts that this evidence establishes that he contacted the consultant "following [its] inspection of all of the procedures followed by [J]ust USA * * * [and] the pharmacies with which [J]ust USA had arrangements." Resp. Br. (Pt. II) at 14. The e-mail does not, however, discuss any issue other than various proposals that were part of an Illinois patient safety initiative.

As further support for his contention that he performed due diligence in attempting to ascertain whether his prescribing practices were legal, Respondent introduced into evidence a document which appears to be a legal opinion (dated June 21, 2006) prepared by a Tampa, Florida-based lawyer. [FN11] See RX 7D. In stating the issue, the opinion noted that "[a]s your Pharmacy and Prescribing Doctors are located within the States of Florida, this Memorandum's analysis focuses on Florida law as well as Federal law concerning appropriate prescribing standards." Id. at 6. Continuing, the opinion observed that "[t]he state laws and professional standards concerning telemedicine and prescribing practices vary from state to state, and because I am licensed to practice in the State of Florida, this Memorandum's analysis is limited to Florida law as well as Federal law concerning appropriate prescribing standards." Id. The opinion further noted that it "specifically" did not address such issues as "physician and pharmacy licensure." Id.

FN11 The text of the letter appears to have been cut and inserted into various internet-based text messages which occurred between Respondent and Challen Sullivan, the owner of Just USA Meds. See RX 7-D; Tr. 119 & 125-26. Nor does the text of the memorandum appear in the exhibit in the order that is customarily used by lawyers in preparing legal opinions for their clients. See id.

As for its legal conclusions, the opinion stated that "[p]rescribing standards vary dramatically from state to state and in some instances vary within a particular state for the prescription of specified pharmaceutical items (e.g., some states have heightened standards for prescribing controlled substances and diet drugs)." Id. at 1. [FN12] ***20730** Moreover, in addition to its discussion of Florida law, the opinion notes that "[o]ther states have adopted statutes specifically relating to prescribing standards and the business of Internet pharmacy--often requiring a face to face physical examination and making non-compliance a crime subject to heavy penalties. These statutes are usually more comprehensive in requiring compliance by all of the website operators, physicians and pharmacies involved. Most sophisticated and established Internet pharmacy operators avoid conducting business in these more restrictive states." Id. at 4 (emphasis added).

[FN13]

FN12 The opinion provides a lengthy discussion of Florida's standards, and appears to conclude that under Florida law and regulations, a physician need ¢mnot have personally performed a physical examination in order to prescribe a drug (other than a diet drug). Id. at 2-3. However, as found above, Respondent prescribed to residents of numerous other States.

FN13 The opinion also observed that the American Medical Association's "standards suggest that the physician must personally conduct the physical examination," RX 7D at 3, and while suggesting that the AMA's positions were inconsistent, quoted another AMA guideline which states in relevant part: "Licensure: Physicians who prescribe medications via the Internet across state lines, without physically being located in the state(s) where the patient (clinical) encounter(s) occurs, must possess appropriate licensure in all jurisdictions where patients reside." Id. at 4.

The opinion also discussed Federal prescribing standards. In discussing this Agency's 2001 Guidance, the opinion states that "[a]lthough the DEA acknowledges that state law ultimately controls the issue of whether a prescription is written in the usual course of professional practice, the DEA feels that the weight of legal and professional authority requires the [four] elements [set forth in the Guidance] to be present in order to establish a bona fide doctor/patient relationship." Id. The letter then quoted verbatim the four elements set forth in the Guidance.

Furthermore, the opinion also noted that "DEA has in some instances over the past year informally challenged some pharmacies and medical professionals participating in a Medical Records Based Prescribing pharmacy business. The DEA has asserted in such instances that in its opinion Medical Records Based Prescribing does not meet applicable local legal standards which require that an adequate physician-patient relationship exists for the prescription." RX 7D at 5.

The opinion, however, rejected the Agency's view as to the legality of Medical Records Based Prescribing, citing among other things, its author's "understanding that the three largest drug wholesalers * * * have concluded that the DEA does not have a legal basis for making these assertions," the 2003 failure of Congress to enact the Ryan Haight Internet Pharmacy Consumer Protection Act (which prohibits a practitioner's prescribing to a person he/she has not physically examined), [FN14] and the December 2005 testimony of Agency officials to Congress to the effect that the Controlled Substances Act does not provide a statutory definition of "what constitutes a valid 'doctor/patient' relationship." Id. at 5. The opinion thus concluded that "the Websites' Medical Records Based Prescribing Procedures appear to comply with the DEA's published rules and Federal law." Id. [FN15]

FN14 On October 15, 2008, the President signed into law the Ryan Haight Online

Pharmacy Consumer Protection Act of 2008, Public Law No. 110-425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance "by means of the Internet without a valid prescription," and defines, in relevant part, the "[t]he term 'valid prescription' [to] mean [ ] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least 1 in-person medical evaluation of the patient." 122 Stat. 4820. Section 2 further defines "[t]he term 'in-person medical evaluation' [to] mean [ ] a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals." Id. These provisions do not, however, apply to Respondent's conduct.

FN15 Respondent also cites a December 1, 2006 rulemaking which amended DEA regulations to require that a practitioner obtain a separate registration for each State in which he practices, and a December 22, 2006, memo written by the same Tampa-based attorney regarding the applicability of the new rule to internet prescribers. See RX 7G. In light of the fact that almost (if not) all of the actual prescriptions which are in evidence in this matter were issued by Respondent prior to his having reviewed either of these documents, I find it unnecessary to make any findings based on them.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to "dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). Moreover, section 303(f) of the CSA provides that "[t]he Attorney General may deny an application for [a practitioner's] registration if he determines that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. 823(f). In making the public interest determination, the Act requires the consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id.

"[T]hese factors are * * * considered in the disjunctive." Robert A. Leslie, M.D., 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application to renew a registration. Id. Moreover, I am "not required to make findings as to all of the factors." Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); see also Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

Having considered all of the factors, I acknowledge that the record contains no evidence that the State of Illinois has taken action against Respondent's medical license (factor one) or that Respondent has been convicted of an offense related to controlled substances (factor two). [FN16] The record contains, however, an abundance of evidence that Respondent's experience in dispensing controlled substances (factor two) and record of compliance with applicable Federal and State laws (factor four) is characterized by his repeated violation of the CSA's prescription requirement, as well as numerous state laws and regulations prohibiting the unlicensed practice of medicine and setting the standards for prescribing a drug.

FN16 This Agency has long held that a State's failure to take action against a practitioner's authority to dispense controlled substances is not dispositive in determining whether the granting of an application for registration would be consistent with the public interest. See Mortimer B. Levin, 55 FR 8209, 8210 (1990). I further note that the absence of a criminal conviction is not dispositive of the public interest inquiry. See, e.g., Edmund Chein, 72 FR 6580, 6593 n.22 (2007).

Moreover, I reject Respondent's contention that his conduct should be excused because he engaged in due diligence in attempting to ascertain the legal requirement for his prescribing. Even if I was to recognize such a defense in the context of a prescribing practitioner, the record establishes that Respondent's efforts were half-baked at best, and that when he did receive information that his activities were likely illegal, he ignored it. Finally, while Respondent eventually ceased his internet-related prescribing activities, his testimony manifests that he has not accepted responsibility for his misconduct, but rather blames others.

***20731** I therefore conclude that Respondent's continued registration would be "inconsistent with the public interest." 21 U.S.C. 823(f). Accordingly, Respondent's registration will be revoked and his application to renew his registration will be denied.

Factor Two and Four--Respondent's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

The primary issue in this case is whether the prescriptions Respondent issued pursuant to his agreement with Just USA Meds were lawful prescriptions under the

CSA. Under a longstanding DEA regulation, a prescription for a controlled substance is not "effective" unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). This regulation further provides that "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." Id. As the Supreme Court recently explained, "the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135, 143 (1975)).

Under the CSA, it is fundamental that a practitioner must establish a bona fide doctor-patient relationship in order to act "in the usual course of * * * professional practice" and to issue a prescription for a "legitimate medical purpose." Moore, 423 U.S. at 141-43. At the time of the events at issue here, the CSA generally looked to state law to determine whether a doctor and patient have established a bona fide doctor-patient relationship. See Kamir Garces-Mejias, 72 FR 54931, 54935 (2007); United Prescription Services, Inc., 72 FR 50397, 50407 (2007); Dispensing and Purchasing Controlled Substances Over the Internet, 66 FR at 21182-83; but see n.14, supra (discussing the Ryan Haight Act).

Moreover, shortly after the CSA's enactment, the Supreme Court explained that "[i]n the case of a physician [the Act] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice." Moore, 423 U.S. at 140-41 (emphasis added). Accordingly, "[a] physician who engages in the unauthorized practice of medicine" under state laws "is not a 'practitioner acting in the usual course of * * * professional practice' " under the CSA. United Prescription Services, 72 FR at 50407 (quoting 21 CFR 1306.04(a)). This rule is supported by the plain meaning of the Act, which defines the "[t]he term 'practitioner' [to] mean [ ] a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance," 21 U.S.C. 802(21), and "[t]he term 'dispense' [to] mean [ ] to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner." Id. § 802(10). See also id. § 823(f) ("The Attorney General shall register practitioners * * * to dispense * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.").

A controlled-substance prescription issued by a physician who lacks the license or other authority required to practice medicine within a State is therefore unlawful under the CSA. See 21 CFR 1306.04(a) ("An order purporting to be a pre-

scription issued not in the usual course of professional treatment * * * is not a prescription within the meaning an intent of" the CSA); cf. 21 CFR 1306.03(a)(1) ("A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession[.]").

The record establishes that in issuing the prescriptions for Just USA's customers, Respondent repeatedly violated the CSA's prescription requirement. 21 CFR 1306.04(a). This is so for two reasons: (1) Respondent prescribed without establishing a valid doctor-patient relationship in violation of the medical practice standards of numerous States because he failed to physically examine the patients, and (2) Respondent's prescribing typically constituted the unauthorized practice of medicine in the States where the patients were located because he was licensed to practice medicine (and authorized to prescribe) only in Illinois. Furthermore, Respondent issued unlawful prescriptions even where various States had either enacted laws and regulations, rendered decisions in adjudications, or issued policy statements making clear that his prescribing practices were illegal.

For example, as found above, Respondent issued forty hydrocodone prescriptions to residents of California. In 2000, California enacted Cal. Bus. & Prof. Code § 2242.1, [FN17] which specifically prohibits the prescribing or dispensing of a dangerous drug "on the Internet for delivery to any person in this state, without an appropriate prior examination and medical indication therefore, except as authorized by Section 2242." Moreover, the statute, which provides for a fine or civil penalty of twenty-five thousand dollars for a violation, further directs that "[i]f the person or entity that is the subject of an action brought pursuant to this section is not a resident of this state, a violation of this section shall, if applicable, be reported to the person's or entity's appropriate professional licensing authority." Id. at (e).

FN17 This statute was effective January 1, 2001.

Relatedly, in 2003, the Medical Board of California revoked a physician's medical license for engaging in the same type of prescribing practices as Respondent did here. See In re John Steven Opsahl, M.D., Decision and Order, at 3 (Med. Bd. Cal. 2003) (available by query at http:// publicdocs.medbd.ca.gov/pdl/mbc.aspx). In Opsahl, the Medical Board expressly found that "[b]efore prescribing a dangerous drug, a physical examination must be performed." Id. Continuing, the Board found that "[a] physician cannot do a good faith prior examination based on a history, a review of medical records, responses to a questionnaire and a telephone consultation with the patient, without a physical examination of the patient." Id. Finally, the Board found that:

Medical indication means having a condition that warrants specific treatment. It is determined after the physician takes a history, performs a physical examination and makes an assessment about the patient's condition. * * * A physician cannot

determine whether there is a medical indication for prescription of a dangerous drug without performing a physical examination.

Id. [FN18]

FN18 Dr. Opsahl's prescribing practices involved "verifying patient identity," "obtaining and reviewing medical records," "having direct contact with the patient, though personal contact was not required," and "having an opportunity for follow-up." Decision at 4. Opsahl prescribed both non-controlled and controlled drugs including combination drugs containing hydrocodone, benzodiazepines, schedule three drugs containing codeine, as well as Ambien, phentermine, and phendimetrazine. Id. at 6.

***20732** Moreover, prior to Respondent's engaging in internet-based prescribing, the Medical Board of California had issued numerous Citation Orders to out-of-state physicians for internet prescribing to California residents. These Orders invariably cited not only the physicians' failure to perform "a good faith prior examination," but also their lack of "a valid California Physician and Surgeon's License to practice medicine in California." Citation Order, Martin P. Feldman (Aug. 15, 2003); see also Citation Order, Harry Hoff (Jun. 17, 2003); Citation Order, Carlos Gustavo Levy (Jan. 28, 2003); Citation Order, Carlos Gustavo Levy (Nov. 30, 2001). Moreover, the Board had issued several press releases setting forth its position that internet prescribing is unlawful. See GX 11 at 9 (Feb. 2004 Action Report) ("The Board has taken action against California physicians and licensees from other states for prescribing over the Internet without a good faith prior exam, and continues to investigate cases as it becomes aware of the practice."); Record Fines Issued by Medical Board to Physicians in Internet Prescribing Cases (News Release Feb. 10, 2003) (available at http://www.mbc.ca.gov/board/media/releases--2003--02-10--internet--drugs.html). Respondent thus clearly violated both California law and the CSA in issuing these prescriptions.

Respondent issued forty-eight prescriptions for hydrocodone drugs to residents of Texas. Respondent did not, however, hold a Texas medical license. See Tex. Occ. Code § 155.001; see also id. § 151.056(a) ("A person who is physically located in another jurisdiction but who, through the use of any medium, including an electronic medium, performs an act that is part of a patient care service initiated in this state, * * * and that would affect the diagnosis or treatment of the patient, is considered to be engaged in the practice of medicine in this state and is subject to appropriate regulation by the board."); 22 Tex. Admin. Code § 174.4(c) ("Physicians who treat and prescribe through the Internet are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.").

Respondent also lacked the state registration required to prescribe a controlled substance. See Tex. Health & Safety Code § 481.061(a) (requiring state registra-

tion to dispense); id. § 481.063(d) (requiring as a condition for registration that "a practitioner [be] licensed under the laws of this state"). Respondent thus also violated Texas law, and the CSA, in prescribing controlled substances to that State's residents. See Moore, 423 U.S. at 140-41 ("In the case of a physician [the CSA] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice.") (emphasis added); United Prescription Services, 72 FR at 50407 ("A controlled-substance prescription issued by a physician who lacks the license [or other authority required] to practice medicine within a State is * * * unlawful under the CSA."); 21 U.S.C. 802(10) (defining " 'dispense' [to] mean[ ] to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner").

Respondent issued nineteen prescriptions for drugs containing hydrocodone to North Carolina residents. Respondent did so notwithstanding that under North Carolina law, "prescribing medication by use of the Internet or a toll-free telephone number, shall be regarded as practicing medicine" in the State and subjects the practitioner to North Carolina law "and appropriate regulation by the North Carolina Medical Board." N.C. Gen. Stat. Ann. § 90-18(b). North Carolina law further provides that "[n]o person shall practice medicine * * * nor in any case prescribe for the cure of diseases unless the person shall have been first licensed and registered to do so." Id. § 90-18(a). Moreover, if "the person so practicing without a license is an out-of-state practitioner who has not been licensed and registered to practice medicine and surgery in this State, the person shall be guilty of a Class I felony." Id. [FN19]

FN19 While North Carolina exempts from these requirements an out-of-state practitioner who "on an irregular basis, consults with a resident registered physician," Respondent does not maintain that he was consulting with a North Carolina physician. N.C. Gen. Stat. Ann. § 90-18(c)(11).

In addition, in February 2001, the North Carolina Medical Board issued a Position Statement entitled: Contact With Patients Before Prescribing. GX 25 at 11. Therein, the Board stated "that prescribing drugs to an individual the prescriber has not personally examined is inappropriate except as noted * * * below." Id. The Board further explained that "[b]efore prescribing a drug, a physician should make an informed medical judgment based on the circumstances of the situation and on his or her training and experience. Ordinarily, this will require that the physician personally perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription." Id. While the North Carolina Board recognized that it may be appropriate to prescribe to a patient without having performed a physical exam "under certain circumstances," none of these apply to Respondent. [FN20] I thus conclude that Respondent violated both North Carolina law and the CSA in prescribing to the State's residents.

FN20 These circumstances "may include admission orders for a newly hospitalized

patient, prescribing for a patient of another physician for whom the prescriber is taking call, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment." GX 25 at 11. The Board also noted that "[e]stablished patients may not require a new history and physical examination for each new prescription, depending on good medical practice." Id.

Respondent issued thirteen prescriptions for hydrocodone to Ohio residents. Ohio law defines " 'the practice of telemedicine' [to] mean[ ] the practice of medicine in this state through the use of any communication, including oral, written, or electronic communication, by a physician outside th[e] state," and authorizes "[t]he holder of a telemedicine certificate [to] engage in the practice of telemedicine in this state." Ohio Rev. Code Ann. § 4731.296(A) & (C). See also id. § 4731.41 ("No person shall practice medicine and surgery, or any of its branches, without the appropriate certificate from the state medical board to engage in the practice."). Moreover, under the regulations of the State Medical Board of Ohio, "a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substances to a person who the physician has never personally examined and diagnosed" except for in limited situations not applicable here. [FN21] Ohio Admin. Code § 4731-11-09(A). I thus conclude that Respondent violated both Ohio law and the CSA in issuing prescriptions to Ohio residents.

FN21 The exceptions are for "institutional settings, on call situations, cross coverage situations, situations involving new patients," (but limited to where "the physician has scheduled or is in the process of scheduling an appointment to examine the patient and the drugs are intended to be used pending that appointment"), "protocol situations," "nurses practicing in accordance with standard care arrangements, and hospice settings." Ohio Admin. Code § 4731-11-09.

Respondent issued thirteen prescriptions for hydrocodone to Virginia residents. Under Virginia law, it is "unlawful for any person to practice medicine * * * in the Commonwealth without a valid unrevoked licensed issued by the Board of Medicine," Va. Code Ann. § 54.1-2902; and "[a]ny person shall be ***20733** regarded as practicing the healing arts who actually engages in such practice as defined in this chapter." Id. § 54.1-2903; see also id. § 54.1-2900 (the "[p]ractice of medicine" * * * means the prevention, diagnosis and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities by any means or method"); id. § 54.1-2929 ("No person shall practice * * * medicine * * * without obtaining a license from the Board of Medicine"). [FN22] Furthermore, "[a] prescription for a controlled substance may be issued only by a practitioner of medicine * * * who is authorized to prescribe controlled substances." Va. Code § 54.1-3303(A). Moreover, "[t]he prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons * * * with whom the practitioner has a bona fide practitioner-patient relationship." Id.

FN22 Respondent does not claim that his prescribing came within one of the limited exceptions for out-of-state practitioners recognized by Virginia law. See Va.

Code Ann. § 54.1-2901(A)(7) (authorizing "[t]he rendering of medical advice * * * through telecommunications from a physician licensed to practice medicine in * * * an adjoining state to emergency medical personnel acting in an emergency situation").

The Virginia statute also provides that "a bona fide practitioner-patient relationship means that the practitioner shall * * * perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription." Id. (emphasis added). I thus conclude that Respondent violated Virginia law and the CSA in prescribing to Virginia's residents.

Respondent issued ten prescriptions for hydrocodone to Indiana residents. Under Indiana law, "[i]t is unlawful for any person to practice medicine * * * in this state without holding a license or permit to do so." Ind. Code § 25- 22.5-8-1. Moreover, the practice of medicine includes the "prescription * * * of any form of treatment, without limitation." Id. § 25-22.5-1-1.1(a)(1)((B); see also id.§ (a)(4).

The Medical Licensing Board of Indiana has also adopted a regulation (similar to Ohio's), which provides that except for in limited situations, "a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed." 844 Ind. Admin. Code 5-4-1(a). [FN23] This rule has been effect since October 2003. I thus conclude that Respondent violated Indiana law and the CSA in prescribing to Indiana residents.

FN23 The exceptions are for "institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority." 844 Ind. Admin. Code 5-4-1(a). Respondent does not claim that his prescribing falls within any of these exceptions.

Respondent issued nine prescriptions for hydrocodone to Colorado residents. In November 2000, the Colorado State Board of Medical Examiners issued a policy statement entitled "Guidelines Regarding Prescribing for Unknown Patients." In this statement, the Colorado Board declared that:

It is unprofessional conduct for a physician to provide treatment and consultation recommendations, including issuing a prescription via electronic or other means, unless the physician has obtained a history and physical evaluation of the patient adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided. Issuing a prescription on the basis of a questionnaire, Internet-based consultation, or a telephonic con-

sultation, all without a valid pre-existing patient/practitioner relationship does not constitute an acceptable standard of care.

Before prescribing a drug, a physician should make an informed medical judgment based on the circumstances of the situation and on his/her training and experience. Ordinarily, this will require that the physician perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription. [FN24]

FN24 The Colorado Board has also recognized limited exceptions similar to those adopted by Ohio and Indiana.

GX 12 at 14. I thus conclude that Respondent acted outside of the course of professional practice in issuing the prescriptions to Colorado residents and violated the CSA.

Respondent issued eight prescriptions for hydrocodone to Mississippi residents. In May 2000, the Mississippi State Board of Medical Licensure issued a policy statement on Internet Prescribing. See GX 21 at 6. The Mississippi Board advised that the "[e]ssential components of proper prescribing and legitimate medical practice requires [sic] that the physician obtains a thorough medical history and conducts an appropriate physical examination before prescribing any medication for the first time." Id.

Moreover, since 1997, Mississippi law has provided that "no person shall engage in the practice of medicine across state lines (telemedicine) in this state, hold himself out as qualified to do the same, or use any title, word or abbreviation to indicate to or induce others to believe that he is duly licensed to practice medicine across state lines in this state unless he has first obtained a license to do so from the State Board of Medical Licensure and has met all education and licensure requirements as determined by the State Board * * *. " Miss. Code Ann. § 73-25-34(2). The statute specifically defines the terms "telemedicine, or the practice of medicine across state lines," as including "[t]he rendering of treatment to a patient within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from within this state to such physician or his agent." Id. § 73-25-34(1)(b). [FN25] I thus conclude that Respondent violated Mississippi law and the CSA when he prescribed to the State's residents.

FN25 Mississippi exempts an out-of-state physician from the licensure requirement when the physician provides an evaluation, treatment recommendation, or medical opinion at the request of "a physician duly licensed to practice medicine in th[e] state," and the requesting physician "has already established a doctor/patient relationship with the patient to be evaluated and/or treated." Miss. Code Ann. § 73-25-34(3). Respondent, however, produced no evidence that any physician had ever requested that he evaluate a Just USA patient.

Respondent also issued eight prescriptions for hydrocodone to residents of Massachusetts, whose law follows nearly verbatim the CSA's prescription requirement. Compare Mass. Gen. Laws ch. 94C, § 19(a), with 21 CFR 1306.04(a). In December 2003, the Massachusetts Board of Registration in Medicine issued the following interpretation of the State's prescription law:

[t]o satisfy the requirement that a prescription be issued by a practitioner in the usual course of his professional practice, there must be a physician-patient relationship that is for the purpose of maintaining the patient's well-being and the physician must conform to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical and/or mental status examination and recording the results. Issuance of a prescription, by any means, including the Internet or other electronic process, that does not meet these requirements is therefore unlawful.

Commonwealth of Massachusetts, Board of Registration in Medicine, Policy 03-06 INTERNET PRESCRIBING (Adopted Dec. 17, 2003). [FN26] As the ***20734** Board's interpretation makes plain, Respondent acted outside of the usual course of professional practice when he prescribed controlled substances to residents of Massachusetts, and therefore violated both Massachusetts law and the CSA.

FN26 The ALJ also concluded that Respondent was required to be licensed to practice medicine in Massachusetts and violated its law by prescribing ¢mto residents of that State. ALJ at 34. In light of the Massachusetts' Board clear interpretation as set forth in its policy on Internet Prescribing, I conclude that it is unnecessary to address whether Respondent also violated the State's provisions requiring a license and controlled substance registration which appear to allow an out-of-state practitioner to issue a prescription to a state resident in some instances. Id. Mass. Gen. Laws ch. 94C, 18(c).

Respondent issued seven prescriptions for hydrocodone for residents of Georgia. Under the rules of the Georgia Composite State Board of Medical Examiners, it is "unprofessional conduct" to "[p]rovid[e] treatment and/or consultation recommendations via electronic or other means unless the licensee has performed a history and physical examination of the patient adequate to establish differential diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended." Ga. Comp. R. & Regs. 360- 3-.02(6). [FN27] Moreover, Respondent violated Georgia law because he engaged in the unlicensed practice of medicine. See Ga. Code Ann. § 43-34-31.1. [FN28] I thus conclude that Respondent violated the CSA in prescribing to Georgia residents.

FN27 It is noted that the rule does "not prohibit a licensee who is on call or covering for another licensee from treating and/or consulting a patient of such other licensee." Ga. Comp. R. & Regs. 360-3-.02(6). Respondent did not maintain that he was covering for, or consulting with, other physicians who were treating the Georgia residents he prescribed to.

FN28 This statute provides:

(a) A person who is physically located in another state * * * and who, through the use of any means, including electronic * * * or other means of telecommunication, through which medical information or data is transmitted, performs an act that is part of a patient care service located in this state * * * that would affect the diagnosis or treatment of the patient is engaged in the practice of medicine in this state. Any person who performs such acts through such means shall be required to have a license to practice medicine in this state and shall be subject to regulation by the board.

Ga. Code Ann. § 43-34-31.1(a). While the statute includes exceptions when, inter alia, the physician "[p]rovides consultation services at the request of a physician licensed in this state," or "[p]rovides consultation services in the case of an emergency," id. § 43-34-31.1(b)(1) & (2), neither exception applies to Respondent.

Respondent issued six prescriptions for hydrocodone to Missouri residents. Under Missouri law--which was last amended in 1998--it is "unlawful for any person not now a registered physician within the meaning of the law to practice medicine [or] * * * to engage in the practice of medicine across state lines * * * except as herein provided." Mo. Ann. Stat. § 334.010(1). The statute defines "the practice of medicine across state lines" to mean in relevant part, "[t]he rendering of treatment to a patient within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from within this state to such physician or physician's agent." Id. § 334.010(2)(2). While the statute exempts from the licensure requirement an out-of-state physician who consults with a Missouri-licensed physician when the latter "retains ultimate authority and responsibility for the * * * diagnoses and treatment * * * of the patient located within th[e] state," id. § 334.010(3), Respondent makes no claim that his prescribing falls within this exemption. [FN29] Respondent thus violated both Missouri law and the CSA when he prescribed to the State's residents.

FN29 The Missouri statute contains two other exemptions which are not remotely applicable to Respondent's conduct. See Mo. Ann. Stat. § 334.010(3) (providing medical opinion or testimony in judicial or administrative proceeding) & (4) (performing "utilization review").

Finally, Respondent issued four prescriptions for hydrocodone to Oklahoma residents. In January 2001, the Oklahoma State Board of Medical Licensure and Supervision issued its Policy on Internet Prescribing. GX 27, at 19. Therein, the Oklahoma Board explained that "[u]nprofessional conduct includes 'prescribing * * * a drug * * * without sufficient examination and the establishment of a valid physician/patient relationship'* * * . The members of the Oklahoma Medical Board have interpreted that a 'sufficient examination' and 'establishment of a valid physi-

cian/patient relationship' can NOT take place without an initial face to face encounter with the patient." Id. (emphasis in original and quoting Okla. Stat. tit. 59, § 509-13). I thus conclude that Respondent acted outside of the usual course of professional practice when he prescribed to Oklahoma residents and thus violated the CSA.

As the forgoing demonstrates, Respondent, in issuing the prescriptions for Just USA, repeatedly violated both state laws prohibiting the unlicensed practice of medicine and those establishing standards of medical practice. As the California Court of Appeal has noted, "the proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine." Hageseth v. Superior Court, 59 Cal. Rptr. 3d 385, 403 (Ct. App. 2007). The same is true of the standards for establishing a valid doctor-patient relationship.

I thus hold that Respondent acted outside of "the usual course of * * * professional practice," and lacked "a legitimate medical purpose," 21 CFR 1306.04(a), in issuing numerous prescriptions for the customers of Just USA. I further conclude that Respondent has committed acts which render his continued registration "inconsistent with the public interest." 21 U.S.C. 824(a)(4).

Sanction

Under Agency precedent, where, as here, "the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.' " Medicine Shoppe-Jonesborough, 73 FR 364, 387 (2008) (quoting Samuel S. Jackson, 72 FR 23848, 23853 (2007) (quoting Leo R. Miller, 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' ALRA Labs, Inc. v. DEA, 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." Medicine Shoppe, 73 FR at 387; see also Jackson, 72 FR at 23853; John H. Kennedy, 71 FR 35705, 35709 (2006); Prince George Daniels, 60 FR 62884, 62887 (1995). See also Hoxie v. DEA, 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor" in the public interest determination).

Respondent contends that his conduct should be excused because he "exercised due diligence to ensure that his medical behavior was within the law." Resp. Br. (Pt. II) at 11. In Respondent's words, "[d]ue diligence, of course, does not mean that all mistakes were avoided. What it means, is that every effort is being made to

search out whether or not any mistakes were being made." Id. Respondent further contends that "his due diligence was not a one time, flash-in-the pan" effort, and that he "pursu[ed] and ***20735** persist[ed] in his efforts to assure compliance with the law." Id.

Even were I to recognize a due diligence defense in the context of a practitioner's obligation to know the law, Respondent's contention is wholly unpersuasive. First, while Respondent testified that he relied on Just USA's representation that it did not ship to seven States because it had examined their laws and determined that these States either required a face-to-face meeting between the patient and doctor, or prohibited an out-of-state doctor from prescribing to State residents, Tr. 95, Respondent nonetheless issued multiple prescriptions to persons who resided in those States.

Respondent attempted to justify his issuance of these prescriptions, explaining that he relied on the employees of Just USA to screen out such customers. Respondent's explanation ignores that he is the physician and is thus ultimately responsible for his prescribing. In short, his explanation is nothing more than excuse-making.

More broadly, Respondent is a licensed physician, and is thus properly charged with the obligation to determine what the law required with respect to his prescribing activities. See, e.g., Hageseth, 59 Cal. Rptr. 3d at 403 (licensed health care provider cannot "reasonably claim ignorance" of state provisions regulating medical practice). Moreover, those who voluntarily engage in commerce by dispensing controlled substances to persons located in other States are properly charged with knowledge of the legal requirements applicable to the practice of medicine in those States. United, 72 FR at 50407.

In this regard, Respondent offered no evidence that he contacted any of the Medical Boards of the various States where the recipients of his prescriptions resided, to determine what their laws required with respect to both obtaining a license and establishing a legitimate doctor-patient relationship. Indeed, for all of his professed interest in the internet, Respondent does not maintain that he ever visited the Web site of any state board to research what the legal requirements were to prescribe.

In his brief, Respondent also claims that the legal opinion prepared by a Florida-based lawyer (RX 7D) "expresses * * * the idea that Respondent * * * behave[d] within the law." Resp. Br. (Pt. II) at 14. According to Respondent, this document was offered "purely and exclusively to show that [he] had exercised due diligence, regardless of what the letter said in its content." Id. Moreover, it shows that "in the middle of the year 2006, [he] was continuing to persist in the due diligence investigation of his * * * practice." Id.

It is clear why Respondent does not rely on the content of the opinion. The opin-

ion expressly stated that it was limited to Florida law, that it was not addressing issues such as physician licensure, warned that "[p]rescribing standards vary dramatically from state to state," noted that other States had adopted prescribing standards which "often require[] a face to face physical examination and mak[e] non-compliance a crime subject to heavy penalties." RX 7D at 4 & 6. Respondent nonetheless prescribed to persons in States whose prescribing standards did require face-to-face examinations, and did so even after he received the opinion--in June 2006 according to his brief and testimony. See generally GX 39. It is thus clear that even when Respondent was provided information as to the potential illegality of his activities, he ignored it. [FN30]

FN30 While the opinion letter concluded that "the Websites' Medical Records Based Prescribing Procedures appear to comply with the DEA's published rules and Federal law," the opinion was based on its analysis of Florida's telemedicine rule and did not purport to analyze whether these practices were legal in any other State. Nor did it address whether under Florida law, a physician who is not licensed in the State, can prescribe a controlled substance to a Florida resident. Rather, in its conclusion the opinion states only that "Florida's laws and professional standards * * * indicate * * * that a prescribing physician located in Florida can prescribe using Medical Records Based Prescribing procedures." RX 7D at 1 (emphasis added).

In his brief, Respondent also maintains that as part of his efforts he reviewed various DEA pronouncements, and that in them, "there is not one word regarding face-to-face physical examinations being required by federal rules or instructions." Resp. Br. (Pt. II) at 12-13. Respondent further contends that "[a]ny requirements for face-to-face physical examinations are to be found exclusively in State laws." Id. at 13.

That much is true--at least for the prescriptions at issue here which were written before the enactment of the Ryan Haight Act--but it provides no comfort to Respondent. As I have previously explained, "in enacting the CSA, Congress did not adopt a federal standard for determining whether a valid doctor-patient relationship exists," and that "on this issue, the CSA recognizes the traditional role of the States in regulating the practice of medicine." Paul H. Volkman, 73 FR 30630, 30643 (2008) (citing Gonzales, 546 U.S. at 270). Taking the steps necessary to establish a valid doctor-patient relationship under state laws and medical practice standards is thus fundamental to a practitioner's establishing that he acted in "the usual course of professional practice" and issued a prescription for "a legitimate medical purpose" as required by Federal law. Most significantly, nothing in the 2001 Guidance Document or any other Agency pronouncement can reasonably be construed as stating that Respondent's prescribing practices were legal under Federal law. [FN31]

FN31 Respondent also contends that "there was zero testimony regarding any complaints or inquiries directed toward [him] by any State." Resp. Br. (Pt. II) at

13. The contention is beside the point as there is no evidence in the record that any of the States whose laws Respondent violated were aware of his misconduct. Moreover, even if a State was aware of Respondent's misconduct and declined to take action, DEA would not be precluded from acting because Congress vested authority to enforce the CSA in the Attorney General and not state officials. See Edmund Chein, 72 FR 6580, 6590 (2007).

Respondent also contends that the DI "never suggested what it is that [he] might have been doing wrong." Resp. Br. (Pt. II) at 15. The testimony establishes, however, that when Respondent told the DI that he "had some telemedicine internet practice going," the DI responded "that there might be a problem with that." Tr. 87. Even if it is the case that the DI did not specifically identify why Respondent's telemedicine prescribing was unlawful, it is not as if the DI told him it was lawful.

As the forgoing demonstrates, when Respondent did obtain legal advice that his practices were likely unlawful, he ignored it and continued to prescribe in violation of the laws of numerous States and the CSA. Moreover, when Respondent was confronted at the hearing with the evidence that he had prescribed to residents of States where--according to his testimony--it was illegal to do so, he denied that he was responsible and instead blamed others.

The record thus amply demonstrates the absurdity of Respondent's contentions that he made "heroic" and "serious efforts to assure himself that he was behaving correctly * * * relative to the law," that any "mistakes and errors * * * would have been readily corrected had they been brought to his attention," and that "[i]t would be rare to find someone who is attempting so studiously to abide by the law." Resp. Br. (Pt. II) at 15. In short, Respondent's contentions are disingenuous.

Moreover, the record establishes that Respondent was aware of the fact that Just USA had used his registration to issue several backdated prescriptions. These too were violations of the CSA, because a prescription "may be issued only by an individual practitioner who is: (1) [a]uthorized to prescribe * * * by the jurisdiction in which he is licensed to practice * * * and (2) [e]ither registered or exempted from registration," see 21 CFR 1306.03(a) & ***20736** 1306.04, and obviously lacked a legitimate medical purpose. See also 21 U.S.C. 822(a)(2) ("Every person who dispenses * * * shall obtain from the Attorney General a registration. * * *"); id. § 841(a)(1) ("Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally * * * to * * * distribute, or dispense * * * a controlled substance"); id. § 843(a)(2) ("It shall be unlawful for any person knowingly or intentionally * * * to use in the course of the * * * distribution[] or dispensing of a controlled substance * * * a registration number which is * * * issued to another person").

Respondent did not report the violations, Tr. 170, and in his brief he trivial-

ized the violations as just "mistakes" of the sort that "[c]lerks, and other people who work for doctors, make." Resp. Br. (Pt. II) at 22. Notwithstanding the illegal nature of these acts (which had happened shortly after Respondent began his arrangement with Just USA), and that Respondent had no way of confirming the validity of Just USA's representation that its employees had used his name and registration to backdate prescriptions only once or twice, Respondent continued to work for them.

As the record demonstrates, Respondent issued hundreds of illegal prescriptions for highly abused and dangerous controlled substances. [FN32] While Respondent ceased his illegal activity--after engaging in it for approximately one year--he maintained throughout the hearing that his "prescribing was appropriate," Tr. 99, and that it was illegal in only about two or three other States in addition to the seven States identified by Just USA and where he prescribed to anyway. Id. at 161. Moreover, when confronted with the evidence showing that that he had prescribed to persons in those seven States, Respondent's did not accept responsibility for having done so, but rather blamed others.

FN32 As found above, Respondent maintained at the hearing that hydrocodone is not addictive or dangerous. Yet in 2002, the abuse of hydrocodone drugs resulted in more than 27,000 emergency room visits. Moreover, the drug is also highly abused by teenagers, among others. Respondent's testimony buttresses my conclusion that Respondent cannot be trusted to acted responsibly.

I thus conclude that Respondent has not accepted responsibility for his misconduct and that he has failed to rebut the Government's prima facie showing that his continued registration "would be inconsistent with the public interest." 21 U.S.C. 823(f). Accordingly, Respondent's registration will be revoked and his pending application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, AS2352653, [FN33] issued to Patrick W. **Stodola,** M.D., be, and it hereby is, revoked. I further order that any pending application to renew or modify the registration be, and it hereby is, denied. This Order is effective June 4, 2009.

FN33 While the Show Cause Order did not expressly reference Respondent's registration number XS2352653, which authorizes him to dispense narcotic drugs for the purposes of maintenance or detoxification treatment, the holding of a practitioner's registration under 21 U.S.C. 823(f) is a prerequisite for obtaining the separate registration required to conduct narcotic treatment under 21 U.S.C. 823(g). See id. § 823(g)(2)(D)(i). Accordingly, the revocation of Respondent practitioner's registration requires the revocation of his registration under 21 U.S.C. 823(g).

Dated: April 24, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9-10245 Filed 5-4-09; 8:45 am]

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74 FR 20727-01, 2009 WL 1180958 (F.R.)

END OF DOCUMENT

United Prescription
Services, Inc.

NOTICE

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 7-21]

United Prescription Services, Inc. Revocation of Registration

Friday, August 31, 2007

***50397** On February 13, 2007, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to United Prescription Services, Inc. (Respondent), of Tampa, Florida. The Order immediately suspended Respondent's DEA Certificate of Registration, BU6696073, as a retail pharmacy, based on my preliminary finding that Respondent was diverting large quantities of controlled substances and that its continued registration during the pending of these proceedings " would constitute an imminent danger to the public health and safety because of the substantial likelihood that [it would] continue to divert controlled substances." Show Cause Order at 4 (citing 21 U.S.C. 824(d)). The Order also sought the revocation of Respondent's registration on the ground that its "continued registration is inconsistent with the public interest." Id. at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

The Show Cause Order alleged that Respondent distributed large quantities of controlled substances based on prescriptions that it knew or should have known "were not written for a legitimate medical purpose or were written by a practitioner not acting in the usual course of professional practice." Id. More specifically, the Show Cause Order alleged that between ***50398** October 1, 2005, and January 31, 2006, Respondent distributed 1,808,693 dosage units of controlled substances and that more than 1,275,000 dosage units of these controlled substances were prescribed by a single physician. Id. at 3. Relatedly, the Show Cause Order alleged that during this period, Respondent filled 11,830 prescriptions which were written under a single physician's registration. Id.

The Show Cause Order further alleged that Respondent "is owned and operated by Mr. Samuel Ballinger," and that Mr. Ballinger also "controlled and operated University Physician Resources, Inc.," (hereinafter, University), which either employed or contracted with physicians and other persons who issued prescriptions for controlled substances that were ordered through several internet sites, and which were then filled by Respondent. Id. at 1-2. The Show Cause Order also alleged that Respondent filled prescriptions issued by physicians who were affiliated with other internet sites. Id.

The Show Cause Order alleged that Respondent knew or should have known that the prescriptions were invalid. Id. at 2. Specifically, the Show Cause Order alleged that "the prescribing physicians were geographically separated from the majority of their customers," thus indicating that it was likely that the physicians had not examined the customers, and that "[t]he volume of the prescriptions generated by one physician in a given period of time was so excessive as to indicate that the practitioner could not have conducted an appropriate medical exam, obtained a medical history, or made a prior diagnosis." Id. Relatedly, the Show Cause Order alleged that while Respondent required the physicians "to submit an affidavit indicating that [they] had supervised and directed a medical exam[,] [it] knew that, in many cases, the prescribing physician had not directed and supervised any examination." Id.

As for those instances "in which physicians obtained medical records from other medical professionals prior to issuing" a controlled-substance prescription, the Show Cause Order alleged that Respondent "knew the physicians did not consult with the medical professionals who conducted the physical examinations." Id. The Show Cause Order also alleged that "Mr. Ballinger directed individuals without a DEA registration to issue prescriptions for controlled substances using the DEA registration of physicians employed by University" and that Respondent "then filled those invalid prescriptions for controlled substances." Id. Relatedly, the Show Cause Order alleged that Respondent filled numerous prescriptions issued by Dr. Wayne Starks after the expiration of Starks' registration and its retirement from the DEA database. Id. at 3.

The Show Cause Order also alleged that Respondent violated various other provisions of Federal law and regulations. Specifically, the Show Cause Order alleged that Respondent was purchasing bulk hydrocodone powder and manufacturing controlled substances without a manufacturer's registration as required by 21 U.S.C. 822(b). Id. at 4. The Show Cause Order alleged that this activity was not compounding because it was not done "pursuant to individual prescriptions." Id. The Show Cause Order also alleged that Respondent violated 21 CFR 1306.05(a) by filling prescriptions which "either did not contain the full address of the patient or contained an incorrect address for the patient," id., and by dispensing a prescription which bore one physician's DEA number but which "appeared to be signed by" a different physician. Id. at 3.

Finally, the Show Cause Order alleged that Respondent violated various provisions of state law. Specifically, the Show Cause Order alleged that Respondent "dispensed controlled substances into a number of states in which the dispensing violated the state law" because the prescription had not been written by a physician licensed under the laws of the patient's state. Id. (citing Cal. Health & Safety Code § 11352). Relatedly, the Show Cause Order alleged that Respondent had "shipped controlled substances into * * * Kentucky in violation of Kentucky law." Id. at 3-4 (citing Ky. Rev. Stat. Ann. § 315.320).

On February 14, 2007, the Show Cause Order was served on Respondent. Thereafter, on March 5, 2007, Respondent, through its counsel, requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing on April 9 through 13, 2007, in Arlington, Virginia. At the hearing, both parties elicited the testimony of witnesses and introduced documentary evidence. Following the hearing, both parties submitted briefs containing their proposed findings of fact and conclusions of law.

On May 31, 2007, the ALJ issued her decision. In that decision, the ALJ found "that the prescriptions that Respondent filled were not issued in the course of a legitimate physician-patient relationship" and thus were "not valid prescriptions." ALJ at 67. In support of this finding, the ALJ noted that it was "undisputed that Dr. Reppy" (who worked for University and wrote a large number of the prescriptions filled by Respondent), "examined few, if any, of the patients to whom he issued prescriptions." Id. at 65. While the ALJ acknowledged Dr. Reppy's testimony that he had "spoke[n] with some of the doctors who had previously treated patients with whom [he] consulted by telephone," the ALJ found dispositive that "there is no evidence that any of these doctors referred their patients to University or Dr. Reppy." Id. Relatedly, the ALJ noted that there was also "no evidence whatsoever that any physicians who had examined Respondent's customers had referred them to the physicians who prescribed to them and sent the prescriptions to Respondent to be filled." Id. at 66. Finally, the ALJ noted that "in some instances the records show that physicians who had examined these individuals refused to prescribe analgesics to them." Id. The ALJ thus concluded "that there was no physician-patient relationship between Dr. Reppy--or any of the other physicians discussed above who issued prescriptions that Respondent filled--and the customers to whom they issued those prescriptions." Id.

Relatedly, the ALJ found that "Mr. Ballinger established a scheme whereby University, which he controlled, would employ a physician to issue prescriptions for Respondent to fill, and that representatives of Respondent also actively arranged with operators of websites that solicited customers to obtain prescriptions after telephonic consultations with physicians that the physicians would send those prescriptions to Respondent to be filled." Id. at 66. The ALJ thus further found that Respondent knew the prescriptions were invalid and violated 21 CFR 1306.04(a) when it filled them. Id. at 67.

Moreover, having concluded that the prescriptions Respondent filled were invalid, the ALJ further held that "Respondent's production of dosage form controlled substances was not compounding within the meaning of the Controlled Substances Act * * * and that * * * Respondent manufactured controlled substances without holding a DEA registration to do so." Id. The ALJ thus further found that Respondent violated 21 U.S.C. 841(a). Id. at 68.

Finally, the ALJ rejected--as unsupported by the record--Respondent's assertion that in January 2007, it changed its practices. Id. at 68-69 (quoting Resp. Br. at

12). The ALJ *50399 thus concluded that "Respondent's continued registration would be inconsistent with the public interest" and recommended that its registration be revoked and that its pending application for renewal be denied. Id. at 69.

Thereafter, Respondent filed exceptions. Therein, Respondent "agrees with the Recommended Ruling's finding that the evidence showed that in many instances, prescriptions by Dr. Reppy were issued based on a telephonic interaction with the patient after review of medical records that included a physical examination which was conducted by a practitioner who did not necessarily have a referral arrangement with Dr. Reppy." Resp. Exceptions at 4 n.4.

Respondent argues, however, that the ALJ's proposed decision imposes "a requirement that a prescribing practitioner either personally conduct a physical examination of a patient or have a referral arrangement with another health care practitioner who personally conducts a physical examination of a patient in order to have a valid doctor-patient relationship." Id. at 3. Respondent argues that the ALJ's decision thus "adopts a new national standard for the requirements of a valid doctor-patient relationship that is completely unsupported by current federal law and regulation and which is outside the scope of the Controlled Substances Act." Id. Respondent thus contends that the ALJ's decision "seeks to * * * regulate the practice of medicine." [FN1] Id. at 3 n.2 (citing Gonzales v. Oregon, 126 S.Ct. 904, 923 (2006)).

FN1 Relatedly, Respondent also contends that it was improper for the ALJ to rely on the testimony of DEA's expert witness, Dr. Carmen Catizone, "as the basis for a legal standard applicable to the regulation of the practice of medicine." Id. at 6.

On June 26, 2007, the ALJ forwarded the record to me for final agency action. Having reviewed the entire record, I hereby issue this Decision and Final Order. While I do not adopt the ALJ's reasoning with respect to the validity of the prescriptions, the record nonetheless establishes that both Dr. Reppy and the other physicians issued prescriptions in violation of various state laws because the physicians were engaged in unlicensed activity and/or failed to comply with applicable state standards of practice for issuing treatment recommendations including the prescribing of controlled substances. I further conclude that the record establishes that Respondent had reason to know that numerous prescriptions it filled were unlawful because the prescribing physicians either did not establish a valid doctor/patient relationship or were engaged in the unlicensed practice of medicine.

Relatedly, I find Respondent violated Federal law by filling numerous prescriptions issued by a physician whose DEA registration had expired and a physician assistant who lacked authority to prescribe controlled substances under Florida law. I therefore adopt the ALJ's ultimate conclusion that Respondent's continued registration would be inconsistent with the public interest and will revoke its regis-

tration and deny its pending application for renewal. I make the following findings.

Findings

Respondent United Prescription Services, Inc., is licensed in the State of Florida as a community pharmacy and as a retail pharmacy wholesaler. Resp. Ex. 1, at 2-5. Respondent also holds or has held [FN2] numerous out-of-state or non-resident pharmacy licenses. See id. at 6-124.

FN2 As the ALJ observed, some of these licenses had expired.

Respondent is also the holder of DEA Certificate of Registration, BU6696073, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy at the registered location of 2304 E. Fletcher Ave., Tampa, Florida. Gov. Ex. 1, at 1. While Respondent's certificate indicates that its registration expired on May 31, 2006, id., Respondent submitted a timely application for renewal of its registration. ALJ Ex. 4, at 1. I therefore find that Respondent holds a current registration (albeit in suspended status) pending the issuance of this Final Order. See 5 U.S.C. 558(c).

Respondent was founded by Mr. Robert Carr, a Tampa, Florida personal injury lawyer, "to fill prescriptions for personal injury patients." Gov. Ex. 87, at 2. Mr. Samuel Ballinger, Respondent's current owner, was an administrator at a law firm where Carr practiced. Id. According to a statement given by Mr. John Todd Miller, Ballinger and Carr were partners in Respondent. Id. However, Respondent introduced into evidence a copy of a sales agreement dated March 25, 2005, under which Carr, who was then the sole shareholder and owner of Respondent sold his interest to Ballinger. Resp. Ex. 5, at 1.

In addition to Mr. Miller's statement, the record contains evidence indicating that Ballinger was involved in the operation of Respondent from before the date of this transaction. For example, Ballinger was listed on several of Respondent's Uniform Business Reports as a corporate officer or director. See GX 97, at 6 (Jan. 27, 2001 filing listing Ballinger as Respondent's President/Director); GX 74 (August 18, 2002 filing listing Ballinger as Respondent's President). While on Respondent's January 2003 filing Ballinger was no longer listed as Respondent's President, GX 97, at 9; the record also contains a July 16, 2003 letter from a physician, Mildred E. Watson, to Ballinger, at Respondent's address, in which she expressed her excitement at joining Respondent's "nationwide physicians network." GX 62, at 83.

Moreover, during the cross-examination of Robert Reppy, a physician who worked for Ballinger at University Physician Resources [FN3] between early 2004 and October 2006, Respondent's counsel stipulated that Ballinger had a relationship/affiliation with Respondent during the period of Reppy's employment at University. Tr. 1172-73. Consistent with Mr. Miller's statement that Carr and Ballinger were part-

ners, see GX 87, at 2; Reppy testified that "Ballinger was a major stockholder" in Respondent and was Carr's partner. Tr. 1173. Furthermore, Reppy testified that Ballinger directed that the prescriptions he issued be faxed to Respondent. Id. at 1179; see also GX 87, at 4 (statement of Miller). Thus, even if Ballinger did not have an equity interest in Respondent prior to the sale, it is clear that Ballinger had a relationship with Respondent and its owner during Reppy's employment with University.

FN3 University's role is discussed below.

According to Mr. Miller, Respondent "did not do well initially." GX 87, at 3. Eventually, Mr. Ballinger obtained "a computer program for an Internet pharmacy business" and Ballinger and Carr opened "their own Internet pharmacy site and began filling internet prescriptions." Id. Miller also introduced a Florida-based physician, Juan Ibanez, to Ballinger and Carr. Id. Thereafter, Ibanez began issuing prescriptions for persons who visited Ballinger's and Carr's Web site. Id. Numerous patient files (that were seized from Respondent) indicate that it filled these prescriptions. See, e.g., GX 110 (Excerpt 2 at 4893-94); id. (Excerpt 3, at 5277, 5279, 5284), id. (Excerpt 6, at 9750, 9758, 9764, 9770), id. (Excerpt 9, at 3937, 3938). According to Miller, both the computer servers and call center for the internet business "were located inside" Respondent at its Tampa location. GX 87, at 3.

Miller further stated that five or six internet pharmacy Web sites were affiliated with Respondent. Id. at 5. ***50400** Throughout the patient files, there are numerous documents indicating that Respondent filled prescriptions that were sent to it through internet sites such as http:// www.fedxmeds.com, PhoneConsultation.Com, and accuratemd.com. Id.; see also GX 110 (Excerpt 3, at 5202-03; and Excerpt 4, at 6980, 6994-96); GX 84 at 2 (affidavit of Robert Reppy).

Ballinger was also the owner of University, a clinic which provided both in-office medical treatment and what it termed "telemedicine." See GX 22; GX 87, at 4; GX 84, at 1 (affidavit of Robert Reppy). University employed various physicians including Dr. Robert Reppy, a doctor of osteopathy, and a physician's assistant, John Protheroe. GX 84, at 2-4. Ballinger hired Reppy in early 2004, to replace other physicians (Juan Ibanez, M.D., and Richard Long, M.D.) who had left the clinic. Id. at 2. With the exception of the period between November 2004 and March 2005 when he was on a leave of absence, Reppy worked for University until October 2006. Id. at 2-5. During the course of his employment at University, Ballinger "directed [its] operations." Id. at 5.

At University, Reppy, who was licensed only in the State of Florida, id. at 1, reviewed the medical records provided by individuals and conducted telephone consultations with them. Id. at 3. According to Reppy, "most of [his] patients * * * were telephone consultation patients who were referred to University by an Internet Web site." [FN4] Id. Moreover, "many of [his] patients were from outside the

[S]tate of Florida." Id. Based on his review of a person's medical records and the telephone consultation, Reppy would decide whether to issue a prescription for the person's purported condition. Id. Most of the prescriptions Reppy issued were for controlled substances such as schedule III drugs containing hydrocodone and schedule IV benzodiazepines such as alprazolam and diazepam. See GX 99, at 15; see also GX 66.

FN4 According to Dr. Reppy's sworn statement, when he started working at University, his "patients" were referred to him by fedexmeds.com and this continued until he went on his leave of absence. GX 84, at 2-3. When, in March 2005, Reppy returned to University, fedexmeds was no longer referring "patients" to it. Id. at 3. Other websites were, however, and Reppy admitted that he continued to issue prescriptions based on medical records and a telephonic consultation. Id.

At University, Reppy "consulted with approximately 30 patients per day." GX 84, at 3. Reppy also "reviewed the * * * files for the patients for whom Mr. Protheroe wrote prescriptions," which were also based on a review of medical records and a telephone consultation. Id. at 2. According to Reppy's affidavit, "[m]ost of the prescriptions written by Mr. Protheroe were for controlled substances," and were then "sent to [Respondent] to be filled unless otherwise directed by the patient." Id.; see also Tr. at 1139. Reppy further testified that Ballinger directed that University's prescriptions be faxed to Respondent. Id. at 1179.

While Reppy was on his leave of absence, "Protheroe continued to write prescriptions for controlled substances using [Reppy's] DEA number and electronic signature." GX 84 at 4. According to Reppy, Protheroe did not have "permission to issue prescriptions in my name while I was on leave," and was authorized "to issue prescriptions [only] while he worked under [Reppy's] supervision." Id.

In his testimony, Reppy stated that Protheroe wrote "over 14,000 prescriptions" without his permission during the period of his leave of absence. Tr. at 1182-83, 1193, 1198. To rebut this testimony, Respondent introduced Protheroe's sworn statement in which he "specifically denied" having issued prescriptions without Reppy's "knowledge or permission." Resp. Ex. 33.

Respondent also introduced into evidence the affidavit of Richard Furlong, who asserted that he worked at University from February through May 2005. See Resp. Ex. 23. In his declaration, Mr. Furlong stated that "Reppy supervised and authorized prescriptions issued by Mr. Protheroe and was uncompromising that the decision to issue a prescription rested with him." Id. at 1. Furlong added that while he "was there on an everyday basis, [he] never heard any discussion about nor saw information indicating that Mr. Protheroe was not practicing under the supervision of Dr. Reppy, or that he took direction from anyone, including Samuel Ballinger, other than Dr. Reppy." [FN5]

FN5 In his testimony, Reppy denied knowing Furlong. Tr. 1207-08.

The ALJ did not make any findings regarding this factual dispute. See ALJ at 67 n.97. As ultimate fact finder, I do. I credit Dr. Reppy's testimony noting that he was subject to Respondent's re-direct examination [FN6] and stuck to his story. In contrast, Respondent did not call either Protheroe or Furlong to testify and thus they were not subject to cross-examination by the Government. Furthermore, Mr. Furlong was at University for only a short period after Reppy returned to work, and Reppy, in his April 4, 2007 affidavit, stated that he had only "recently bec[o]me aware" of these prescriptions. GX 84, at 4. I thus find that at the time Furlong worked at University, Reppy was unaware of Protheroe's activities during his leave of absence. I further find that because Ballinger allowed Protheroe to work out of the office, Tr. 1199-1200, 1210; the records may not even have been in the clinic.

FN6 Reppy was called by Respondent.

In his testimony, Reppy maintained that his practice did not involve making new diagnoses, but rather, "monitoring stable patients whose diagnoses are already well known." Id. at 1109. Dr. Reppy further asserted that many of his patients contacted him because their original doctors were "not willing to do pain management for them because that's not their main purview." Id. at 1116. Dr. Reppy also stated that "many" of his patients "have tried to get pain management from their local hospital or pain management centers," but "they are expected to come in" either every two weeks or every month, and that their "prescriptions are not refilled unless they show up in person," and that these office visits "will often cost them $150 or more." Id.

Reppy further asserted that he had "rejected hundreds" of "patients" because they "cannot prove that they have the condition they claim" or had submitted "fraudulent records." Id. at 1117-18. Reppy also maintained that he never "diagnose[d] over the phone" because "[t]hat would be inappropriate medicine," id. at 1123, that the initial diagnosis was performed by the "local doctor that actually saw them and performed the physical examination," id., and that the "patients are required to submit documentation from their own local physicians, including radiology reports" before he would conduct a consultation. Id. at 1124. Reppy also testified that there are certain conditions that are too complex to be "appropriately * * * treated in a telemedicine format" such as heart conditions and pancreatitis. Id. at 1125- 26.

Reppy further testified that during his consultations he would ask his patients to subjectively rate their pain on a scale of one-to-ten, with the latter being "the worst pain they can imagine." Id. at 1129-30. Reppy acknowledged, however, that this was "not as useful as the evaluation of the pain you're getting from the" notes of the doctor who examined the patients, "but it's still useful because you're getting an idea of the patient's own perception of" his pain level, and that it was useful to evaluate the evolution of a patient's "pain over time." Id.

***50401** Reppy also stated that "[i]t's always preferable to see * * * the patient face to face," and that he "strongly urge[s] the patient to make a visit to the office here in Florida." Id. at 1130. Reppy further testified that he took a medical history on every patient, that he was convinced that each patient had a medical complaint, that there was a logical connection between the prescription he wrote and the complaint, and that there was a valid doctor-patient relationship with every person he issued a prescription for. Id. at 1164-65; see also id. at 1152.

On cross-examination, Reppy admitted that since the year 2000, he has not held a medical license in any State other than Florida. Id. at 1166. Reppy also admitted that the medical records of his telemedicine patients were "usually" sent to him by his patients rather than by the physician who had examined them. Id. at 1170-71. Reppy also admitted that sometimes the records for the patients that were referred to him by fedexmeds.com were provided by the Web site. Id. at 1171.

Reppy admitted that "less than five percent" of his "telemedicine patients" went to Florida to obtain a physical exam from him. Id. at 1174. Reppy also acknowledged that he "generally did not" consult "on a regular basis" with the physicians who had performed the physical examinations of his telemedicine patients, and that he did so "less than once a day" and only when he "had specific questions." Id. at 1175. Finally, Reppy stated that when his patient's refills ran out, he required a new physical exam before issuing a new prescription only if the physical exam was "too dated." Id. at 1176. The Government did not, however, ask Reppy at what point a physical exam becomes too dated.

The record establishes that during the period between October 1, 2005, and January 31, 2006, Respondent filled 11,830 prescriptions issued by Dr. Reppy, which totaled 1,275,400 dosage units of both controlled and non-controlled drugs. GX 99, at 13-16. Approximately 1.058 million of these dosage units (83%) were for drugs containing hydrocodone. Id. at 15-16. During this period, Reppy also authorized prescriptions totaling 41,651 dosage units of alprazolam, a schedule IV controlled substance, and approximately 84,000 dosage units of other controlled substances. Id.

Moreover, during this period, Reppy's prescribing accounted for approximately seventy-one percent of the prescriptions filled by Respondent and seventy percent of the dosage units dispensed by it. Id. at 8-11. Moreover, only 1094 (approximately 9.2%) of Reppy's prescriptions were for Florida residents. Id. at 13-14.

Respondent's dispensing log for December 2005 establishes that Reppy issued numerous controlled-substance prescriptions to persons resident in States where he was not licensed to practice. See GX 101, Excerpt 18. My review of the log found that during this month alone, Reppy issued new controlled-substance prescriptions to residents of Tennessee (89 Rxs), California (65 Rxs), Illinois (32 Rxs), North

Carolina (18 Rxs), and Louisiana (14 Rxs).

In addition, during December 2005, Reppy issued numerous controlled-substance prescriptions to persons resident in States which clearly require that the prescribing physician perform a physical exam of a patient except in limited situations not applicable here. These States include California, Tennessee, Louisiana, and Indiana (9 new Rxs).

I take official notice [FN7] of the following State statutes: Cal. Bus. & Prof. Code §§ 2052 [FN8] (unlicensed practice) & 2242.1(a) (internet prescribing); Cal. Health & Safety Code § 11352(a) (prohibiting furnishing a controlled substance "unless upon the written prescription of a physician * * * licensed to practice in this state"); 225 Ill. Comp. Stat. Ann. § 60/3 (licensure requirement), § 60/3.5 (prohibiting unlicensed practice); § 60/49 (listing acts constituting holding oneself out to the public as a physician); § 60/49.5 (requiring persons engaged in telemedicine to hold Illinois license); N.C. Gen. Stat. § 90-18 ("prescribing medication by use of the Internet or a toll-free telephone number, shall be regarded as practicing medicine" in the State).

FN7 In accordance with the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding--even in the final decision." U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request to an opportunity to show to the contrary." 5 U.S.C. § 556(e); see also 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order, which shall commence with the mailing of the order.

FN8 In Hageseth v. Superior Court, 59 Cal. Rptr.3d 385 (Ct. App. 2007), the California Court of Appeal upheld the State's jurisdiction to criminally prosecute an out-of-state physician who prescribed a drug to a California resident over the internet, for the unauthorized practice of medicine.

I also take official notice of the following state administrative rules: 844 Ind. Admin. Code § 5-3-3 ("issuing a prescription, based solely on an on-line questionnaire or consultation is prohibited") & id. § 5-4-1 (prohibiting the issuance of a controlled-substance prescription "to a person who the physician has never personally physically examined and diagnosed" except for "in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority practicing in accordance with standard care arrangements"); Tenn. Comp. R. & Regs. 0880-2.14(7) (prerequisites to issuing prescriptions); [FN9] & id. 0880-2.16 (requiring telemedicine license). [FN10]

FN9 The text of this rule is discussed shortly below.

FN10 I also take official notice of the Medical Board of California's Decision and Order in Jon Steven Opsahl, M.D., at 3 (Med. Bd. Cal. 2003) (revoking medical license and finding that "a physician cannot do a good faith prior examination based on a history, a review of medical records, responses to a questionnaire and a telephone consultation with the patient, without a physical examination of the patient" and that "[a] physician cannot determine whether there is a medical indication for prescription of a dangerous drug without performing a physical examination"); see also id. at 17.

In addition, the Medical Board of California has issued numerous Citation Orders to out-of-state physicians for internet prescribing to State residents. See, e.g., Citation Order Harry Hoff (June 17, 2003); Citation Order Carlos Gustavo Levy (Nov. 30, 2001). It has also issued press releases announcing its position on the issuance of prescriptions by physicians who do not hold a California license. See Medical Board of California, Record Fines Issued by Medical Board to Physicians in Internet Prescribing Cases (News Release Feb. 10, 2003) (available at http://www.mbc.ca.gov/NR--2003-- 02-10--Internetdrugs.htm). I also take official notice of these materials.

I also take official notice of the Louisiana State Board of Medical Examiner's Statement of Position on "Internet/Telephonic Prescribing," which was issued on May 24, 2000. According to the Louisiana Board, "it is unlawful for a physician to prescribe medication, treatment or a plan of care generally if the physician has not examined the patient and established a diagnostic basis for such therapy." Id. at 2. After discussing the acts which establish a doctor-patient relationship, the Board further stated that "an online or telephonic evaluation by questionnaire for an individual that a physician has never seen is inadequate." Id. at 2-3. The Board also explained that "[a]n individual who issues a prescription or orders medication for an individual who is a resident of or located in Louisiana, who does not possess a Louisiana medical license or other authorization to practice medicine in this state, is necessarily engaged in the unauthorized practice of ***50402** medicine in contravention of the Medical Practice Act." Id. at 3. [FN11]

FN11 The Board recognized that "prescribing for a patient whom the physician has not personally examined may be suitable under certain, limited circumstances." Internet/Telephonic Prescribing, at 3 n. 7. According to the Board, these "may include admission orders for a newly hospitalized patient, prescribing for a patient of another physician for whom the prescriber is taking the call or continuing medication on a short-term basis for a new patient prior to the patient's first appointment." Id. The Board also explained that it was not "attempt[ing] * * * to limit true consultations between out-of-state physicians and Louisiana licensed physicians." Id. at 4. None of these exceptions applies to the conduct of the prescribing physicians in this case.

In addition to the prescriptions issued by Reppy, Respondent also filled numerous prescriptions issued by physicians who were affiliated with phoneconsultation.com. These physicians included Dr. Dora Fernandez, who was located in, and licensed by, the Commonwealth of Puerto Rico, see GX 58 at 3, 7, 16; and George Wallace Merkle, who was located in, and licensed by the State of Indiana. See GX at 64, at 5, 9-10. Neither of the files which Respondent kept on these two physicians contains any additional medical licenses. See generally GX 58 & 64. Moreover, Respondent produced no evidence to show that either of these physicians had additional medical licenses beyond those contained in their files. I therefore find that Dr. Fernandez was licensed only in Puerto Rico and Dr. Merkle was licensed only in Indiana.

According to the December 2005 Daily Audit Log, in just the last twelve days of the month, Dr. Fernandez issued new controlled-substance prescriptions to residents of various States where she was not licensed including Tennessee (35 Rxs), California (29 Rxs), Louisiana (26 Rxs), Illinois (9 Rxs), and North Carolina (8 Rxs). Dr. Fernandez violated the laws of these States by engaging in the unlicensed practice of medicine. Moreover, in light of the respective locations of Dr. Fernandez and her "patients," it is most unlikely that she complied with the laws of Tennessee, California, Louisiana, and Indiana (8 new Rxs) regarding the prerequisites for prescribing a drug.

During December 2005, Respondent also filled new controlled-substance prescriptions issued by Dr. Merkle to residents of States where he was not licensed including California (17 Rxs), North Carolina (9 Rxs), and Louisiana (2 Rxs). Likewise, given the respective locations of Dr. Merkle (in Indiana) and his "patients," it is highly improbable that he complied with either the regulations of his own State or the laws of California and Louisiana which require the performance of a physical examination before prescribing a drug.

Finally, Respondent also filled numerous controlled substances prescriptions issued by Dr. Elizabeth Jamieson, another Tampa-based physician, who is licensed only in Florida and Pennsylvania. See GX 63, at 3. During December 2005, Dr. Jamieson issued new controlled-substance prescriptions to residents of Tennessee (31 Rxs), California (23 Rxs), Illinois (6 Rxs), Louisiana (5 Rxs), and North Carolina (5 Rxs). [FN12]

FN12 A review of Respondent's January 2006 daily audit log shows that Reppy issued new controlled-substance prescriptions to residents of Tennessee (121 Rxs), California (72 Rxs), Illinois (30 Rxs), North Carolina (16 Rxs), Louisiana (15 Rxs), and Indiana (10 Rxs). Dr. Fernandez issued new controlled-substance prescriptions to residents of California (23 Rxs), Tennessee (22 Rxs), Louisiana (6 Rxs), North Carolina (5 Rxs), Illinois (5 Rxs), and Indiana (3 Rxs). Dr. Merkle issued new controlled-substance prescriptions to residents of California (43 Rxs), Louisiana (10 Rxs), Tennessee (9 Rxs), and North Carolina (6 Rxs).

The patient files also establish that Respondent filled numerous prescriptions issued by Dr. Wayne Starks of Detroit, Michigan, who was affiliated with er-meds.com. GX 101 (Excerpt 8, at 9998). While Dr. Starks held a DEA Registration, it expired on February 28, 2003, and Starks did not submit a new application until August 23, 2004, which he withdrew on March 21, 2005. [FN13] See GX 103; see also GX 93, at 12 (Stark's file maintained by Respondent). Starks was therefore without authority to prescribe controlled substances after February 28, 2003. GX 103.

FN13 Starks has also submitted two additional applications, which are currently under review. GX 103.

The patient file for J.I., a resident of Alabama, indicates that Starks issued him prescriptions for 120 Lortab (10 mg.), a schedule III controlled substance containing hydrocodone and acetaminophen on January 9, 2004 (with two refills), April 16, 2004 (with two refills), June 24, 2004 (with no refills) and September 22, 2004 (with two refills). GX 101 (Excerpt 8, at 9997-99, 10008). Respondent filled each of these prescriptions including the refills. See id.

The patient file of K.Q., a resident of Texas, includes numerous prescriptions which Starks issued for Xanax (alprazolam) and Norco (hydrocodone/acetaminophen) after the expiration of his DEA registration and which Respondent filled. See GX 101 (Excerpt 9). More specifically, Starks issued K.Q. prescriptions for these drugs with refills on July 29, 2003; October 14, 2003; December 31, 2003; March 16, 2004; May 25, 2004; August 12, 2004; and October 27, 2004. [FN14] See id. at 3877, 3885, 3895, 3905, 3907, 3912, 3914, 3917, 3921, 3923, 3928, 3930. Respondent filled each of the new prescriptions and refilled these prescriptions numerous times.

FN14 The Norco prescriptions were for 120 Norco 10/325 (hydrocodone/acetaminophen); the Xanax (alprazolam) prescriptions were either for 45 (2 mg.) tablets or 30 (1 mg.) tablets.

The patient files also indicate that Respondent filled prescriptions issued by Dr. Richard Kienzle of Copperhill, Tennessee, a Tennessee-licensed physician. See GX 101 (Excerpts 6, 7, & 14); GX 60, at 2. More specifically, Kienzle issued T.H., a California resident, prescriptions for 90 Norco (10/325) with two refills on January 25, 2003; April 22, 2003; July 10, 2003; October 1, 2003; and 120 Norco on December 19, 2003. GX 101 (Excerpt 6 at 9744, 9738, 9732, 9726, & 9720). Respondent filled all of the prescriptions including the refills. See generally id. at 9720-44.

Respondent also filled several Vicodin prescriptions Kienzle issued to K.H., a Pennsylvania resident. Specifically, on December 7, 2003, and March 1, 2004, Kienzle prescribed 120 Vicodin ES (hydrocodone/apap 7.5/750) with two refills. [FN15] Id. (Excerpt 7, at 9585 & 9579), Respondent filled both the initial prescriptions and the refills. See id. On November 18, 2003, Kienzle issued to R.J., another

Pennsylvania resident, prescriptions for 120 Norco (10/325) with two refills, and on February 2, 2004, a prescription for 120 Lortab (10/500) with two refills. Id. (Excerpt 14 at 4731, 4736). Respondent filled both the initial prescriptions and the refills. Id. The patient file also includes copies of documents entitled "Fedxmeds Management Index," which were faxed to Respondent by Kienzle. Id. at 4674-75.

FN15 The record also includes copies of a document entitled "Fedxmeds Management Index" for K.H., which indicate that they were faxed to Respondent from Dr. Kienzle on December 7, 2003, and February 3, 2004. GX 101 (Excerpt 7, at 9530-31).

On July 20, 2005, pursuant to an Agreed Order with the Tennessee Board of Medical Examiners, Kienzle agreed to surrender his medical license. See GX 60, at 29. Kienzle also admitted that he had prescribed through several internet sites including FedexMeds.com, numerous dosage units of various controlled substances including compounds containing hydrocodone and codeine, as well as alprazolam, diazepam, and lorazepam and other scheduled drugs, to persons located in forty-six different States. Id. at 20. The Order also related that Kienzle had "admitted in correspondence to treating ***50403** via the internet or other electronic means, approximately one thousand eighty four (1,084) patients by and through his affiliation with" two websites which included FedexMeds.Com. Id. at 20-21. Kienzle also admitted that "as a matter of routine course, [he] utilized 'telephone consultations' conducted in reliance on data derived from the * * * FedexMeds.com internet database[ ], to speak with patients whose credibility and authenticity he could not verify, and whose symptoms he could not evaluate through tactile examination, visual observation, or through other means of clinical evaluation required by the standard of care." Id. at 23.

Kienzle further admitted that his internet prescribing violated various provisions of the Tennessee Medical Examiners Practice Act, including prohibitions on unprofessional conduct and dispensing controlled substances in violation of State or Federal law. Id. at 24-28. Most significantly, Kienzle admitted that his internet prescribing violated the Board's Rule 0880-2-.14(7), which sets forth the "prerequisites to issuing prescriptions or dispensing medications in person, electronically, and over the internet." Id. at 27. This provision states that it is "a prima facie violation" of the State's Medical Practice Act:

for a physician to prescribe or dispense any drug to any individual, whether in person or by electronic means or over the internet or over telephone lines, unless the physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, has first done and appropriately documented, for the person to whom a prescription is to be issued or drugs dispensed * * * an appropriate history and physical examination[.] [FN16]

FN16 The rule also requires that the physician has "[m]ade a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good

medical care," "[f]ormulated a therapeutic plan and discussed it, along with the basis for it," and "[i]nsured availability of the physician or coverage for the patient for appropriate follow-up care." GX 60, at 28.

GX 60, at 27 (quoting Tenn. Comp. R. & Regs. 0880-2-.14(7)).

The Government also introduced evidence showing that Respondent was engaged in the compounding of large quantities of controlled substances. More specifically, Respondent was purchasing hydrocodone bitartrate powder and compounding it with either acetaminophen or dextromethorpan hydrobromide in various combinations. See GX 37 (invoices for hydrocodone bitartrate powder); see also GX 36 (compounding log). Moreover, Respondent was also compounding a formulation of phentermine and lorazepam (both schedule IV controlled substances, see 21 CFR 1308.14). GX 36, at 16. The run size of the compoundings was 7500 capsules. See generally GX 36.

In another proceeding, Mr. Decker, Respondent's pharmacist-in-charge, testified that approximately one-third of the drugs it dispensed were compounded. See Resp. 25, at 177. Mr. Decker also testified that Respondent never had on hand "more than 15 days" supply of compounded drugs. Id. at 178. Mr. Decker further stated in an affidavit that the drugs were "compounded only to the extent that they are prescribed by the physician, and to fulfill remaining refills as indicated on the original prescription." GX 70, at 1. Respondent is registered as a retail pharmacy and not as a manufacturer. See GX 1.

The record further establishes that Respondent violated Kentucky law by failing to report its dispensing of controlled substances to Kentucky residents through the State's electronic monitoring system (KASPER). See GX 85 (affidavit of Jennifer Shearer, Agent Manager, Kentucky Bureau of Investigation (KBI) (citing KRS §§ 218A.202 & 315.0351)). More specifically, Agent Shearer recounted that on June 1, 2006, a KBI agent received information from the United Parcel Service that it was "shipping 'a lot' of packages" that came from Respondent. GX 85, at 1. Upon receiving this information, Agent Shearer contacted the Inspector General's office of the Kentucky Cabinet of Health Services and determined that Respondent had not filed its KASPER reports since April 2005. Id.

On June 9, 2006, KBI agents obtained a search warrant "for any and all packages being shipped by [Respondent] by [UPS] from June 5, 2006-June 9, 2006." Id. The agents subsequently seized fifty-four bottles of prescription drugs which included the controlled substances alprazolam, diazepam, clonazepam and hydrocodone. Id. On the same date, Agent Shearer was contacted by an employee of Respondent who wanted to know why its shipments had been seized. Id. Agent Shearer told the employee that the packages had been seized because Respondent "had not been reporting to KASPER." Id. Agent Shearer also advised Respondent's employee that the prescriptions it was dispensing were illegal because "none of the Kentucky residents * * * had ever seen" the prescribing physician and "there was no physician/patient relationship." Id. Agent Shearer then told the employee that Respondent must stop

shipping to Kentucky residents until it complied with the State's law. [FN17]

FN17 In similar vein, the record also contains a copy of various documents of the Wyoming Board of Pharmacy. See GX 41, at 1. These include a March 31, 2005 letter to Respondent notifying it that the Board had become aware that it had dispensed a prescription issued by Dr. Reppy to a Wyoming resident and expressing that the Board had "strong reasons to believe that no doctor/patient relationship has been established between [the resident] and the prescribing physician * * * other than via the internet," and that "[a] prescription * * * dispensed based solely on a web-based questionnaire without establishing a valid doctor/patient relationship is considered to be a violation of the Wyoming Pharmacy Act." Id. The letter further requested that Respondent "cease dispensing to Wyoming residents immediately." Id. The record also includes a copy of an April 8, 2005 letter from the Wyoming Board to the Florida Department of Health filing a complaint against Respondent for its dispensing to this resident. Id. at 12.

Thereafter, KBI agents received information that Respondent had begun shipping prescription drugs under the name of "Makes and Models Magazine," another business owned by Ballinger. Id. at 2; see also GX 84, at 5; GX 87 at 5. Accordingly, on June 16, 2006, KBI agents obtained another search warrant "for any and all packages being shipped by [Respondent] and Makes and Models Magazine by [UPS] from June 9, 2006-June 16, 2006." GX 85, at 2. Upon executing the warrant, KBI agents seized twelve bottles of drugs which contained alprazolam, diazepam, and hydrocodone. Id. Makes and Models Magazine is not licensed as an out-of-state pharmacy under Kentucky law. Id.

In another proceeding, Mr. Decker (Respondent's Pharmacist-in-Charge) testified that Respondent had shipped under the "Makes and Models" name based on the suggestion of its UPS account representative. Resp. Ex. 25, at 171. In this testimony, Decker claimed that Respondent's personnel thought that the packages had been stolen and were unaware that they had been seized by the KBI. Id. at 174. Decker admitted, however, that Respondent did not report the purported thefts to either DEA or the KBI. Id. at 174-75; see also 21 CFR 1301.76(b) (requiring reporting of a theft of controlled substances).

Based on Respondent's failure to report the purported thefts and Agent Shearer's statement that on June 9, 2006 (the date the first warrant was executed), she was contacted by an employee of Respondent who wanted to know why the packages had been seized, I reject Respondent's claim that the reason it shipped controlled substances under the "Makes and Models" label was to prevent them from being stolen. See Resp. Proposed Findings at 21. Instead, I find that Respondent knew that the packages had ***50404** been seized by the KBI and that it used the "Makes and Models" label to circumvent Kentucky law.

The record also includes files that Respondent maintained on the various prescribing physicians. The files typically include copies of each physician's state

license and DEA registration. See generally GXs 55-65. Most of the files also include a copy of an affidavit and/or letter in which the physician was required to state that "any prescription sent to [Respondent] will be for a legitimate medical purpose within the usual course of professional practice and based on [a] legitimate patient-physician relationship." See, e.g., GX 56, at 74 (Reppy).

These affidavits and/or letters also required the physicians to state that their practice had policies and procedures in place to satisfy the following criteria:

Our records include a positive identification of the patient.

The patient's medical complaint has been verified.

The patient's chart includes copies of prior medical records.

An extensive physician interview and consultation has been accomplished.

That if an in-person examination was not possible that we have supervised and directed an examination by a consulting medical professional, for which a copy is in the patient file.

That in review of all of the above criteria contained in our medical file we have determined the appropriateness of medications and have issued a prescription based upon our patient/physician relationship.

Id.

The Expert Testimony

The Government called as an expert witness, Carmen Catizone, Executive Director, National Association of Boards of Pharmacy. GX 81. Mr. Catizone is a registered pharmacist in Illinois and holds a Bachelor of Science degree in pharmacy and a Master of Science degree in pharmacy administration and has worked as a pharmacist and as a pharmacist-in-charge. Id. at 2-5. Mr. Catizone also holds an honorary Doctor of Pharmacy license from the Oklahoma State Board of Pharmacy. Id. Mr. Catizone has been qualified as an expert in administrative proceedings in all States except Alaska and has previously been qualified as an expert in the United States District Court for the District of Minnesota and in other DEA proceedings. Tr. 313. The Government offered Mr. Catizone "as an expert witness in pharmacy practice, pharmacy regulation, pharmacy legislation and internet pharmacy practices." Id.

Mr. Catizone testified that under "all state pharmacy practice acts," a "pharmacist is responsible to ensure that the prescription is valid, has been written within the scope of practice for that prescriber, [that] the prescriber is appropriately licensed[,] and that [the] prescription is valid for [the] patient's disease, symptoms or conditions." Id. at 323. Mr. Catizone also testified that for a prescription to be valid under federal and state laws, it must be based on "a bona

fide relationship between the prescriber and the patient." Id. at 322.

Mr. Catizone also reviewed Respondent's daily audit logs for the periods March 30-31, 2005, and November 9 through December 9, 2006 (GXs 18 & 39). Based on his review, Mr. Catizone opined that the prescriptions showed "disturbing patterns." Tr. 333. Most significantly, Mr. Catizone observed that "the overwhelming majority of prescriptions [were] written by one physician, and that physician is located in [a] different state[] than all of the patients." Id. Moreover, "the overwhelming prescription drug written for is hydrocodone, which you do not see that volume or that selectivity in any other retail pharmacy that I'm aware of." [FN18] Id.

FN18 Mr. Catizone also noted the absence of prescriptions for non-controlled drugs that are used to treat such conditions as diabetes, asthma, and high blood pressure that are found "in a traditional retail pharmacy." Tr. 333.

Mr. Catizone testified that he had not seen a dispensing mix like Respondent's "except for internet pharmacies that we've studied in the past that have been involved in illegal activities involving controlled substances." Id. at 334. Mr. Catizone further testified that he had "not seen these types of prescribing patterns for physicians unless they were pain medication specialists * * * except in instances where we've looked at internet pharmacies that were operating illegally and prescribing controlled substances illegally." Id. at 335.

Finally, Mr. Catizone testified that based on the dispensing records, Respondent had not met its corresponding responsibility to ensure that the prescriptions it filled had been issued in the usual course of professional practice. Id. at 343-44. Moreover, based on his review of the dispensing records and the fact that Reppy was licensed only in Florida, Mr. Catizone further testified that Respondent had not fulfilled its responsibility to ensure that that there was sufficient evidence of a legitimate doctor-patient relationship before filling Dr. Reppy's prescriptions. Id. at 344.

On cross-examination, Mr. Catizone explained that he formed his opinion solely on the basis of the dispensing records and had not done any further investigation to determine whether Reppy's prescriptions were issued pursuant to a legitimate doctor-patient relationship or whether Reppy treated chronic pain patients. Id. at 352-53. Mr. Catizone also testified he had not done any similar investigation with respect to the other doctors whose prescriptions were filled by Respondent. Id. at 353-54. Mr. Catizone further stated that his opinion was based strictly on "the numbers and the prescribing patterns and the location of the patients." Id. at 355.

Mr. Catizone agreed that under federal and state laws it is not "a necessary prerequisite to the issuance of a prescription that the prescriber be the person who conducted the physical examination." Id. at 355-56; see also id. at 359-61. He further asserted, however, that "[t]he federal requirement is that there's a bona

fide relationship. And if that relationship can be established as a referral from another prescriber or physician that's made that examination," then the prescriber does not have to have performed the physical examination. Id. at 356. Clarifying his testimony, Mr. Catizone asserted that there had to be a relationship between the examining physician and the prescriber, "as well as between the patient and the initial physician who has performed the medical examination. If care is shifted to the other physician, then that physician also has to have a relationship with that patient to ongoingly prescribe medications." Id. at 357.

Relatedly, Mr. Catizone acknowledged that under Florida law, a physician may issue a prescription even though he did not physically examine the patient. Id. at 359. Mr. Catizone then testified that if one physician ordered a diagnostic test and the results of those tests were sent to another practitioner for review and that practitioner took a medical history and talked to the patient, the practitioner could then issue a prescription. Id. at 361.

On further cross-examination, Mr. Catizone was shown Government Exhibit 86 which memorialized several interviews conducted by a Diversion Investigator of Dr. Reppy's patients. In some instances, these persons told the DI that they had been required to obtain a physical exam from another physician or that they had at some point been physically examined by Reppy. GX 86 at 2, 10, & 12. Others, however, told the investigator that they had not been seen by Reppy and had not been required to obtain a physical exam. Id. at 4, 6-9. While Mr. Catizone acknowledged that it was "important to have the entire picture," he also noted that in some instances the "patients" could not even recall the prescribing physician's name. ***50405** Tr. 366; see also GX 86 at 3, 7 & 8. Mr. Catizone then added that this exhibit "substantiate[d] my contention * * * that the practices were not legal and not meeting the standards of care." Tr. 367.

Finally, Respondent's counsel asked Mr. Catizone whether his conclusion that Respondent had dispensed invalid prescriptions would be altered by the fact that Respondent had verified that the prescriber was licensed and had a DEA registration, that "there had been direct communication between the patient and the physician," and that it had obtained "an affidavit from the physician attesting to the existence of a physician/patient relationship." Id. at 371- 72. Mr. Catizone testified that these facts would not lead him to change his testimony "unless [it] was documented for every single patient." Id. at 372.

Respondent excepted to the testimony of Mr. Catizone, asserting that he "is not competent to offer any expert opinion, much less an opinion on the requirements of a valid doctor-patient relationship." Resp. Exceptions at 4. Respondent asserts that Mr. Catizone is "little more than a fraud" because he "refers to himself as 'Dr. Catizone"' when "he has never earned a doctorate degree nor even been conveyed with an honorary one from an academic institution," but rather, holds an "honorary title" granted by the Oklahoma Board of Pharmacy. Id. at 4-5.

The short answer to Respondent's contention is that whether Mr. Catizone can properly call himself Dr. Catizone is irrelevant because what matters are his qualifications to testify as an expert. And contrary to Respondent's contention, a witness can be qualified as an expert by virtue of his skill, training, knowledge, education or experience. Cf. F.R.E. 702. Accordingly, Mr. Catizone's lack of a degree at the doctoral level does not disqualify him from testifying as an expert. Nor does the fact that he "has not worked in a clinical pharmacy setting since 1995." Resp. Exceptions at 5. Mr. Catizone's expertise in pharmacy practice is amply established by his prior work as a practicing pharmacist, his professional experience as the Executive Director of the National Association of Boards of Pharmacy, and his extensive writings. I therefore find that Mr. Catizone was competent to testify as to the scope of a pharmacist's obligations under Federal law and the pharmacy practice acts of the various States.

Respondent also excepted to Mr. Catizone's testimony on the ground that there is no evidence that he has "received any medical training or has ever been involved in patient care in any form which would provide him a basis to opine on the requirements of a doctor-patient relationship." Id. Relatedly, Respondent argues that the Government has not shown "that Mr. Catizone has received any legal training which would qualify him to interpret uncited, yet apparently relied upon, court cases regarding same." Id.

I need not resolve this issue because I decline to adopt the ALJ's reasoning as to why the prescriptions written by Dr. Reppy and the other physicians were not based on valid doctor-patient relationships. The States have the primary responsibility for regulating the practice of medicine. I therefore conclude that the appropriate course in determining whether Dr. Reppy and the other physicians prescribed pursuant to valid doctor-patient relationships is to examine the specific legal authorities of the various States. [FN19]

FN19 This is not to say that Mr. Catizone is not competent to testify in this area. A pharmacist has a "corresponding responsibility" to ascertain whether a prescription has been "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). Determining whether a physician has acted in accordance with this standard necessarily requires that the pharmacist have knowledge of the applicable State's law. See United States v. Smith, 2006 WL 3702656 (D. Minn 2006).

The Government also introduced the declaration of George Van Komen, M.D., the former President of the Federation of State Medical Boards (FSMB), as well as Dr. Van Komen's testimony in In re Trinity Health Care Corp., 72 FR 30849 (2007). See GXs 78 & 83. In his written declaration, Dr. Komen explained the standard for establishing a legitimate doctor-patient relationship under the FSMB's guidelines:

The standard in terms of forming a legitimate doctor-patient relationship is that there needs to be a documented face-to-face history and physical * * * evaluation

of the patient, and then if this patient chooses to receive further consultative work or be established with a physician who practices on the Internet, that the Internet physician first of all and most importantly needs to be identified, and he needs to have a license in the state in which the patient resides.

* * * * *

And we also feel that [the] primary care doctor who did the history and physical needs to stay in touch with the patient, even though the patient might be seeking further consultation from another physician through the Internet.

GX 78, at 14-15. [FN20]

FN20 In his written declaration, Dr. Van Komen further explained that "[t]here is no way to detect abuse or monitor the appropriate treatment or care of a patient by reviewing an online questionnaire, because a doctor has no way of knowing that the person that filled out that questionnaire filled it out honestly. If I had to describe a drug addict by using one word, the word I would use is 'dishonest.' " GX 78, at 17. Dr. Van Komen did not, however, address the legitimacy of prescribing using the methods employed by Dr. Reppy.

In Trinity Healthcare, Dr. Van Komen testified, however, that "under certain circumstances," a physician can write a lawful prescription without ever meeting the patient. GX 83 (Tr. 608). Besides the situation where a physician is covering for another physician, Dr. Van Komen explained that under the FSMB guidelines, "there are physicians who have internet practices, and they are provided information from the physician who the patient had previously seen. And they provide them with information through a request of the patient's medical records, and the patient themselves usually do not provide those medical records." Id. Continuing, Dr. Van Komen explained: "[s]o there [are] no alternate medical records by the patients themselves and then the physician who has an internet practice uses that history and physical from what I call the primary care physician with whom the patient has had face-to-face contact." Id. at 609.

Dr. Van Komen's testimony raises a strong suspicion that Reppy's prescriptions were not issued pursuant to a valid doctor-patient relationship. But neither Dr. Van Komen's declaration nor his Trinity Health Care testimony addressed whether the laws of Florida (where Dr. Reppy was located) or any other State where the prescribers or the patients were located, prohibit a physician from prescribing because he received the medical records from the patients themselves. [FN21]

FN21 Dr. Van Komen's testimony also does not establish at what point a physical exam becomes too dated to be relied upon. Finally, while Dr. Van Komen also testified in Trinity Healthcare that "[t]here is absolutely no way that you can continue to prescribe controlled substances without a review of how the patient is doing[,] [a]nd that cannot be evaluated without a face-to-face confrontation," GX 83 (Tr. 579), his testimony did not specify at what point this encounter must occur.

I therefore do not make any findings as to whether Reppy issued unlawful prescriptions because he relied on physical examinations which were too dated or continued to prescribe without requiring an in-person follow-up examination.

Respondent also put on an expert witness, Dr. Thomas E. Johns. Dr. Johns holds a Doctor of Pharmacy degree and serves as the Assistant Director, Clinical Pharmacy Services, Department of Pharmacy, Shands at the University of Florida, a teaching hospital which is affiliated with the University of Florida. RX 28, Tr. 1256. Dr. Johns also teaches at the University of Florida College of Pharmacy as an adjunct faculty member. Tr. 1256. Dr. Johns has responsibilities related to the institution's compliance ***50406** with applicable pharmacy laws and regulations. [FN22] Id. 1260-61.

FN22 As is the case with Mr. Catizone, Dr. Johns does not actively engage in the actual dispensing of prescription drugs. Tr. 1271.

On direct examination, Dr. Johns asserted that both the Agency's 2001 guidance document on dispensing controlled substances over the internet [FN23] and the Pharmacist's Manual were unclear regarding the scope of a pharmacist's corresponding responsibility under 21 CFR 1306.04(a). Tr. 1273. Dr. Johns testified that if a prescription creates a suspicion that it has been issued "for an illegitimate purpose or that the [doctor-patient] relationship is not valid," then the pharmacist should call the doctor. Id. at 1275. Dr. Johns further asserted that if the physician affirms that there "is a valid doctor/patient relationship," then "no further action is really needed or warranted on the part of the pharmacist." Id. Dr. Johns also testified that the DEA Pharmacist Manual states that the "frequency and volume [of prescriptions] in and of itself is not indicative of fraud or abuse." Id. at 1277; see also id. at 1278. [FN24]

FN23 See DEA, Dispensing and Purchasing Controlled Substances over the Internet, 66 FR 21181 (2001). The guidance document is included in the record as GX 6.

FN24 Dr. Johns also addressed the allegation that Respondent should not have filled prescriptions that lacked the patient's address. Tr. at 1279. Dr. Johns testified that while there are certain items of information that appear on a prescription which a pharmacist "cannot change" even in consultation with the physician, "the pharmacist is authorized to fill in the patient's address if it's not on the prescription." Id. DEA's regulations are, however, to the contrary. See 21 CFR 1306.05(a).

Dr. Johns further testified that in his experience, it is not "the usual and customary practice in the distributive pharmacy setting to verify the existence of a doctor/patient relationship before filling a prescription." Id. at 1280 (quoting question of Respondent's counsel). Dr. Johns also testified that it is not "the usual and customary practice" in the distributive pharmacy setting to verify the prescriber's medical license and DEA registration. Id. Finally, Dr. Johns testi-

fied that it is not the responsibility of a pharmacist to "second guess" a prescribing practitioner's diagnosis. Id.

On cross-examination, Dr. Johns admitted that in preparing for his testimony, he was only "actually shown the first or second page of a prescription log" and nothing "other than that." Id. at 1286; see also id. at 1289. Dr. Johns further admitted that he had never been in a pharmacy which asked physicians to send in the medical records of its customers as Respondent did. Id. at 1286-87; see also GXs 29 & 30 (patient files). Dr. Johns further stated that he could not think of a reason why a retail pharmacy would require a physician to send in a customer's medical records. Tr. 1286-87.

Dr. Johns further testified that he had never visited Respondent, id. at 1289, and that his knowledge regarding Respondent's actual operations was based on the Show Cause Order and a document "which described [its] business model." Id. at 1290. Dr. Johns also acknowledged that volume in combination with other factors could raise a suspicion that a particular physician's prescriptions were not legitimate. Id. at 1292. Dr. Johns then admitted that "it could" create a suspicion if a physician was located in Puerto Rico and issuing eighty new prescriptions a day to persons who were not located in Puerto Rico. Id. at 1293. He also acknowledged that "if the pharmacist knew that patients were being solicited over the internet [it] would certainly raise a red flag to that pharmacist that there could be an invalid doctor/patient relationship." Id.

Relatedly, Dr. Johns testified that if a prescription indicated that it was faxed from a website, it would make him "curious" as to what the website was engaged in, id. at 1311, and that it would create a suspicion that the drugs would be diverted. Id. at 1317. Dr. Johns also admitted that it is not the usual course of practice for a pharmacy to solicit physicians to send their prescriptions to it and that it is inappropriate for a pharmacy to do so. Id. at 1296-98.

Dr. Johns maintained, however, that it was "probably" not inappropriate to fill a prescription for controlled substances issued by a practitioner whose DEA registration had expired even if the pharmacy had a copy of the expired registration on file. Id. at 1300. Subsequently, Dr. Johns admitted that while a pharmacist is not required to "proactively * * * determine whether the physician has [a] valid DEA number," if "something raises a suspicion of irregularity, then perhaps a more thorough investigation" is required. Id. at 1301.

The Government then asked whether it would be suspicious "if a physician was practicing medicine in a jurisdiction where [he wasn't] licensed?" Dr. Johns answered: "If [he] knew that [he wasn't] licensed in that jurisdiction." Id. at 1302. Dr. Johns then admitted that a pharmacy must know not only a State's law regarding pharmacy practice, but also the law of the State where the dispensing is occurring regarding the requirements for a lawful prescription. Id. Relatedly, Dr. Johns testified that a pharmacy has "a professional obligation to know the law."

Id. at 1303. Finally, Dr. Johns testified that if he "knew that [a] physician was away from his practice and prescriptions were being issued under his name, [he] would be suspicious." Id. at 1320.

Discussion

Section 304(a) of the Controlled Substance Act (CSA) provides that "[a] registration * * * to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a). Section 304(d) further provides that "[t]he Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety." 21 U.S.C. 824(d).

In determining the public interest, the CSA directs that the following factors be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. § 823(f).

"[T]hese factors are * * * considered in the disjunctive." Robert A. Leslie, M.D., 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem [ ] appropriate in determining whether a registration should be revoked." Id. Moreover, case law establishes that I am "not required to make findings as to all of the factors." Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); see also Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

In this case, I conclude that factors two and four are dispositive and establish that Respondent's continued registration would "be inconsistent with the public interest." 21 U.S.C. 823(f). I also find unpersuasive Respondent's contention that it is attempting to comply with the law. Accordingly, ***50407** Respondent's registration will be revoked and its pending application for renewal of its registration will be denied.

Factors Two and Four--Respondent's Experience in Dispensing Controlled Substances and Its Compliance With Applicable Federal, State, and Local Laws

Under DEA's regulation, a prescription for a controlled substance is unlawful unless it has been "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). Moreover, while "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, * * * a corresponding responsibility rests with the pharmacist who fills the prescription." Id. Accordingly, "the person knowingly filling such a purported prescription, as well as the person issuing it, [is] subject to the penalties provided for violations of the provisions of law relating to controlled substances." Id.

DEA has interpreted the regulation "as prohibiting a pharmacist from filling a prescription for controlled substances when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose."' Trinity Health Care Corp., 72 FR 30849, 30854 (2007) (quoting Medic-Aid Pharmacy, 55 FR 30043, 30044 (1990)); see also Frank's Corner Pharmacy, 60 FR 17574, 17576 (1995); Ralph J. Bertolino, 55 FR 4729, 4730 (1990). See also United States v. Seelig, 622 F.2d 207, 213 (6th Cir. 1980). This Agency has further held that "[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription." Bertolino, 55 FR at 4730 (citations omitted).

As the ALJ recognized, one of the primary issues in this case is whether the prescriptions Respondent filled were issued by physicians pursuant to valid doctor-patient relationships. Reasoning that "[t]here is no evidence * * * that any physicians who had examined Respondent's customers had referred them to the physicians who prescribed to them and sent the prescriptions to Respondent to be filled," the ALJ concluded that "there was no physician-patient relationship between Dr. Reppy--or any of the other physicians * * * who issued prescriptions that Respondent filled" and its customers. ALJ at 66. The ALJ thus held that the prescriptions were not issued pursuant to valid doctor-patient relationships. Id.

The ALJ did not, however, cite any legal authority for this holding. Instead, the ALJ apparently based her holding on Mr. Catizone's testimony that "if the prescriber has not performed the physical examination, then there must be some relationship between the person who did conduct the examination and the physician who issues the prescription." Id. at 65.

Mr. Catizone's testimony was not supported by reference to the laws, regulations, or decisions (either judicial or administrative) of any particular State. While Mr. Catizone's testimony appears to be consistent with the guidance of the American Medical Association, see GX 3, at 5; the AMA's statement does not have the force and effect of law absent its adoption by competent state authorities. Moreover, this Agency has not promulgated such a rule through either notice-

and-comment rulemaking or adjudication.

That there is no Federal standard requiring a referral or consultative arrangement between the examining and prescribing physicians does not mean that the prescriptions issued by Dr. Reppy and the other physicians were lawful under Federal law. As the 2001 Guidance Document explained, the CSA looks to state law in determining whether a physician has established a valid doctor-patient relationship. See 66 FR at 21182-83. Moreover, the CSA also requires that a physician be acting "in the usual course of * * * professional practice" in order to issue a lawful prescription. 21 CFR 1306.04(a). Finally, as noted above, the public interest inquiry mandates that a registrant's compliance with applicable state laws be considered. 21 U.S.C. 823(f)(4).

As found above, in December 2005, Respondent filled numerous prescriptions issued by prescribers who were engaged in the practice of medicine without the required state licenses in violation of various state laws. For example, even though Dr. Reppy was licensed only in Florida, he issued new controlled-substance prescriptions to residents of California, Tennessee, Illinois, North Carolina, and Louisiana. Both Dr. Fernandez (who was licensed only in Puerto Rico) and Dr. Jamieson (who was licensed only in Florida and Pennsylvania) also issued new controlled-substance prescriptions to residents of these same States. Finally, Dr. Merkle, who was licensed only in Indiana, issued new controlled substance prescriptions to residents of California, North Carolina, and Louisiana.

A physician who engages in the unauthorized practice of medicine is not a "practitioner acting in the usual course of * * * professional practice." 21 CFR 1306.04(a). Under the CSA, the "[t]he term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance." 21 U.S.C. 802(21). See also 21 U.S.C. 823(f) ("The Attorney General shall register practitioners * * * to dispense * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices."). As the Supreme Court has explained: "In the case of a physician [the CSA] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice." United States v. Moore, 423 U.S. 122, 140-41 (1975) (emphasis added). A controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under the CSA. Cf. 21 CFR 1306.03(a)(1) ("A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession[.]").

Respondent had ample reason to know that these prescriptions were unlawful under both Federal and state law. As the California Court of Appeal has noted: the "proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and cer-

tainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine." Hageseth v. Superior Court, 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007). Moreover, as Respondent's expert admitted, an entity which voluntarily engages in commerce by shipping controlled substances to persons located in other States is properly charged with knowledge of the laws regarding the practice of medicine in those States. See Tr. at 1302.

While this allegation was included in the Show Cause Order and litigated, see ALJ Ex. 1, at 3; in its brief, Respondent largely sweeps it under the rug. [FN25] See ***50408** Resp. Prop. Findings at 22. I find, however, that Drs. Reppy, Jamieson, Fernandez, and Merkle, repeatedly issued unlawful prescriptions when they prescribed controlled-substances to residents of States where they were not licensed to practice medicine. Respondent knew the physicians were generally licensed in only one State and yet dispensed the prescriptions. I thus find that Respondent had ample reason to know that these prescriptions were unlawful, that it deliberately ignored these state licensure requirements, and thus, that it repeatedly violated the CSA. See 21 CFR 1306.04(a).

FN25 In its proposed findings, Respondent asserts that "there is a conflict in California law" regarding ¢mthe legality of an unlicensed physician's issuance of a prescription to a resident of the State. Resp. Prop. Finding at 22. () 120). Respondent does not, however, cite to any statutory language to support its claim of conflict, but rather, relies on a document it created which the Government entered into evidence. See id. (citing GX 7, at 1). I therefore reject this contention.

Ignoring these patent violations of both Federal and state laws, Respondent contends that Dr. Reppy and the other physicians were engaged in the legitimate practice of "telemedicine" because "there is no requirement that the prescribing physician personally conduct a physical examination of a patient for a valid doctor-patient relationship to exist." Resp. Proposed Findings and Conclusions of Law at 26 () 143). In support of its contention, Respondent argues that the practitioners whose prescriptions it filled "required, at a minimum, the patient to provide recent medical records, including a physical examination, to substantiate the objective portion of the diagnosis, prior to the telephonic consultation with the doctor." Id.

I also reject this contention. Even if Dr. Reppy's (and Dr. Jamieson's) conduct established a valid doctor-patient relationship under Florida law (a dubious proposition at that, see GX 56, at 53-54), both physicians violated the laws of other States which clearly require that the prescriber personally perform the physical exam except in limited situations not applicable here. Dr. Reppy violated the laws of California, Tennessee, Indiana, and Louisiana. Dr. Jamieson (and Dr. Fernandez) violated the laws of California, Tennessee, and Louisiana. Moreover, Dr. Merkle violated the laws of California, Tennessee, and his own State, Indiana. [FN26]

FN26 As found above, Respondent also filled numerous controlled-substance prescriptions issued by Dr. Kienzle, a Tennessee-licensed physician who ultimately surrendered his medical license for prescribing over the internet.

In its exceptions, Respondent argues that it is the victim of "unclear" guidance because the Agency's regulations and Practitioner's Manual do not state "that the prescribing physician [must] personally conduct a physical examination." Resp. Exceptions at 9-10. This argument misses the mark because as the 2001 Guidance Document recognized, whether certain acts by a physician establish a bonafide doctor-patient relationship is a question of state law, see 66 FR at 21182-83, and as explained above, some States allow a physician to prescribe without performing a physical exam in various, but limited, circumstances.

The rules (and/or interpretations) adopted by the States of California, Tennessee, Indiana, and Louisiana (among others) requiring that a prescribing physician perform the physical exam were issued well in advance of the conduct at issue here. [FN27] These rules and interpretations were also clear enough to put Respondent on notice that the prescriptions being issued to residents of those States were unlawful.

FN27 California adopted its internet prescribing statute in 2000, see Cal. Bus. & Prof. Code § 2242.1 (West 2007). Tennessee published its proposed rule on internet and telephonic prescribing on September 26, 2000; while the rule was subsequently renumbered it became effective shortly thereafter. See 26 Tenn. Admin. Reg. 62-63 (Oct. 2000). Likewise, on May 24, 2000, Louisiana issued its position statement on internet and telephonic prescribing. Finally, Indiana adopted its regulation on prescribing to persons not seen by the physician in October 2003. See 844 Ind. Admin. Code 5-4-1.1.

Respondent argues that before it filled prescriptions, it "required the physicians to execute an affidavit attesting that the physician issued their prescriptions for a legitimate medical purpose within the usual course of their practice and based on a valid physician-patient relationship." Resp. Proposed Findings at 4 () 15, citing Resp. Ex. 3 & GX 55, at 17-19). Relatedly, Dr. Johns testified that it is not "the usual and customary practice in the distributive pharmacy setting to verify the existence of a doctor/patient relationship before filling a prescription." Tr. 1280 (quoting Resp.'s Counsel).

As for Dr. Johns' testimony, Respondent was not engaged in "the usual and customary practice of" pharmacy. Rather, it was filling prescriptions that were issued by physicians who were frequently located nowhere near their "patients." Indeed, that is undoubtedly why Respondent required the physicians to sign letters attesting to the purported validity of their doctor-patient relationships.

The letters/affidavits were not a bona fide method of determining the legitimacy of the prescriptions. Rather, they were a sham, and as such, do not immunize Re-

spondent from its obligations to know the laws of each State into which it sent controlled substances and to independently determine whether the physicians were in compliance with the States' licensure requirements and specific standards for issuing treatment recommendations and prescribing controlled substances.

I therefore also find that Respondent repeatedly violated 21 CFR 1306.04(a) by filling numerous prescriptions that it had reason to know were issued by physicians who had not established valid doctor-patient relationships under the laws of various States. Both this finding and my previous finding regarding Respondent's filling of prescriptions issued by unlicensed physicians provide independent and adequate grounds to conclude that Respondent has committed acts "inconsistent with the public interest," and which warrant the revocation of its registration. 21 U.S.C. 824(a)(4).

While this conduct provides reason alone to revoke Respondent's registration, the record also contains substantial evidence of additional violations. As found above, Respondent filled numerous prescriptions issued by Dr. Starks well after his DEA registration expired on February 28, 2003. Moreover, Respondent did so even though it had on file a copy of Respondent's registration. For example, Starks issued new prescriptions (with refills) for Lortab, which Respondent filled, to J.I. of Alabama on January 9, 2004, April 16, 2004, June 24, 2004, and September 22, 2004. Starks also issued new prescriptions (with refills) for Norco and Xanax, which Respondent filled to K.Q. of Texas, on seven separate occasions between July 29, 2003, and October 27, 2004.

Under DEA regulations, a prescription for a controlled substance can be issued only by a practitioner who is properly registered. [FN28] 21 CFR 1306.03(a). The prescriptions Starks issued after the expiration of his registration were therefore illegal.

FN28 Respondent does not contend that Starks was exempt from registration.

Regarding this allegation, Dr. Johns testified that it was "probably" not inappropriate to fill a controlled-substance prescription issued by a practitioner whose DEA registration had expired even though the pharmacy had a copy of the expired registration on file. Tr. 1300. This testimony is nonsense. While filling a prescription issued by a practitioner whose registration has recently expired might be excusable, Respondent's repeated filling of ***50409*** numerous prescriptions long after the expiration of Starks' registration clearly was not appropriate and was unlawful. If, in fact, it is the custom of the pharmacy industry to dispense controlled substances in the face of information that the prescriber's registration has expired, then the entire industry is violating the CSA. Cf. The T.J. Hooper, 60 F.2d 737, 740 (2d Cir. 1932) ("[T]here are precautions so imperative that even their universal disregard will not excuse their omission.").

Respondent also violated the CSA by filling prescriptions that were issued by Mr.

Protheroe, a physician assistant, who used Dr. Reppy's DEA registration while Reppy was on leave of absence and not supervising him. As Reppy testified, Protheroe was authorized to issue prescriptions only "while he worked under [Reppy's] supervision," and did not have "permission to issue prescriptions in [Reppy's] name while [Reppy] was on leave." GX 84, at 4. These prescriptions violated the State of Florida's regulations (of which I also take official notice) stating that "[a] supervising physician may delegate to a prescribing physician assistant only such authorized medicinal drugs as are used in the supervising physician's practice, [and are] not listed" in the State's formulary. Fla. Admin. Code Ann. R. 64B8-30.008(2).

As Reppy testified, during his leave of absence he was not in any sense supervising Protheroe. Indeed, it appears that all of the controlled-substance prescriptions written by Protheroe were illegal because the State's regulations prohibit a physician assistant from prescribing controlled substances even under a physician's supervision. Id. R 64B8-30.008(1). [FN29]

FN29 The prescriptions were also illegal for the same reasons that Reppy's prescriptions were illegal.

I further conclude that Respondent had reason to know that Protheroe was writing illegal prescriptions and filled them anyway. See GXs 16-18 (daily audit logs). The record amply establishes that Ballinger directed the operations of University during the relevant time period. Moreover, while the sale agreement for Respondent indicated that Carr was then its sole owner, both Reppy and Miller testified that Ballinger and Carr were partners in Respondent and other business ventures involving the distribution of controlled substances over the internet prior to the March 2005 sale of Respondent to Ballinger. GX 87, at 2-4; Tr. 1172-73. Moreover, Respondent's counsel stipulated that Ballinger had a relationship with Respondent during Reppy's employment at University. Tr. 1172. Finally, the evidence also establishes that Ballinger directed that University fax its prescriptions to Respondent. Id. at 1179. I therefore hold that Ballinger knew that Protheroe was issuing illegal prescriptions and that this knowledge is properly imputed to Respondent. Respondent thus violated 21 CFR 1306.04 by filling these prescriptions. This finding thus provides additional support for the conclusion that Respondent's registration is "inconsistent with the public interest." [FN30] 21 U.S.C. 823(f).

FN30 I also find that Respondent violated Kentucky law by failing to report its dispensing of controlled substances.

Finally, Respondent argues that it made "numerous attempts to meet with DEA to ensure compliance with DEA's interpretations of applicable laws and regulations" and that it "change[d] its business model to assuage DEA's concerns." Resp. Prop. Findings at 29-30. Respondent further asserts that "in January 2007, * * * [it] began requiring physicians who issued prescriptions through [it] to have personally physically examined the patient involved." Id. at 12 (citing Tr. 877).

The purported support is not, however, testimony, but rather, part of a question asked by Respondent's counsel of a DEA witness, to which the latter answered: "I don't recall that." Tr. 877. Likewise, the further statement by Respondent's lawyer during a colloquy with the ALJ that its reforms "began in earnest in the beginning of January," id., is not evidence. Moreover, given the abundant evidence establishing that Respondent filled numerous illegal prescriptions, and the failure of Mr. Ballinger to testify, Respondent's assertion of its new-found willingness to reform cannot be taken seriously. I therefore reject it. [FN31]

FN31 Given the abundant evidence of Respondent's failure to comply with applicable laws, I conclude that there is no need to address whether its compounding activities also violated the CSA. Moreover, in light of the evidence, I find it unnecessary to draw an adverse inference based on Mr. Ballinger's failure to testify with respect to the conduct alleged in the Show Cause Order and thus do not address Respondent's exception on this point. I do, however, rely on Mr. Ballinger's failure to testify to draw an adverse inference regarding its assertion that it has reformed its practices.

* * * * *

As the Supreme Court recently explained, "the prescription requirement * * * ensures [that] patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." Gonzales v. Oregon, 126 S.Ct. 904, 925 (2006) (citing Moore, 423 U.S. at 135). Even if it is not the usual and customary practice in the traditional brick-and-mortar pharmacy setting to verify the existence of the doctor/patient relationship before filling a prescription, see Tr. 1280 (testimony of Dr. Johns), the prescribing and dispensing of controlled substances over the internet poses an extraordinary threat to public health and safety. Southwood Pharmaceuticals, Inc., 72 FR 36487, 36504 (2007) (discussing reports of the National Center on Addiction and Substance Abuse and the National Institute of Drug Abuse); see also William R. Lockridge, 71 FR 77791 (2006). Indeed, as even Respondent's expert admitted, if a prescription was faxed from a Web site, it would create a suspicion that the drugs would be diverted and require the pharmacist to perform additional investigation before filling the prescription. Tr. 1317. Furthermore, when a pharmacy receives a prescription which indicates that the prescriber and patient are located nowhere near each other, it should be obvious that further inquiry is warranted to determine whether the prescription was issued pursuant to a valid doctor-patient relationship. This is so regardless of whether the pharmacy is a traditional retail pharmacy or a mail order/internet pharmacy.

In sum, because Respondent's dismal record of compliance with federal and state laws and its experience in dispensing controlled substances amply demonstrate that its continued registration is inconsistent with the public interest, there is no need to address the other statutory factors. Moreover, for the same reasons which led me to find that Respondent's registration posed an "imminent danger to the

public health or safety," 21 U.S.C. 824(d), I conclude that the public interest requires that its registration be revoked effective immediately. See 21 CFR 1316.67.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, BU6696073, be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This Order is effective immediately.

***50410** Dated: August 23, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7-17223 Filed 8-30-07; 8:45 am]

BILLING CODE 4410-09-P

72 FR 50397-01, 2007 WL 2455578 (F.R.)

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Bob's Pharmacy and
Diabetic Supplies

NOTICES

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bob's Pharmacy and Diabetic Supplies; Revocation of Registration

Wednesday, April 29, 2009

On August 15, 2008, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to **Bob's** Pharmacy and Diabetic Supplies (Respondent), of Winter Haven, Florida. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, FB0181216, as a retail pharmacy, and the denial of any pending application to renew or modify its registration, on the ground that Respondent has committed acts which render its "continued registration inconsistent with the public interest." Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4)).

The Show Cause Order alleged that Respondent was "knowingly engaging in a scheme to distribute controlled substances based on * * * prescriptions that [were] issued for other than legitimate medical purpose and by physicians acting outside [of] the usual course of professional practice, in violation of * * * Federal and State law." Id. (citing 21 CFR 1306.04; United Prescriptions Servs., Inc., 72 FR 50397 (2007)). More specifically, the Show Cause Order alleged that Respondent was "dispensing controlled substances into states in which it is not licensed to do so," and that it was "aiding physicians in the unauthorized practice of medicine in those states that require physicians to be licensed by the state before prescribing controlled substances to state residents." Id. at 2 (citing United, 72 FR 50407-08). The Show Cause Order also alleged that Respondent had "dispensed large quantities of controlled substances based on prescriptions purportedly written by Sheila Soman, M.D., a physician who was not authorized by DEA to prescribe controlled substances." Id. Based on the above, I further found that there was a "substantial likelihood that [Respondent ***19600** would] continue to divert large quantities of controlled substances," and concluded that Respondent's continued registration during the pendency of the proceeding "would constitute an imminent danger to the public health and safety." Id. I therefore ordered that Respondent's registration be immediately suspended. [FN1] Id.

FN1 The Show Cause Order also informed Respondent of its right to request a hearing on the allegations; the date, time, and place of the hearings; its right to submit a written statement in lieu of a hearing; and the consequences if it failed to request a hearing. Show Cause Order at 2.

On August 20, 2008, a DEA Investigator personally served the Order on Respondent. Since that time neither Respondent, nor anyone purporting to represent it, has requested a hearing. Because more than thirty days have elapsed since Respondent was served with the Order, and Respondent has not requested a hearing, I conclude that Respondent has waived its right to a hearing. 21 CFR 1301.43(d). I therefore enter this Decision and Final Order based on relevant material contained in the investigative file and make the following findings. Id. 1301.43(e).

Findings

Respondent is the holder of DEA Certificate of Registration, FB0181216, which authorizes it to dispense, as a retail pharmacy, controlled substances in schedules II through V, at the registered location of 2860 Highway 17 N., Winter Haven, Florida 33881. Respondent was first registered with the Agency on or about March 14, 2007; its registration does not expire until July 31, 2009. Respondent is owned by Mr. Robert L. Grable.

In August 2007, a DEA Investigator (DI) obtained a report which indicated that between April 15 and June 28, 2007, Respondent had purchased 767,900 dosage units of drugs containing hydrocodone, a controlled substance highly popular with drug abusers. Moreover, between June 28 and September 12, 2007, Respondent ordered a further 258,000 dosage units of hydrocodone from just one of its suppliers. Subsequent reports further showed that between April 25 and December 28, 2007, Respondent had purchased 2.3 million dosage units of drugs containing hydrocodone, or approximately 287,000 dosage units per month. By way of contrast, I have previously found that the national average purchase of combination hydrocodone drugs by retail pharmacies is approximately 6,000 dosage units. See Southwood Pharmaceuticals, Inc., 71 FR 36487, 36490 (2007).

On January 10, 2008, the DEA Nashville Diversion Group received a letter from the compliance officer for Top Rx, Inc., a registered distributor. The letter indicated that Respondent had applied to become a customer of Top Rx and had completed a questionnaire on which it indicated that it did not dispense controlled substances through the internet. Top Rx's compliance office determined, however, that Respondent may have been affiliated with a Web site which provided illegal prescriptions for controlled substances.

Approximately a week later, the DI received information from the New York Diversion Group that Respondent had ordered 700 grams of pure hydrocodone powder (a schedule II controlled substance) from another distributor. Finally, in a December 27, 2007 letter, a third distributor identified Respondent as having placed excessive orders.

On June 27, 2008, two DIs visited Respondent. During the visit, the DIs obtained prescriptions which had been issued by two physicians (one based in Tampa, Florida; the other based in Deridder, Louisiana) which had been issued to persons

throughout the United States, and which were dispensed by Respondent. Ninety-seven percent of the prescriptions were for schedule III controlled substances containing hydrocodone and were typically for ninety tablets; some of the remaining prescriptions were for alprazolam, a schedule IV controlled substance.

On August 20, 2008, an Administrative Inspection Warrant was served on Respondent. Pursuant to the search, the DIs obtained numerous prescription records. According to the sworn declaration of a DI who reviewed the records, between May 3, 2007, and the date that the warrant was executed, Respondent had filled in excess of 38,000 prescriptions for controlled substances, the great majority of which were for schedule III drugs containing hydrocodone.

The DI found that Respondent had filled more than 6,000 prescriptions issued by Dr. Celeste Lujan, who was authorized to practice medicine and prescribe controlled substances only in Louisiana and Texas. According to the DI, most of the prescriptions were issued to persons who resided in States where Dr. Lujan was not authorized to practice medicine including Alaska, Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Utah, Virginia, Washington, Wisconsin, West Virginia, and Wyoming.

The DI further found that between January 1 and August 18, 2008, Respondent filled more than 3,000 prescriptions which were written under the DEA registration issued to Dr. Sheila Soman of New York, NY. Dr. Soman had, however, previously voluntarily surrendered her registration; on December 17, 2007, the Agency retired her registration.

Discussion

Section 304(a) of the Controlled Substance Act provides that "[a] registration * * * to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a). In determining the public interest, the Act directs that the Attorney General consider the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. § 823(f).

"[T]hese factors are * * * considered in the disjunctive." Robert A. Leslie, M.D., 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem [] appropriate in determining whether a registration should be revoked." Id. Moreover, case law establishes that I am "not required to make findings as to all of the factors." Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); see also Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Finally, where the Government has made out its prima facie case, the burden shifts to the Respondent to show why its continued registration would be consistent with the public interest. See, e.g., Theodore Neujahr, 65 FR 5680, 5682 (2000); Service Pharmacy, Inc., 61 FR 10791, 10795 (1996).

***19601** In this case, having considered all of the factors, I conclude that the Government's evidence with respect to factors two and four establishes a prima facie case that Respondent's continued registration is "inconsistent with the public interest." 21 U.S.C. 823(f). Accordingly, Respondent's registration will be revoked and any pending applications for renewal of its registration will be denied.

Factor Two--Respondent's Experience in Dispensing Controlled Substances

Under DEA's regulation, a prescription for a controlled substance is unlawful unless it has been "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). The regulation further provides that while "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, * * * a corresponding responsibility rests with the pharmacist who fills the prescription." Id. (emphasis added). Continuing, the regulation states that "the person knowingly filling such a purported prescription, as well as the person issuing it, [is] subject to the penalties provided for violations of the provisions of law relating to controlled substances." Id.

DEA has long interpreted this provision "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.' " Medicine Shoppe-Jonesborough, 73 FR 363, 381 (2008) (quoting Medic-Aid Pharmacy, 55 FR 30043, 30044 (1990)), aff'd Medicine Shoppe-Jonesborough v. DEA, 2008 WL 4899525 (6th Cir. 2008); see also Frank's Corner Pharmacy, 60 FR 17574, 17576 (1995); Ralph J. Bertolino, 55 FR 4729, 4730 (1990); United States v. Seelig, 622 F.2d 207, 213 (6th Cir. 1980). This Agency has further held that "[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not

intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription." Bertolino, 55 FR at 4730 (citations omitted). [FN2]

FN2 The Supreme Court has recently explained that "the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135 (1975)).

In United Prescription Services, Inc., I further held that "[a] physician who engages in the unauthorized practice of medicine is not a 'practitioner acting in the usual course of * * * professional practice.' " 21 CFR 1306.04(a). This rule derives from the text of the CSA, which defines "[t]he term 'practitioner' [to] mean[ ] a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance." 21 U.S.C. 802(21). See also 21 U.S.C. 823(f) ("The Attorney General shall register practitioners * * * to dispense * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices."). As the Supreme Court has explained: "In the case of a physician [the CSA] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice." United States v. Moore, 423 U.S. 122, 140-41 (1975) (emphasis added). A controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under the CSA. Cf. 21 CFR 1306.03(a)(1) ("A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession[.]").

Respondent had ample reason to know that the prescriptions issued by Dr. Lujan were unlawful under both Federal and state law. As the California Court of Appeal has noted: The "proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine." Hageseth v. Superior Court, 59 Cal. Rptr. 3d 385, 403 (Ct. App. 2007); [FN3] see Cal. Bus. & Prof. Code § 2052 (prohibiting unlicensed practice of medicine); Cal. Health & Safety Code § 11352(a) (prohibiting furnishing a controlled substance "unless upon the written prescription of a physician * * * licensed to practice in this state"). See also e.g., Ala. Code § 34-24-501(a) (defining practice of medicine across state lines); id. § 34-24-502(a) (requiring special purpose license to practice medicine across state lines); Ga. Code Ann. § 43- 34.31.1(a) (defining practice of medicine to include electronic prescribing by "[a] person who is physically located in another state" and requiring Georgia license); 225 Ill. Comp.

Stat. Ann. § 60/3 (licensure requirement); id. § 60/3.5 (prohibiting unlicensed practice); id. § 60/49 (listing acts constituting holding oneself out to the public as a physician); id. § 60/49.5 (requiring persons engaged in telemedicine to hold Illinois license); N.H. Rev. Stat. § 329:1 (defining practice of medicine); id. § 329:24 (unlicensed practice).

FN3 In Hageseth, the California Court of Appeal upheld the State's jurisdiction to criminally prosecute an out-of-state physician, who prescribed a drug to a California resident over the internet, for the unauthorized practice of medicine.

Moreover, the Medical Board of California has issued numerous Citation Orders to out-of-state physicians for internet prescribing to state residents. See, e.g., Citation Order Harry Hoff (June 17, 2003); Citation Order Carlos Gustavo Levy (Nov. 30, 2001). It has also issued press releases announcing its position on the issuance of prescriptions by physicians who do not hold a California license. See Medical Board of California, Record Fines Issued by Medical Board to Physicians in Internet Prescribing Cases (News Release, Feb. 10, 2003) (available at http://www.mbc.ca.gov/NR--2003--02-10-- Internetdrugs.htm).

As I have previously explained, an entity which voluntary engages in commerce by shipping controlled substances to persons located in other States is properly charged with knowledge of the laws regarding both the practice of medicine and pharmacy in those States. United, 72 FR at 50408. In short, given that Dr. Lujan was licensed to practice medicine and prescribe in only Louisiana and Texas, and yet was prescribing to persons who did not reside in those States and lived hundreds of--and in many instances more than a thousand--miles away, Respondent had ample reason to know that the prescriptions were unlawful under both the CSA and the laws of numerous States. See id. at 50409.

Moreover, under DEA regulations, a prescription for a controlled substance can be issued only by a practitioner who holds a registration with the Agency. 21 CFR 1306.03(a) ("A prescription for a controlled substance may be issued only by an individual practitioner who is * * * registered."). [FN4] Respondent thus also violated the CSA when it filled more than 3,000 prescriptions which were purportedly issued by Dr. Soman, a physician who had previously voluntarily surrendered her registration.

FN4 It is unclear whether the prescriptions issued under Dr. Soman's expired registration were actually issued by her. What is clear is that no prescription could be lawfully issued (or filled) under her registration number.

***19602** As the foregoing demonstrates, Respondent's experience in dispensing controlled substances is characterized by its repeated and flagrant violations of the CSA and state laws. Indeed, within less than one month of obtaining its registration, Respondent proceeded to purchase hundreds of thousands of dosage units of hydrocodone, quantities which exceeded by nearly fifty times the average purchase

of this drug by legitimate pharmacies. As this evidence shows, Respondent was engaged in a criminal scheme to divert controlled substances.

I therefore hold that Respondent's continued registration is "inconsistent with the public interest" and that its registration should be revoked. 21 U.S.C. 823(f). For the same reasons that I ordered the immediate suspension of Respondent's registration, I further hold that this Order shall be effective immediately.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, FB0181216, issued to **Bob's** Pharmacy and Diabetic Supplies be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This Order is effective immediately.

Dated: April 3, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9-9797 Filed 4-28-09; 8:45 am]

BILLING CODE 4410-09-P

74 FR 19599-03, 2009 WL 1137632 (F.R.)

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Taylor

physicians on almost every other day it was open for business.

As recognized in other cases, the sheer volume of prescriptions thus establishes that it more likely than not that Respondent's owner knew that the prescriptions were illegitimate and intentionally ignored this. *See, e.g., Bertolino*, 55 FR 4729, 4730. Beyond that, the prescriptions were being sent to persons in every part of the country. Moreover, there is also some evidence that the iPharmacy physicians performed their reviews in rapid-fire fashion. Yet none of this prompted Respondent's owner to question the legality of the prescriptions. Contrary to Mr. Enemchukwu's assertion that "everything we are looking at now is from hindsight," Tr. 850, shortly into the relationship with iPharmacy, Mr. Enemchukwu was receiving abundant evidence—on a nearly daily basis—to know that iPharmacy (and its doctors) were engaged in illegal activity.[12]

I thus conclude that Respondent is responsible for the dispensing of more than 43,000 illegal prescriptions and the diversion of more than two million dosage units of various controlled substances. Not only is this a violation of federal law, *see* 21 U.S.C. 841(a), and appears to be a violation of Florida law,[13] *see* Fla. Stat. 465.016(s), it is manifest that diversion on this scale creates an extraordinary threat to the public health and safety. Respondent's experience in dispensing controlled substances and its record of compliance with applicable laws thus provide abundant reason to conclude that Respondent committed acts which rendered its registration "inconsistent with the public interest" and thus warranted the suspension of its registration under section 304(a). 21 U.S.C. 824(a)(4).[14]

Order

Pursuant to the authority vested in me by 21 U.S.C. 824, as well as 28 CFR 0.100(b) & 0.104, the order of immediate suspension of DEA Certificate of Registration, BT2863668, issued to Trinity Health Care Corporation, d/b/a/ Oviedo Discount Pharmacy, is hereby affirmed.

Dated: May 21, 2007,

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–10627 Filed 6–1–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Dale L. Taylor, M.D.; Revocation of Registration

On February 2, 2007, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Dale L. Taylor (Respondent) of Winter Haven, Florida. The Order immediately suspended Respondent's Certificate of Registration, BT8732631, as a practitioner, based on my preliminary finding that Respondent was diverting large quantities of controlled substances through an internet-prescribing scheme. Show Cause Order at 2. I therefore concluded that Respondent's "continued registration during the pendency of these proceedings would constitute an imminent danger to the public health and safety because of the substantial likelihood that [he would] continue to divert controlled substances to drug abusers." *Id.* at 3.

The Show Cause Order also alleged that Respondent's "continued registration is inconsistent with the public interest." *Id.* at 1. More specifically, the Show Cause Order alleged that beginning in May 2004, Respondent had been issuing prescriptions for controlled substances over the Internet "without the benefit of a legitimate doctor-patient relationship and outside the course of professional practice." *Id.* The Show Cause Order alleged that Respondent had admitted to DEA investigators that he had done such prescribing for three different internet entities including Pacific MD, Norco Worldwide, and *BestRxCare.com*. *Id.* at 1–2.

The Show Cause Order further alleged that Respondent had admitted that he would log onto a Web site and view a list of customers, review their medical records, and then contact each person by telephone. *Id.* at 2. The Show Cause Order alleged that Respondent had admitted that his "role was simply to make sure that the type of medication, strength and quantity were consistent with the online customers' alleged medical need," and he had "never called patients after authorizing their drug orders to provide aftercare." *Id.* Relatedly, the Show Cause Order alleged that Respondent told investigators that he took "the on-line patient's word when determining their need for hydrocodone." *Id.*

The Show Cause Order alleged that BestRxCare.com's orders were filled by CRJ Pharmacy and that the pharmacy's records for the period from July 3, 2006, to January 22, 2007, showed that it had dispensed "approximately 6,000 [i]nternet drug orders that [Respondent] authorized." *Id.* The Show Cause Order alleged that "approximately 85% of these [i]nternet drug orders were for hydrocodone combination products." *Id.*

Finally, the Show Cause Order alleged that Respondent had admitted to investigators that he had "authorized controlled substance [prescriptions] for online customers throughout the United States" even though he acknowledged that he was "only licensed to practice medicine in" Florida. *Id.* The Show Cause Order thus alleged that Respondent had violated various state laws that prohibit "unlicensed, out-of-state physicians issuing controlled substance prescriptions to state residents." *Id.*

On February 6, 2007, DEA Investigators served the Show Cause Order and Immediate Suspension, which notified Respondent of his right to a hearing, by leaving it at his residence with his wife. *Cf.* F.R.C.P. 4(e). Since that time, neither Respondent, nor anyone purporting to represent him, has responded. Because (1) more than thirty days have passed since service of the Show Cause Order, and (2) no request for a hearing has been received, I conclude that Respondent has waived his right to a hearing. *See* 21

[12] Respondent's owner makes no claim that it was reasonable for him to rely on the representations made by Mr. Butler both orally and in the contract regarding the legality of internet prescribing and dispensing. This is rightly so for three reasons: (1) Mr. Enemchukwu is a licensed professional and is responsible for knowing the rules applicable to the practice of his profession, (2) in April 2001, nearly three years before he entered into the contract with Mr. Butler, DEA published guidance which explained the application of existing federal laws and regulations to the proposed arrangement, and (3) other bodies such as the AMA and Federation of State Medical Boards had published information regarding the invalidity of internet prescribing under both ethical and legal standards. *See* Gov. Exs. 3 & 4.

[13] The Government also argues that Respondent violated various state laws by dispensing to persons in States where it was not licensed to do so. *See* Gov. Br. at 48. In its brief, the Government did not, however, cite to specific laws establishing the licensure requirements of various States. Moreover, the Government's proof was largely confined to an e-mail in which Respondent sought reimbursement for the fees it paid to obtain the permits. The Government's evidence did not cite to specific instances in which Respondent dispensed in violation of a particular State's law. *See* Tr. 361–62.Therefore, I conclude that this allegation had not been proved with substantial evidence.

[14] Based on Mr. Enemchukwu's insistence that he did not know and had no reason to believe that the iPharmacy prescriptions were unlawful, the ALJ further concluded that he had failed to acknowledge his wrongdoing and thus was not "willing to accept the responsibilities inherent in a DEA registration." ALJ at 31. While I agree with the ALJ's view of the evidence, there is neither an existing registration to revoke nor a pending application to deny. As this case is now limited to a review of the validity of the suspension, there is no need to considerer this finding and weigh it against the slight mitigating evidence in the case.

CFR 1301.43(d). I therefore enter this final order without a hearing based on relevant material in the investigative file and make the following findings.

Findings

Respondent is the holder of DEA Certificate of Registration, BT8732631, as a practitioner, with an expiration date of November 30, 2006. On October 11, 2006, Respondent, however, applied for a renewal of his registration via the Internet. Therefore, in accordance with the Administrative Procedure Act, Respondent's registration remains in existence pending the issuance of a final order in this matter. *See* 5 U.S.C. 558(c).

According to the investigative file, on January 26, 2007, DEA investigators interviewed Respondent regarding his participation in various schemes involving the dispensing of controlled substance over the Internet. Respondent told the investigators that in early to mid 2004, he answered an advertisement placed by an entity known as Pacific MD in a Gainesville, Florida newspaper which sought physicians to perform internet consultations. In May 2004, Pacific MD engaged Respondent to review patient records and if the records were not more than two years old, contact the "patient" and authorize a prescription which was typically for either combination products containing hydrocodone, a schedule III controlled substance, *see* 21 CFR 1308.13(e), or Xanax (alprazolam), a schedule IV controlled substance. *See* 21 CFR 1308.14(c). Respondent related that in June 2005, he quit working for Pacific MD because it owed him money.

At some date not specified in the investigative file, Respondent submitted his credentials to a temporary employment service that specialized in medical staffing. Thereafter, Respondent was contacted by another entity, Norco Worldwide, and began working for it. Norco gave Respondent a password which enabled him to review medical records submitted by Norco's customers. According to Respondent, a physician's assistant would contact and talk to the patients and authorize a prescription for a controlled substance using his DEA registration. Respondent further admitted that he wrote prescriptions on a computer program, which were then submitted electronically to a pharmacy which filled them. Respondent stated that he worked for Norco from October 2004 through December 2004 and authorized approximately forty prescriptions per day. Respondent further told investigators that he quit Norco because he wasn't comfortable with the fact that a physician's assistant was authorizing controlled substance prescriptions using his DEA registration.

Shortly thereafter, Respondent was contacted by one Chris Larson. Larson had also formerly worked for Norco and had started two Web sites, BestRx.com, and your painmanagement.com, which allowed persons to order controlled substances over the Internet by completing a questionnaire and submitting their "medical records." Larson also owned several pharmacies that filled prescriptions for his Web sites.

Respondent told investigators that he would log onto the *BestRx.com* Web site and obtain a list of "patients" with "appointments." Respondent would then review the "patient's" medical records before telephoning the person. Respondent asserted that he required the records to be on the previous physician's letterhead and be signed. Respondent further maintained that he reviewed the records to determine whether the drug sought was consistent with the customer's medical condition.

When asked by investigators whether he had ever contacted any of the customer's prior physicians, Respondent claimed that he had but could not recall their names. Respondent further admitted that he was not authorized to require that a customer undergo additional testing and that the customer had to go to their original physician to obtain such tests.

Respondent admitted that he simply trusted that the records submitted by the website's customers were not fraudulent and took the customer's word during the phone consultation. Based on the medical records and the phone conversation, Respondent would prescribe controlled substances. Respondent further admitted that he never called a customer to follow up. Respondent also admitted that on numerous occasions, customers would call him seeking more drugs.

One of the investigators then asked Respondent if he maintained any patient files. Respondent claimed that he kept meticulous record for all of his "patients" at his residence in a plastic storage bin located in his office. Respondent's wife, however, told investigators that the bin did not contain any medical records but merely the names and addresses of persons Respondent had spoken with.

Respondent admitted that he had authorized controlled substances prescriptions for persons located throughout the United States even though he held only a Florida medical license. Respondent further admitted that he authorized as many as twenty to twenty-five prescriptions a day while working for *BestRxCare.com*.

The investigators asked Respondent to voluntarily surrender his DEA registration. Respondent refused and stated that he intended to continue authorizing prescriptions through the Internet because on-line medicine is the wave of the future. Respondent acknowledged that absent use of a webcam, it was not possible to verify the validity of a "patient" and his or her medical needs. Respondent stated that until then, he would continue to take online patients at their word and accept their records as authentic.

On January 22, 2007, DEA personnel executed an Administrative Inspection Warrant at CRJ Pharmacy and YPM Total Care Pharmacy, two of the businesses owned by Chris Larson. During the search, DEA obtained each pharmacy's dispensing records; the records were then reviewed by a DEA intelligence analyst. According to the records of CRJ Pharmacy, between July 2006 and January 2007, Respondent authorized 6,069 prescriptions for 1,098 persons who resided in forty-six States and the District of Columbia. Of the prescriptions, 5,156 were for hydrocodone-combination products, and 526 were for alprazolam.

The records for YPM showed that from November 27, 2006, through January 17, 2007, Respondent authorized prescriptions for another 171 patients who resided in thirty-six States. More specifically, Respondent authorized 367 orders for hydrocodone-combination products and thirty-three orders for alprazolam. The records also showed that on a single day, Respondent had written as many as fifty-six orders which were filled by YPM.

Discussion

Section 304(a) of the Controlled Substances Act provides that a registration to "dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In making the public interest determination, the Act requires the consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the

manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

• "[T]hese factors are * * * considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked." *Id.* Moreover, I am "not required to make findings as to all of the factors." *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

Finally, section 304(d) provides that "[t]he Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety." 21 U.S.C. 824(d). In this case I conclude that Factors Two and Four establish that allowing Respondent to continue to dispense controlled substances would be inconsistent with the public interest and therefore will order the revocation of Respondent's registration and the denial of his pending application for renewal.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Respondent's Compliance With Applicable Laws

The central issue in this case is whether the prescriptions Respondent issued pursuant to his employment with the Web sites *BestRx.com* and *yourpainmanagement.com* complied with Federal law. As explained below, the evidence conclusively demonstrates that Respondent used his prescribing authority to act as a drug pusher; the only difference between him and a street dealer was that he did not physically distribute the drugs to the customers of the aforementioned websites.

Under DEA regulations, a prescription for a controlled substance is not "effective" unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). This regulation further provides that "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances." *Id.* As the Supreme Court recently explained, "the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales* v. *Oregon*, 126 S.Ct. 904, 925 (2006) (citing *Moore*, 423 U.S. 122, 135 (1975)).

It is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to be acting "in the usual course of * * * professional practice" and to issue a prescription for a "legitimate medical purpose." Under the State of Florida's regulations, a physician "shall not provide treatment recommendations, including issuing a prescription, via electronic or other means, unless the following elements have been met:

(a) A documented patient evaluation, including history and physical examination to establish the diagnosis for which any legend drug is prescribed.

(b) Discussion between the physician * * * and the patient regarding treatment options and the risks and benefits of treatment.

(c) Maintenance of contemporaneous medical records meeting the requirements of [Florida regulations].

Fla. Admin. Code R. 64B8–9.014.

Relatedly, the American Medical Association's *Guidance for Physicians on Internet Prescribing* has explained that to establish a bonafide doctor-patient relationship, a "physician shall":

i. Obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided; ii. have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s); iii. as appropriate, follow up with the patient to assess the therapeutic outcome; iv. maintain a contemporaneous medical record that is readily available to the patient and * * * to his * * * other health care professionals; and v. include the electronic prescription information as part of the patient medical record.

(quoted in *William R. Lockridge*, 71 FR 77791,77798 (2006)).

To similar effect are the guidelines issued by the Federation of State Medical Boards of the United States, Inc. *See Model Guidelines for the Appropriate Use of the Internet in Medical Practice.* According to the Guidelines, "[t]reatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. *Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.*" Id. at 4 (emphasis added). Cf. DEA, *Dispensing and Purchasing Controlled Substances over the Internet*, 66 FR 21181, 21183 (2001) (guidance document) ("Completing a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship.").[1]

Under the Florida rule and standards of the medical profession, it is clear that Respondent did not prescribe controlled substances pursuant to a bonafide doctor-patient relationship and thus did not comply with federal law. Respondent did not physically examine the "patients." Nor did he ever act in a consultative capacity "with another physician who ha[d] an ongoing relationship with the patient, and who ha[d] agreed to supervise the patient's treatment, including the use of any prescribed medications." Fla. Admin. Code R. 64B8–9.014(4).

Moreover, Respondent admitted that he was not authorized by his employer to order that a customer undergo additional testing. Respondent also admitted that he never called a "patient" to follow-up on whether the treatment was successful. Finally, notwithstanding his statement to investigators that he kept meticulous records, the evidence establishes that Respondent did not maintain medical records on his purported patients. Thus, it is clear that under Florida law as well as existing professional standards, Respondent did not establish a bonafide doctor-patient relationship with the persons he prescribed controlled substances for. *See, e.g.*, Fla. Admin. Code R. 64B8–9.014.

Moreover, the investigative file establishes that Respondent issued thousands of prescriptions for controlled substances and did so notwithstanding the potential for fraud that was inherent in the scheme and his admission that on numerous occasions, customers called him requesting more controlled substances. As recognized in *Lockridge* and other agency orders, "'[le]gally there is absolutely no

[1] The guidance document reflects this Agency's understanding of what constitutes a bonafide doctor-patient relationship under state laws and existing professional standards. 66 FR 21182–83.

difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription.'" 71 FR at 77800 (quoting *Mario Avello, M.D.*, 70 FR 11695, 11697 (2005)). See also *Floyd A. Santner, M.D.*, 55 FR 37581 (1990). In short, Respondent was not engaged in the legitimate practice of medicine, but rather, was dealing drugs.

Accordingly, Respondent's experience in dispensing controlled substances and his record of compliance with applicable laws makes plain that his continued registration would "be inconsistent with the public interest." 21 U.S.C. 824(a)(4). Moreover, for the same reasons which led me to find that Respondent posed "an imminent danger to the public health or safety," *id. section 824(d)*, I conclude that the public interest requires that his registration be revoked effective immediately and his pending application for renewal be denied. *See* 21 CFR 1316.67.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate Registration, BT8732631, issued to Dale L. Taylor, M.D., be, and it hereby is, revoked. I further order that Respondent's pending application for renewal of his registration be, and it hereby is, denied. This order is effective immediately.

Dated: May 21, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–10622 Filed 6–1–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Emergency Review; Comment Request

May 29, 2007.

The Department of Labor has submitted the following information collection request (ICR), utilizing emergency review procedures specified in 5 CFR 1320.13, for the Office of Management and Budget (OMB) review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). OMB approval has been requested by June 19, 2007. A copy of this ICR, with applicable supporting documentation, from *RegInfo.gov at http://www.reginfo.gov/public/do/PRAMain* or by contacting Darrin King on 202–693–4129 (this is not a toll-free number) / e-mail: *king.darrin@dol.gov.*

Comments and questions about the ICR listed below should be submitted to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, Office of Management and Budget, Room 10235, Washington, DC 20503 (202–395–7316) (this is not a toll-free number), and received 5 days prior to the requested OMB approval date.

The Office of Management and Budget is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarify of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Agency: Office of the Assistant Secretary for Administration and Management.

Title: Contractor Data Collection Form.

OMB Number: 1225–0NEW.

Frequency: On occasion.

Affected Public: Individuals.

Number of Respondents: 5,000.

Estimated Time per Respondent: 12 minutes.

Total Burden Hours: 1,000.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintaining): $0.

Description: Under Homeland Security Presidential Directive 12 (HSPD–12), federal agencies are required to comply with a standard for identification issued to Federal employees and contractors known as FIPS–201 Personal Identity Verification (PIV) of Federal Employees and Contractors. In order to comply with the directive and issue the new federal credential to contractor personnel, the DOL must collect certain data required for the creation of an applicant record in its Personal Identity Verification II (PIV–II) system and for issuance of the PIV–II badge.

The information will be used to determine suitability for the issuance of DOL credentials. The information will be used to identity proof and register applicants as part of the Personal Identity Verification process. Providing this information is voluntary; however, failure to submit this information may result in denial of a DOL credential. Without this form, DOL contractors are not reviewed with the same rigor applied to its Federal staff with respect to HSPD–12/PIV–II credentialing standards.

Edward C. Hugler,

Deputy Assistant Secretary for Administration and Management.

[FR Doc. E7–10649 Filed 6–1–07; 8:45 am]

BILLING CODE 4510–23–P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Investment Act; Lower Living Standard Income Level

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of determination of lower living standard income level.

SUMMARY: Under Title I of the Workforce Investment Act (WIA) of 1998 (Pub. L. 105–220), the Secretary of Labor annually determines the Lower Living Standard Income level (LLSIL) for uses described in the law. WIA defines the term "Low Income Individual" as one who qualifies under various criteria, including an individual who received income for a six-month period that does not exceed the higher level of the poverty line or 70 percent of the LLSIL. This issuance provides the Secretary's annual LLSIL for 2007 and references the current 2007 Health and Human Services "Poverty Guidelines."

DATES: *Effective Date:* This notice is effective on the date of publication in the **Federal Register.**

ADDRESSES: Send written comments to: Mr. Evan Rosenberg, Department of Labor, Employment and Training Administration, 200 Constitution Avenue, NW., Room N–4464, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Please contact Mr. Evan Rosenberg, telephone 202–693–3593; fax 202–693–3532 (these are not toll free numbers).

SUPPLEMENTARY INFORMATION: It is the purpose of the Workforce Investment Act of 1998 "to provide workforce investment activities, through statewide and local workforce investment systems,

Shyngle

NOTICES

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Ladapo O. Shyngle, M.D.; Denial of Application

Wednesday, February 4, 2009

On April 15, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Ladapo O. Shyngle, M.D. (Respondent), of Tampa, Florida. The Show Cause Order proposed the denial of Respondent's pending application for a DEA Certificate of Registration as a practitioner, on the ground that his registration "would be inconsistent with the public interest." Show Cause Order at 1.

More specifically, the Show Cause Order alleged that Respondent had issued controlled-substance prescriptions to customers of an internet site who were located throughout the United States based on a questionnaire and/or telephone consultation, and that these prescriptions lacked "a legitimate medical purpose" and were issued "outside the usual course of professional practice, in violation of 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1)." Id. The Order further alleged that notwithstanding that his Florida medical license had expired on August 24, 2002, Respondent continued to issue prescriptions for controlled substances. Id. Relatedly, the Order alleged that Respondent had violated other state laws prohibiting the unauthorized practice of medicine by issuing prescriptions for controlled substances to residents of States where he was not licensed to practice. Id. at 1-2.

On or about April 19, 2008, the Show Cause Order was served on Respondent by delivery to his residence. On May 14, 2008, Respondent requested a hearing on the allegations and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJ).

On the same date, Respondent also sought to withdraw his application, explaining that the State of Florida had criminally charged him with engaging in the unlicensed practice of medicine, that he intended "to vigorously defend" against this charge, and that in light of the pending proceeding, it was premature for the Agency to consider his application. On May 29, 2008, the Deputy Assistant Administrator denied Respondent's request, reasoning that "the facts supporting the Order to Show Cause will not be affected by the outcome of the state prosecution" and that Respondent "intend[ed] to continue professional medical practice and * * * reapply for a * * * [r]egistration at the conclusion of the state criminal case." Letter from Joseph T. Rannazzisi to Respondent's Counsel (May 29, 2008).

Thereafter, on July 9, 2008, Respondent withdrew his request for a hearing. The next day, the ALJ issued an order terminating the proceeding.

Based on Respondent's letter withdrawing his request for a hearing, I conclude that Respondent has waived his right to a hearing. I therefore enter this Final Order without a hearing based on relevant material contained in the investigate file, see 21 CFR 1301.43, and make the following findings.

Findings

On October 3, 2005, Respondent applied for a DEA Certificate of Registration as a practitioner which would authorize him to dispense controlled substances in schedules II through V, at the proposed location of 1493 Tampa Park Plaza, Tampa, Florida. Respondent previously held a practitioner's registration which was issued on December 11, 2000, and which expired on February 29, 2004.

On August 24, 2000, the Florida Department of Health issued a "medical doctor restricted" license to Respondent. The license expired, however, on August 24, 2002. Respondent did not obtain another medical license until September 16, 2005, when the Florida Department of Health issued him a "medical doctor" license. This license remains in effect until January 31, 2010. I further find that Respondent was not licensed in any other State when he committed the acts at issue here.

In 2002, Respondent was hired by Kenneth Shobola, the owner of a Tampa, Florida medical clinic (the Kenaday Medical Clinic), to perform consultations on persons who were seeking prescriptions for controlled substances through Shobola's Web sites. While Respondent saw some walk-in patients at the clinic, in an interview with DEA Investigators, he admitted that he saw only about five percent of the persons he prescribed to, and that his contact with most of the patients was limited to a telephone consultation which lasted five to ten minutes.

Based on the consultations, Respondent would then typically issue a prescription for a schedule III controlled substance containing hydrocodone; Respondent also issued prescriptions for diazepam (Valium), a schedule IV controlled substance, 21 CFR 1308.14(c), and some non-controlled drugs. While the prescriptions were initially filled at F & B Pharmacy (another Tampa-based pharmacy which was operated by Olu Oyekoya), F & B eventually pulled out of the arrangement and all of the prescriptions were then filled by Ken Drugs, a pharmacy owned by Shobola.

Respondent would perform up to twenty consultations a day for Shobola's clinic. According to computer records obtained by Investigators, Respondent issued over 3800 prescriptions which were filled by Shobola's pharmacy. Approximately seventy-five percent of the prescriptions were for hydrocodone, and between the original prescriptions and refills, Respondent authorized the dispensing of more than 500,000 dosage ***6057** units of the drug. Moreover, the prescriptions were issued to persons in forty-one different States.

When asked by Investigators how he had established a doctor-patient relationship with the patients he did not see, Respondent maintained that he did so because he "actually spoke to the patient on the phone," and that the Web site which arranged the consultations had the patient's medical records and "the driver's license to identify the patient." Respondent admitted, however, that because of the number of "consults," "seventy percent" of the time he did not see a patient's medical records until after he had issued the prescription. Respondent also admitted that there were occasions when he never saw a patient's medical records. Respondent even admitted that "we did do refills for patients" who had not submitted records because "the patient [was] already in the system, [and] we already kn[ew] about this patient." [FN1]

FN1 Respondent also acknowledged that a patient had to have a physical exam at some point and maintained that the clinic had hired either nurses or paramedics to perform physical exams on patients. Even if true, this does not aid Respondent for two reasons: (1) Respondent has not established the circumstances in which it may be lawful under the laws of the various States for a physician to rely on a physical examination performed by a nurse or paramedic, and (2) Respondent acknowledged that seventy percent of the time he did not see the records until after he prescribed. Respondent thus routinely prescribed without any independent assessment and verification of his patients' medical complaints.

Respondent further stated that he was "not sure whether the law actually gives specific guidelines as to what constitutes the patient/physician relationship because * * * when the laws were drawn there was no internet." When asked whether he was saying that he did not know if his prescribing was legal because he did not know the law, Respondent replied: "No, what I'm saying is * * * I think the law the way it stands * * * makes a loophole available in terms of * * * what constitutes [the] patient/doctor relationship, when you * * * talk to the patient on the phone. * * * [T]hat is a leeway that's provided and that's what I had in mind when I got involved with * * * the whole thing."

Respondent acknowledged, however, that this method of prescribing "certainly" opened the door to drug abuse and that "providing medication through the internet has to provide safeguards to make sure that the patients are genuine, [that] they're not getting multiple drugs from different doctors and that * * * they actually have the problem that they're taking about." Moreover, Respondent stated to Investigators that "the way we practiced * * * in Kennedy there's no way you could get all of those [illegitimate patients] out of the system * * * 100% of the time." Respondent further asserted that "there was a good proportion of people that actually needed help that got the help," but acknowledged that "there were quite a few that [were] just doctor hopping or * * * shopping for medication."

As examples of Respondent's prescribing, the Government submitted copies of fourteen prescriptions which Respondent issued for such drugs as Norco (10/325 mg.), Lortab (10/500 mg.), Vicoprofen (7.5/200 mg.), and Vicodin (7.5/750 mg.), all of

which are schedule III controlled substances containing hydrocodone. Most of the prescriptions were issued between October and December 2003, and were issued to patients in California, Massachusetts, Ohio, Oklahoma, Tennessee, Wisconsin, Washington (State), Mississippi, South Carolina, and Virginia.

Respondent also prescribed controlled substances to a married couple (Mr. & Mrs. C.W.), who had used driver's licenses and medical records of friends and family members, as well as falsified medical records (including MRIs), in order to create multiple identities and obtain larger quantities of drugs such as hydrocodone and alprazolam. The C.Ws. both consumed and sold the drugs.

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that "[t]he Attorney General may deny an application for [a practitioner's] registration if he determines that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. 823(f). In making the public interest determination, the Act requires the consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id.

T]hese factors are * * * considered in the disjunctive." Robert A. Leslie, M.D., 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether an application for a registration should be denied. Id. Moreover, I am "not required to make findings as to all of the factors." Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); see also Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

Having considered all the factors, I find that factors two and four provide ample support for the conclusion that granting Respondent's application for a registration would be "inconsistent with the public interest." [FN2] 21 U.S.C. 823(f). Respondent's application will therefore be denied.

FN2 I acknowledge that there is no evidence that the State of Florida has taken any action against Respondent's authority under State law to prescribe controlled

substances. This Agency has long held, however, that a State's failure to take action against a practitioner's authority to dispense controlled substances is not dispositive in determining whether the granting of an application for registration would be consistent with the public interest. See Mortimer B. Levin, 55 FR 8209, 8210 (1990). I further note that Respondent alluded to his intention to vigorously contest a pending criminal charge based on his having engaged in the unlicensed practice of medicine. Under agency precedent, even if Respondent is acquitted of the charge(s), the judgment would not be dispositive in this proceeding, which focuses on the public interest. Edmund Chein, 72 FR 6580, 6593 n.22 (2007).

Factor Two and Four--Respondent's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

Under a longstanding DEA regulation, a prescription for a controlled substance is not "effective" unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). This regulation further provides that "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." Id. As the Supreme Court recently explained, "the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135 (1975)).

Under the CSA, it is fundamental that a practitioner must establish a bonafide ***6058** doctor-patient relationship in order to act "in the usual course of * * * professional practice" and to issue a prescription for a "legitimate medical purpose." Moore, 423 U.S. at 141-43. At the time of the events at issue here, the CSA generally looked to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. See Kamir Garces-Mejias, 72 FR 54931, 54935 (2007); United Prescription Services, Inc., 72 FR 50397, 50407 (2007); Dispensing and Purchasing Controlled Substances Over the Internet, 66 FR at 21182-83. [FN3]

FN3 On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 110-425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance "by means of the Internet without a valid prescription," and defines, in relevant part, "[t]he term 'valid prescription' [to] mean[] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least 1 in-person medical evaluation of the patient." 122 Stat. 4820. Section 2 further defines "[t]he term 'in-person medical evaluation' [to] mean[] a medical evaluation that is conducted with

the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals." Id. These provisions do not, however, apply to Respondent's conduct.

Moreover, shortly after the CSA's enactment, the Supreme Court explained that "[i]n the case of a physician [the Act] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice." Moore, 423 U.S. at 140-41 (emphasis added). Accordingly, "[a] physician who engages in the unauthorized practice of medicine" under state laws "is not a 'practitioner acting in the usual course of * * * professional practice' " under the CSA. United Prescription Services, 72 FR at 50407 (quoting 21 CFR 1306.04(a)). This rule is supported by the plain meaning of the Act, which defines the "[t]he term 'practitioner' [to] mean[] a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance," 21 U.S.C. 802(21), and "[t]he term 'dispense' [to] mean[] to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner." Id. section 802(10). See also id. section 823(f) ("The Attorney General shall register practitioners * * * to dispense * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.").

A controlled-substance prescription issued by a physician who lacks the license or other authority required to practice medicine within a State is therefore unlawful under the CSA. See 21 CFR 1306.04(a) ("An order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning an intent of" the CSA); Cf. 21 CFR 1306.03(a)(1) ("A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession[.]").

The investigative file establishes numerous instances in which Respondent violated the prescription requirement of Federal law as well as various state laws. As found above, Respondent's initial Florida medical license expired on August 24, 2002, and Respondent did not obtain a new Florida license until September 16, 2005. Thus, at the time Respondent prescribed controlled substances to many of the customers of the Kenaday Medical Clinic, he did not even have authority to prescribe under Florida law, let alone the laws of the forty other States where his patients resided. See Fla. Stat. §§ 456.065 (2003); 458.327(1)(a) (2003); see also, e.g., Cal. Bus. & Prof. Code section 2052(a) (2003) (prohibiting unlicensed practice of medicine); Cal. Health & Safety Code section 11352(a) (2003) (prohibiting furnishing of a controlled substance "unless upon the written prescription of a physician * * * licensed to practice in this state"); Tenn. Comp. R. & Regs. 0880-2.16 (2003) (requiring license to "engage in the practice of medicine across state lines in this State").

As the California Court of Appeal has noted, the "proscription of the unlicensed

practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine." Hageseth v. Superior Court, 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007). In issuing thousands of prescriptions while lacking the authority to do so under the laws of both Florida and the States where the patients resided, Respondent acted outside of "the usual course of * * * professional practice" and thereby violated the prescription requirement of the CSA (as well as numerous state laws). See Moore, 423 U.S. at 140-41; United Prescription Services, 72 FR at 50407; 21 CFR 1306.03.

Respondent violated the CSA's prescription requirement for an additional reason because he did not establish a bonafide doctor-patient relationship with the customers of the Web site. As Respondent admitted to the Investigators, with the possible exception of the small number of customers who appeared at the clinic, Respondent prescribed on the basis of a telephonic consultation and did not personally conduct a physical exam and take a medical history from the patients.

In his interview with the Investigators, Respondent gave two justifications for his prescribing. First, Respondent maintained that the law did not provide specific guidelines that addressed what constitutes a valid doctor-patient relationship in the context of the internet, asserting that those laws were enacted when "there was no internet," and that he acted within a loophole. Second, he maintained that the clinic had hired nurses or paramedics who visited the patients and performed physical exams on them.

As for his first contention, at the time Respondent issued the prescriptions at issue here, numerous States had already adopted laws or regulations, or had issued policy statements, which made clear that Respondent's internet prescribing practices were illegal. See, e.g., Cal. Bus. & Prof. Code section 2242.1(a); Tenn. Comp. R. & Regs. 0880-2.14(7) (2003) ("Prerequisites to Issuing Prescriptions"; prohibiting the prescribing or dispensing of "any drug to any individual, whether in person or by electronic means or over the Internet or over telephone lines unless the physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, has first done and appropriately documented, for the person to whom a prescription is to be issued or drugs dispensed * * * an appropriate history and physical examination"); Ohio Admin. Code 4731-11-09(A) (2003) ("Except in institutional settings, on call situations, cross coverage situations, situation involving new patients, protocol situations involving nurses practicing in accordance with standard care arrangements * * * a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed."); Oklahoma State Board of Medical Licensure and Supervision, Policy on Internet Prescribing (Ratified 01/25/01) ("Unprofessional conduct includes 'prescribing * * * a drug * * * without sufficient examination and the ***6059** estab-

lishment of a valid physician/patient relationship' * * *. The members of the Oklahoma Medical Board have interpreted that a 'sufficient examination' and 'establishment of a valid physician/patient relationship' cannot take place without an initial face to face encounter with the patient.") (emphasis in original and quoting Okla. Stat. tit. 59, section 509-13).

No more persuasive is Respondent's contention that his prescribings were lawful because the clinic used nurses or paramedics to perform physical examinations. Respondent did not provide any evidence to the Agency that the clinic's purported use of nurses to perform physical examinations was a lawful practice under the exceptions recognized by any State. [FN4]

FN4 Even if some States authorize a physician to prescribe in some circumstances based on a physical exam performed by a nurse, Respondent was required to comply with the law of every State in which his patients resided. In any event, Respondent did not establish that his prescribing was lawful under the law of any State.

Moreover, Respondent admitted to the Investigators that he routinely prescribed before he obtained medical records and in some cases he never reviewed records. Thus, even if some States allowed a physician to prescribe based on an exam performed by a nurse or paramedic in certain defined circumstances, a physical examination is a prerequisite to establishing a valid doctor-patient relationship. See Tenn. Comp R. & Regs 0880-2-.14(7). Generally, reviewing an examination conducted after the issuance of a prescription is not the usual course of professional practice. [FN5] I thus conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing the prescriptions.

FN5 It is acknowledged that the States generally allow a practitioner to issue a prescription in an emergency situation before conducting a physical exam. See 49 Pa. Code § 16.92(a). Some States also allow a practitioner to issue a short term continuation prescription for a new patient prior to a patient's first appointment, in an order admitting a patient to a hospital, or for a patient of another physician for whom the prescriber is taking calls. Tenn. Comp. R. & Regs. 0880-2-.14(7)(b). None of these exceptions apply here.

Respondent's prescribing practices clearly resulted in the diversion of controlled substances. As Respondent acknowledged in the interview, "there were quite a few [patients] that [were] just doctor hopping or * * * shopping for medication." [FN6] Indeed, as the record establishes, Respondent prescribed to two people who used falsified records and the driver's licenses of other persons, to obtain such highly abused controlled substances as hydrocodone and alprazolam, which they both personally abused and sold to others. Given the thousands of prescriptions he issued in this manner, there were likely numerous other instances in which he prescribed to persons who were seeking the drugs for illicit purposes.

FN6 I reject as self-serving Respondent's assertion that he believed that "a good proportion of [the] people [he prescribed to] actually needed help" because their original doctors had become "weary" of continuing to prescribe narcotics to them. Notably, Respondent did not identify a single instance in which he contacted the original physicians of the patients to even determine whether a patient had a legitimate medical condition which required the continued prescribing of a controlled substance. As Respondent himself recognized, internet prescribing invites "doctor hopping" and "medication shopping" by drug abusers and drug dealers. In short, as this Agency has found in the course of numerous investigations, the risk of diversion inherent in internet prescribing is extraordinary.

It is therefore clear that Respondent committed acts which establish that granting him a new registration would be "inconsistent with the public interest." 21 U.S.C. 823(f). [FN7] Respondent's application will therefore be denied.

FN7 In his request for a hearing, Respondent "disagreed * * * that [the] prescriptions were issued without a legitimate medical purpose and outside the usual course of professional practice." While Respondent's counsel further represented that he did not intend to "practic[e] medicine in any way related to an Internet pharmacy," Respondent has not satisfied the Agency's standard for obtaining a new registration, which requires that an applicant accept responsibility for his misconduct and acknowledge his wrongdoing. See, e.g., Medicine Shoppe--Jonesborough, 73 FR 364, 387 (2008) (collecting cases), aff'd, Medicine Shoppe-Jonesborough v. DEA, slip op. at 9-10 (6th Cir. Nov. 13, 2008); Hoxie v. DEA, 419 F.3d 477, 483 (6th Cir, 2005) ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) & 0.104, I order that the application of Ladapo O. Shyngle, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective March 6, 2009.

Dated: January 27, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9-2331 Filed 2-3-09; 8:45 am]

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Southwood

and that his registration should be revoked. *Id.* Moreover, for the same reasons that led me to find that Respondent posed "an imminent danger to the public health or safety," *id.* section 824(d), I conclude that the public interest requires that his registration be revoked effective immediately.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, BM5526009, issued to Michael F. Myers, M.D., be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective immediately.

Dated: June 22, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–12771 Filed 7–2–07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 07–7]

Southwood Pharmaceuticals, Inc.; Revocation of Registration

On November 30, 2006, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Southwood Pharmaceuticals, Inc. (Respondent), of Lake Forest, California. The Order immediately suspended Respondent's DEA Certificate of Registration, RS0204898, based on my preliminary finding that its continued registration "constitute[s] an imminent danger to the public health and safety because of the substantial likelihood that Southwood [would] continue to supply pharmacies that divert large quantities of controlled substances." Show Cause Order at 3. The Order also sought the revocation of Respondent's registration on the ground that its continued registration is "inconsistent with the public interest." Id. at 1 (citing 21 U.S.C. 823(d) & 824(a)(4)).

The Show Cause Order alleged that between November 2005 and August 2006, Respondent's sales to pharmacies of hydrocodone products "increased from approximately 7,000 dosage units per month to approximately 3,000,000 dosage units per month," and that the increase was "directly attributable to [its] supplying controlled substances to pharmacies that it knew or should have known were engaged in the widespread diversion of controlled substances." Id. The Show Cause Order alleged that several of Respondent's customers were distributing "large amounts of hydrocodone based on orders placed by customers using various Internet Web sites." Id.

The Show Cause Order specifically alleged that "from December 12, 2005, to August 31, 2006, [Respondent] distributed approximately 8,671,000 dosage units of hydrocodone products to Medipharm-Rx, Inc.," and did so "under circumstances that clearly indicated that Medipharm was engaged in the diversion of controlled substances." Id. at 1–2. The Show Cause Order further alleged that these circumstances included that "ninety-nine percent of Medipharm's business [with Respondent] involved the sale of controlled substances," that Medipharm was owned by an individual who also owned a Web site "that solicit[ed] orders for controlled substances" and used practitioners who issued prescriptions outside of "the usual course of professional practice," and that "Medipharm's orders were of an unusual size, deviated substantially from a normal pattern, and were of an unusual frequency." Id. at 2.

Relatedly, the Show Cause Order alleged that Respondent had "also supplied controlled substances under similarly suspicious circumstances" to fourteen other pharmacies. Id. The Show Cause Order thus alleged that Respondent "repeatedly supplied excessive quantities of hydrocodone to pharmacies that it knew or should have known were diverting hydrocodone." Id. Moreover, the Show Cause Order alleged that notwithstanding "the unusual size and frequency of the orders placed by Medipharm and others, as well as the fact that the orders substantially deviated from the normal pattern of orders received by" it, Respondent never reported any of the orders as suspicious. Id. at 2–3.

Next, the Show Cause Order alleged that on July 17, 2006, the Office of Diversion Control's E-Commerce Section held a conference call with Respondent's representatives to discuss "the distribution of controlled substances to Internet pharmacies." Id. at 3. During the call, DEA officials allegedly presented Respondent with "information on the characteristics of Internet pharmacies and the nature of their illegal activities." Id. DEA officials also allegedly discussed with Respondent such subjects as DEA's 2001 Guidance Document on the use of the Internet to prescribe controlled substances, the requirement for a valid prescription under federal law and existing professional standards, DEA's regulation requiring the reporting of suspicious orders, and the "practices and ordering patterns of internet pharmacies." Id. The Show Cause Order further alleged that notwithstanding this information, in August 2006, Respondent proceeded to distribute large quantities of hydrocodone to five different internet pharmacies. Id. The Show Cause Order thus alleged that Respondent "has failed to maintain effective controls against diversion and that [its] continued registration * * * would be inconsistent with the public interest." Id.

On December 6, 2006, the Show Cause Order was served on Respondent. ALJ Ex. 2. Thereafter, on December 29, 2006, Respondent, through its counsel, requested a hearing. ALJ Ex. 3. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who conducted a hearing in Arlington, Virginia, from February 5 through February 8, 2007. At the hearing, both parties called witnesses and introduced documentary evidence. Following the hearing, both parties submitted briefs containing proposed findings of fact, conclusions of law, and argument.

On March 30, 2007, the ALJ issued her recommended decision (ALJ). In that decision, the ALJ concluded that DEA had proved that "Respondent's continued registration to handle hydrocodone products would be against the public interest." ALJ at 61–62. The ALJ concluded, however, that Respondent "has kept an open dialogue with the DEA and has attempted to come into compliance with the DEA's regulations." Id. at 62. While acknowledging "the egregious quantities of hydrocodone products the Respondent irresponsibly sold to registered [i]nternet pharmacies during 2005 and 2006," the ALJ nonetheless "conclude[d] that revocation of * * * Respondent's entire DEA registration is too severe a remedy." Id.

Continuing, the ALJ explained that "the record contains no evidence of * * * Respondent's improper handling of any other controlled substances, especially in its sales of manufactured products to its practitioner customers." Id. Noting that Respondent had hired an "experienced officer who will be making the final decisions concerning [its] compliance measures," and that this would provide "an increased level of protection of the public interest," the ALJ recommended that Respondent's authority to handle hydrocodone products be revoked but that it retain its

authority to handle other controlled substances. Id. The ALJ further recommended that DEA monitor Respondent to ensure that it comply with both her proposed restrictions and Respondent's decision to cease distributing to Florida-based internet pharmacies. Id.

Thereafter, the Government filed exceptions. In its exceptions, the Government contended that the record established that Respondent had also distributed excessive quantities of other controlled substances included phentermine and alprazolam. See Gov. Exceptions at 2–9. The Government also contended that the ALJ's reliance on Respondent's hiring of a new Chief Operating Officer (COO) was misplaced because the company had, in fact, sold increasing amounts of controlled substances to "rogue [i]nternet pharmacies" for several months thereafter. Id. at 11. The Government further argued that under the "day to day leadership" of its new COO, Respondent had continued to constructively distribute controlled substances to its physician clients after its registration was suspended. Id. According to the Government, this conduct "refutes the ALJ's hypothesis that [the new COO] will effectively manage Respondent's compliance program." Id.

In response, Respondent argued that the Government had "largely buried its concerns" regarding the distribution of phentermine noting that the drug was not mentioned in the Show Cause Order, the lengthy stipulation of facts, or in the Government's opening statement. Respondent's Resp. at 2–3. Respondent further argued that it has stipulated that it will not "ship phentermine to any pharmacy, should its registration be restored." Id. at 2. With respect to alprazolam, Respondent argued that "the government wholly buried its concern with this substance, making explicit reference to it only in its Exceptions." Id. Finally, Respondent argued that the ALJ's findings regarding its new COO are based on credibility determinations and are entitled to deference. Id. at 4–6.

Thereafter, on May 8, 2007, the ALJ forwarded the record to me for final agency action. Having reviewed the record as a whole, I hereby issue this decision and final order. I adopt the ALJ's findings of fact and conclusions of law except as expressly noted herein. However, for reasons explained below, I conclude that the ALJ's proposed remedy is insufficient to protect the public interest. While I am mindful of the corrective measures engaged in by Respondent, its sales of extraordinary quantities of controlled substances to entities which it had reason to know were diverting the drugs caused extraordinary harm to public health and safety. Therefore, Respondent's registration will be revoked and its pending renewal application will be denied. I make the following findings.

Findings

Respondent Southwood Pharmaceuticals, Inc., is the holder of DEA Certificate of Registration, RS0204898, which authorizes it to manufacture controlled substances in schedules 3, 3N, 4, and 5. GX 1. While the expiration date of its registration was February 28, 2007, see id., Respondent submitted a timely renewal application. See Resp. Ex. 110. Respondent's registration thus remains in effect (although in suspended status) pending the issuance of this order. 5 U.S.C. 558(c).

Respondent's market niche was the repackaging of oral dose generic drug products into common prescription quantities which it then distributed. ALJ at 3. Until December 2005, Respondent's customer base was primarily comprised of dispensing physicians who specialized in treating injured workers, pain management and urgent care. Id. at 3–4. Respondent also distributed its products to group practices, specialty clinics and some traditional retail pharmacies. Id. Among the drugs distributed by Respondent were schedule III controlled substances containing hydrocodone.[1] See 21 CFR 1308.13(e).

Respondent's Hydrocodone Sales

According to data submitted by Respondent through DEA's ARCOS system, during the four-month period from August through November 2005, it sold 3,949,454 dosage units of hydrocodone products. ALJ at 4. Of this amount, Respondent's individual practitioner customers purchased 3,882,507 dosage units of the drug. Id. By contrast, Respondent sold approximately 29,940 dosage units of hydrocodone products to its retail pharmacy customers, for an average of 7,485 dosage units per month. Id. at 5.

On December 7, 2005, Respondent entered a new line of business—supplying internet pharmacies—by selling hydrocodone to Medipharm-Rx, Inc. (Medipharm), a Florida-based internet pharmacy.[2] Id. Over the ensuing months, Respondent acquired numerous additional internet pharmacy customers to whom it repeatedly sold large quantities of hydrocodone.

According to the stipulated facts, from December 2005 through October 2006, Respondent supplied Medipharm with an average of 1,011,882 dosage units of hydrocodone per month. ALJ at 5. Respondent also supplied Medipharm with approximately 538,290 dosage units of hydrocodone during the first half of November 2006, at which time Medipharm's registration was immediately suspended under 21 U.S.C. 824(d). Id. at 5–6.

The following table reflects Respondent's monthly distributions of hydrocodone to Medipharm:

Month	Quantity
December 2005	817,010
January 2006	939,340
February 2006	1,142,250
March 2006	1,071,450
April 2006	703,550
May 2006	808,500
June 2006	1,142,000
July 2006	800,340
August 2006	1,246,560
September 2006	1,450,380
October 2006	1,009,320

Id. at 5. According to a July 2006 report created by Respondent of its largest purchasers of controlled substances from December 2005 through June 2006, controlled substances constituted ninety-nine percent of its prescription drug sales to Medipharm. Resp. Ex. 47.

On December 19, 2005, Respondent obtained another Florida-based internet pharmacy customer, Accumed Rx, Inc. (Accumed). ALJ at 7. Respondent supplied Accumed with approximately 5,884,212 dosage units of hydrocodone as tabulated below:

[1] By itself, hydrocodone is a schedule II controlled substance. 21 CFR 1308.12(b)(1). Respondent did not, however, distribute schedule II hydrocodone. Throughout this decision, the term hydrocodone refers to those schedule III controlled substances which contain hydrocodone.

[2] For purposes of this decision, the term "internet pharmacy" refers to a pharmacy that fills a prescription that is issued by the physician without the physician having entered into a legitimate doctor-patient relationship under existing professional standards. Typically, a person seeking controlled substances goes to an internet site, fills out a questionnaire which requests basic medical information and payment/shipping information, and requests a specific drug; some Web sites may require that the patient submit a medical record, which is easily falsified. Thereafter, the customer's information is forwarded to a physician either contracted to or employed by the Web site, who reviews the information and issues a prescription, either with or without the benefit of a perfunctory telephone consultation, but always without having conducted a face-to-face review of the person's medical history and a physical exam. The prescription is then either forwarded to the pharmacy or downloaded electronically by the pharmacy; the pharmacy then fills the prescription and ships it to the customer. See GX 3.

Month	Quantity
December 2005	273,630
January 2006	203,070
February 2006	147,180
March 2006	83,500
April 2006	169,000
May 2006	519,380
June 2006	320,470
July 2006	442,000
August 2006	1,267,770
September 2006	503,020
October 2006	393,610
November 2006	1,561,582

Id. at 8. Between December 2005 and June 2006, controlled substances comprised ninety-nine percent of Respondent's prescription drug sales to Accumed. Resp. Ex. 47.

On December 21, 2005, Respondent obtained another Florida-based internet pharmacy customer, Avee Pharmacy, Inc. (Avee). ALJ at 6. Respondent's sales of hydrocodone to Avee averaged 566,259 dosage units a month and are tabulated below:

Month	Quantity
December 2005	346,140
January 2006	859,860
February 2006	0
March 2006	912,190
April 2006	76,190
May 2006	212,000
June 2006	442,800
July 2006	94,000
August 2006	506,430
September 2006	695,800
October 2006	537,900
November 2006	2,111,800

Id. Respondent also supplied Avee with 238,140 dosage units during the first five days of December 2006. Id. at 7. From December 2005 through June 2006, controlled substances constituted one hundred percent of Respondent's sales to Avee. Resp. Ex. 47.

On November 17, 2006, Respondent notified Avee by letter that effective December 15, 2006, it would not supply the pharmacy, whose registration had been continued on a day-to-day basis past its expiration date and not renewed, unless it obtained a renewal of its registration.[3] Resp. Ex. 77. Between November 17 and December 5, 2006, however, Respondent supplied Avee with approximately 1,804,940 dosage units of hydrocodone. ALJ at 7.

On January 4, 2006, United Prescription Services, Inc. (United), another internet pharmacy, became a customer of Respondent. ALJ at 14. Respondent sold an average of 92,988 dosage units of hydrocodone per month to United as tabulated below:

Month	Quantity
February 2006	341,160
March 2006	288,000
April 2006	18,000
May 2006	18,000
June 2006	37,200
July 2006	18,000
August 2006	18,000
September 2006	0
October 2006	12,000
November 2006	179,520

Id.

From the date United became a customer through June 2006, controlled substances constituted one hundred percent of Respondent's prescription drug sales to it. Resp. Ex. 47. On November 17, 2006, Respondent notified United that it would stop supplying the pharmacy if it did not obtain a renewal of its registration. Id. at 14. From November 21, 2006, through December 5, 2006, however, Respondent distributed to United approximately 158,280 dosage units of hydrocodone. Id.

On January 25, 2006, Respondent acquired two more internet pharmacy customers, RKR Holdings, d/b/a Medichem RX Pharmacy (Medichem), and Bi-Wise Drugs, Inc. (Bi-Wise). ALJ at 11, 13. Between January and November 2006, Respondent sold Medichem a monthly average of 216,638 dosage units of hydrocodone as tabulated below:

Month	Quantity
January 2006	66,000
February 2006	264,000
March 2006	276,000
April 2006	168,000
May 2006	286,200
June 2006	264,000
July 2006	120,000
August 2006	216,000
September 2006	220,680
October 2006	262,140
November 2006	240,000

Id. at 11–12. From the date it became a customer through June 2006, controlled substances constituted one hundred percent of Respondent's prescription drug sales to Medichem. Resp. Ex. 47.

From January 25 through October 2006, Respondent's hydrocodone sales to Bi-Wise averaged 117,150 dosage units per month. ALJ at 13. Moreover, from the date Bi-Wise became a customer through the end of June 2006, controlled substances constituted ninety-nine percent of Respondent's prescription drugs sales to it. Resp. Ex. 47. Respondent's hydrocodone sales to Bi-Wise are tabulated below:

Month	Quantity
January 2006	70,800
February 2006	18,240
March 2006	152,750
April 2006	63,860
May 2006	112,300
June 2006	180,000
July 2006	131,750
August 2006	185,940
September 2006	111,180
October 2006	144,680

ALJ at 13.

On February 16, 2006, Respondent acquired another internet pharmacy customer, Vin-Kash, Inc., d/b/a/ Medicom RX. Id. at 12. Through October 2006, Respondent supplied Medicom with an average of 190,281 dosage units of hydrocodone per month. Id. Respondent's sales are tabulated below:

Month	Quantity
February 2006	14,000
March 2006	54,430
April 2006	157,850
May 2006	175,850
June 2006	231,100
July 2006	227,240
August 2006	117,650
September 2006	164,000
October 2006	375,690
November 2006	385,000

Id. Respondent also supplied Medicom with approximately 82,750 dosage units of hydrocodone during the first five days of December 2006. Id. at 13. Moreover, from the date it became a customer through June 2006, controlled substances comprised one hundred percent of Respondent's prescription drug sales to Medicom. Resp. Ex. 47.

On February 20, 2006, Respondent obtained another internet pharmacy customer, Discount Mail Meds (Discount). ALJ at 8. From the inception of the relationship through November 2006, Respondent supplied Discount with an average of 330,324 dosage units of hydrocodone per month as tabulated below:

Month	Quantity
February 2006	72,000
March 2006	269,500
April 2006	269,000
May 2006	364,500
June 2006	373,600
July 2006	317,780
August 2006	292,720
September 2006	340,100
October 2006	501,280
November 2006	502,760

[3] Effective December 15, 2006, Respondent instituted a policy of not supplying registrants whose registration remained in effect on a day-to-day basis for more than two months past the expiration date. Resp. Ex. 77. Respondent's DEA registration was suspended before the policy became effective.

Id. at 9. Respondent also supplied Discount with 43,200 dosage units of hydrocodone during the first five days of December 2006. Id. Moreover, from the date it became a customer through June 2006, controlled substances comprised one hundred percent of Respondent's prescription drug sales to Discount. Resp. Ex. 47.

On February 22, 2006, Respondent commenced doing business with Universal Rx (Universal). ALJ at 9. From February through October 2006, Respondent supplied Universal with an average of 308,679 dosage units of hydrocodone per month as tabulated below:

Month	Quantity
February 2006	60,000
March 2006	164,250
April 2206	291,000
May 2006	245,250
June 2006	384,700
July 2006	422,670
August 2006	394,070
September 2006	340,500
October 2006	453,690
November 2006	330,660

Id. at 9–10. From the date it became a customer through June 2006, controlled substances comprised one hundred percent of Respondent's prescription drug sales to Universal. Resp. Ex. 47.

On November 17, 2006, Respondent notified Universal that, effective December 15, 2006, it would stop supplying the pharmacy unless it obtained a renewal of its registration. ALJ at 10. During the last two weeks of November 2006, Respondent shipped approximately 150,210 dosage units of hydrocodone to Universal. *Id.* On November 30, 2006, Respondent stopped shipments to Universal. *Id*

On March 3, 2006, Respondent began doing business with Medcenter, Inc. (Medcenter), an entity owned by the same person who owned Medipharm. Id. at 10–11. From March through October 2006, Respondent supplied Medcenter with an average of 333,063 dosage units of hydrocodone per month as tabulated below:

Month	Quantity
March 2006	340,500
April 2006	141,000
May 2006	153,000
June 2006	375,000
July 2006	102,000
August 2006	567,000
September 2006	378,000
October 2006	608,000

Id. Additionally, during the first two weeks of November, at which point Medcenter's DEA registration was suspended pursuant to 21 U.S.C. 824(d), Respondent distributed 313,680 dosages units of hydrocodone to it. *Id.* at 11. Moreover, from the date it became a customer through June 2006, controlled substances constituted one hundred percent of Respondent's prescription drug sales to Medcenter. Resp. Ex. 47.

On March 9, 2006, Respondent commenced doing business with CRJ Pharmacy, Inc. (CRJ). ALJ at 15. From March through October 2006, Respondent sold CRJ an average of 79,803 units of hydrocodone per month as tabulated below:

Month	Quantity
March 2006	63,360
April 2006	76,200
May 2006	25,320
June 2006	49,240
July 2006	52,200
August 2006	75,700
September 2006	96,000
October 2006	200,400

Id. From the date it became a customer through June 2006, controlled substances comprised ninety-eight percent of Respondent's prescription drug sales to CRJ. Resp. Ex. 47.

In May 2006, Respondent acquired another two customers, Grand Pharmacy (Grand), and Akshar Chemists, Inc., d/b/a Medicine Shoppe (Medicine Shoppe). ALJ at 16–17. Respondent supplied Grand with an average of 144,102 dosage units of hydrocodone per month between May and November 2006 as tabulated below:

Month	Quantity
May 2006	24,000
June 2006	228,720
July 2006	180,000
August 2006	180,000
September 2006	144,000
October 2006	144,000
November 2006	108,000

Id. at 17.

During the same period, Respondent supplied the Medicine Shoppe with an average of 73,365 dosage units of hydrocodone per month as tabulated below:

Month	Quantity
May 2006	62,100
June 2006	162,340
July 2006	164,875
August 2006	21,200
September 2006	12,000
October 2006	33,300
November 2006	57,740

Id. During the first five days of December 2006, Respondent also supplied the Medicine Shoppe with approximately 17,010 dosage units of hydrocodone. *Id.*

In July 2006, Q–R–G, Inc., d/b/a Duane's Discount Group (Duane's), began purchasing hydrocodone from Respondent. *Id.* at 16. From July through November 2006, Respondent supplied Duane's with an average of 191,808 dosage units of hydrocodone per month as tabulated below:

Month	Quantity
July 2006	188,400
August 2006	188,940
September 2006	145,500
October 2006	276,900
November 2006	159,300

Id. During the first five days of December 2006, Respondent supplied Duane's with an additional 74,850 dosage units of hydrocodone.[4] Id.

From the date it began supplying internet pharmacies in December 2005 through November 2006, Respondent sold a total of approximately 44,087,355 dosage units of hydrocodone to these entities. Gov. Ex. 43. at 1.[5] Respondent's monthly sales of hydrocodone to these entities grew from approximately 1.44 million dosage units in December 2005 to 5.78 million dosage units in November 2006. Id. at 2. By contrast, during the even longer time frame of August 2005 through November 2006, Respondent's sales of hydrocodone to its retail pharmacy customers never exceeded more than 16,040 dosage units in a month and typically never exceeded 10,000 dosage units in a month. Id. at 3.

The Government also introduced into evidence a table showing the average purchase of hydrocodone products by retail pharmacies in the State of Florida and nationwide during the period October 1, 2005, through January 31, 2006. See Gov. Ex. 45, at 8. This evidence established that Florida retail pharmacies purchased an average of 23,850 dosage units of hydrocodone during the four month period; nationwide, retail pharmacies bought an average of 24,227 dosage units of the drug. Id.

The record further establishes that many of Respondent's Florida-based pharmacy customers were, in fact,

[4] Respondent also sold 502,750 dosage units of hydrocodone to Woody Pharmacy Waterside, Inc., during April and May 2006, for an average of 251,375 units per month. ALJ at 15–16. Respondent also supplied Elite Pharmacy, Inc., with 140,000 dosage units of hydrocodone during the month of January 2006. Id. at 18.

[5] This exhibit covers the period from August 2005 through November 2006. Gov. Ex. 43. As found above, Respondent did not begin distributing to internet pharmacies until December 2005.

dispensing illegal prescriptions for controlled substances. More specifically, the record demonstrates that Avee (see GX 51), Medipharm (see GX 53 & 62), United (see GX 54), YPM Total Care Pharmacy (see GX 66), CRJ (GX 67), Bi-Wise (see Tr. 671–72); Universal (see id.), and Accumed (see id.), were dispensing large numbers of prescriptions which were not issued in the course of a legitimate doctor-patient relationship and thus violated Federal law. See 21 CFR 1306.04; see also Tr. 628–29, 639–45, 655–57, 660–67.

Respondent's Due Diligence Efforts

During the events at issue here, Mr. Robert Goodrich was Respondent's Director of Operations and Regulatory Affairs. Tr. 311. According to Mr. Goodrich, from "a regulatory perspective," Respondent's due diligence in approving a new customer was limited to verifying that the customer had a State license and a DEA registration. Id. at 313–14. When asked by the Government whether Respondent had any processes in place prior to approving a new customer to purchase controlled substances, Mr. Goodrich testified that the primary process was to check the customer's DEA registration and that there was "no" secondary process. Id. at 318; see also ALJ at 34 (FOF 117). Based solely on its verifications of the entities' DEA registrations and state licenses, Respondent commenced to ship large quantities of controlled substances to the various internet pharmacies.

In early February 2006, Mr. Goodrich traveled to the Tampa Bay, Florida area, to conduct on-site visits with Respondent's sales representative, Tom Mollick, at several of the internet pharmacy customers which Respondent had recently acquired including Medipharm, Accumed, Medichem, Bi-Wise, and Avee. Tr. 319. According to Mr. Goodrich, the pharmacies were selected because "it was apparent that they were a different type of a customer than what we'd been used to dealing with." Id.

At Medipharm, Mr. Goodrich found that it was filling 700 prescriptions a day and noted that it was a "Closed-Door (Mail Order) Pharmacy." GX 16. In his report, Mr. Goodrich specifically noted that "[t]he mail order business has ties to internet pharmacy with a large amount of pain management and a growing percentage of traditional maintenance medications." Id.

At Accumed, Mr. Goodrich determined that it was filling 350 prescriptions a day and that it also was a "Closed-Door (Mail Order) Pharmacy." GX 17. In his report, Mr. Goodrich observed that Accumed has "ties to the internet and * * * explained [its] requirement to check prescriber credentials." Id.

At Medichem, Mr. Goodrich found that it was both a "Retail & Closed-Door (Mail-Order) Pharmacy" with a volume of 100 prescriptions per day. GX 18. Mr. Goodrich noted that while "Medichem is primarily filling prescriptions on a local and state level * * * there was evidence of prescriptions being mailed out-of-state as well." Id. Mr. Goodrich further observed that Medichem does "have some ties to the internet community and they appear to be in the process of determining their market niche." Id.

At Avee, Mr. Goodrich found that it was a "Closed-Door (Mail-Order) Pharmacy," with a prescription volume of 500 per day. GX 20. Mr. Goodrich specifically noted that "Avee operates a closed pharmacy that provides mail order fulfillment of prescriptions from various sources, *including internet-connected medical providers who provide patient assessments and diagnosis through unconventional practice models. Many of these prescriptions are connected to pain management therapies involving the prescription of controlled substances.*" GX 20 (emphasis added).

Mr. Goodrich's report further noted that DEA investigators had inspected Avee "earlier that day." Id. Moreover, Avee's management discussed with him "the concerns that DEA had with establishing the validity of the doctor-patient relationship that formed the basis *of the digital diagnosis that resulted in a prescription for controlled substances being submitted to Avee for filling.* Id. (emphasis added). Mr. Goodrich further noted that the position of Avee's management "was that if the prescriber was not authorized to prescribe controlled substances, then the DEA should revoke the prescriber's DEA registration." Id. According to Mr. Goodrich's report, DEA investigators had suggested to Avee's management that they meet with the physicians "from whom they receive the most prescriptions to better evaluate them." Id.

When asked by the Government what constitutes an "unconventional practice model?," Mr. Goodrich testified that as he "understood it, that did not involve a patient going to the doctor's office necessarily and presenting themselves in person." Tr. 347. Mr. Goodrich subsequently acknowledged that he knew as early as February 2006, that "[s]ome of the prescriptions [Avee] filled were not the result of physical contact between the doctor and the patient." Id. at 348. Mr. Goodrich also testified that Avee had provided him with the names of two internet sites which were the source of some of the prescriptions it filled. Id. at 351–52.

Notwithstanding the information he obtained during his visit with Avee, Mr. Goodrich made no follow-up inquiries with its management regarding whether they had determined if the physicians were writing legitimate prescriptions. Id. at 352–53. Indeed, Mr. Goodrich made no further inquiries of Avee regarding its business practices until the middle of August 2006, after a meeting with DEA. Id. at 353. When asked by the Government whether he was concerned by the fact that DEA had visited Avee, Mr. Goodrich acknowledged that he did not "know[] much about this telemedicine thing," but "felt that if [Avee] weren't doing what they were supposed to do right, DEA wouldn't allow them to continue in business." Id. at 354. Mr. Goodrich also testified that he was not troubled by Avee management's contention that "if the prescriber was not authorized to prescribe controlled substances, then the DEA should revoke the prescriber's DEA registration." Id.

Mr. Goodrich further acknowledged that at the time of his visit to Avee, he was not "versed" in the requirement that a prescription must be issued by a physician acting in the usual course of professional practice even though he asserted that he was then "aware that pharmacies had obligations to ensure that they had valid prescriptions." Id. at 355. Mr. Goodrich admitted that he had not gone to DEA's website prior to Respondent's engaging in business with internet pharmacies to determine whether the Agency had posted any guidance on the subject. Id. at 358. Mr. Goodrich further testified that he "received most of" the information regarding the requirements for a valid prescription from DEA during a July 2006 meeting (which will be described more fully below). Id. at 357.

Mr. Goodrich also attempted to visit Bi-Wise, but found that it was closed. Tr. 321; GX 19. According to his report, Bi-Wise was a retail and closed-door pharmacy with minimal prescription volume. GX 19. Mr. Goodrich further described it as a "[v]ery small retail unit located in strip mall" and that the "[c]ustomer is in [the] process of determining direction for [the] business." Id.

Mr. Goodrich testified that he did not attempt to go back to the pharmacy when it was open, Tr. 322, and never contacted anyone from Bi-Wise to further inquire into the nature of its business. Id. at 323. Furthermore,

notwithstanding that Bi-Wise's purchases of hydrocodone from Respondent increased from 18,240 dosage units in February 2006 to 152,750 dosage units in March 2006, Mr. Goodrich never followed up with anyone at Bi-Wise to determine the reason for the increase. Id. at 325–26. This was so, Mr. Goodrich testified, because he did not "routinely look[] at" the data regarding the purchases of Respondent's customers. Id. at 326.

As found above, during the ensuing months, Respondent took on additional internet pharmacies as customers and Respondent proceeded to sell extraordinary quantities of hydrocodone to them. Other than the five pharmacies visited on or about February 8, 2006, there is no evidence that Mr. Goodrich visited any of the other internet pharmacies which Respondent began supplying.

Because of the large quantities of hydrocodone that Respondent was distributing to these entities, Respondent "was invited to the DEA Field Office in Riverside to be educated on the [Agency's] view of Internet pharmacies." ALJ at 22 (FOF 72). On July 17, 2006, Michael Mapes, Chief of the Office of Diversion Control's E-Commerce Section, conducted a conference call with Mr. Goodrich and Ms. Grace Gonzales, Respondent's operations manager[6] to discuss various issues related to the dispensing of controlled substances by internet pharmacies. GX 49. Prior to the conference call, Mr. Goodrich was provided with a document entitled "Internet Diversion of Controlled Pharmaceuticals." Tr. 411–12; GX 45. Included in the document was a table which showed the average sales by McKesson, another distributor, to seven internet pharmacies during the month of October 2005. See GX 45, at 7. Six of the seven pharmacies listed were Respondent's customers: Avee, Medipharm, Accumed, United, Universal, and Bi-Wise. Id. The table included a notation that the "Average Sales by McKesson to Each Targeted Pharmacy" was "311,057 dosage units." Id. (emphasis added). It further indicated that McKesson's average sales of hydrocodone "to other customers" was "2,413 dosage units."[7] Id. The document also included a page labeled "The Internet Pharmacies" which included photographs of both Avee and Medipharm. Id. at 9.

At the time of the conference call, Mr. Goodrich was provided with an additional package of materials which included a powerpoint presentation, two Supreme Court decisions,[8] two agency final orders revoking the registrations of internet pharmacies for dispensing prescriptions that were not issued in the course of valid physician-patient relationships,[9] DEA's April 2001 Guidance Document on "Dispensing and Purchasing Controlled Substances over the Internet,"[10] and a copy of 21 CFR 1301.74, which sets forth the requirements pertaining to suspicious orders. See Gov. Ex. 61. The materials also contained a document from the National Association of Boards of Pharmacy entitled "Verified Internet Pharmacy Practice Sites (VIPPS®) Most Frequently Asked Questions," the American Medical Association's "Guidance for Physicians on Internet Prescribing," the Federation of State Medical Boards' "Model Guidelines for the Appropriate Use of the Internet in Medical Practice," and a list of suggested questions for determining the legitimacy of internet pharmacies. See id. Finally, DEA provided Mr. Goodrich with a copy of 21 U.S.C. 823. Id.

During the conference call, Mr. Mapes specifically discussed the activities of Medipharm, Avee, Accumed, United, Bi-Wise and Universal in distributing controlled substances "through the internet" and reviewed the various slides from the Power Point presentation. Tr. at 30–31. Mr. Mapes also discussed various issues that Respondent should consider in assessing the legitimacy of its customers including the size and frequency of a pharmacy's orders, the range of products ordered by the pharmacy, the percent of controlled substances versus non-controlled drugs ordered, and the locations of/type of facility used by the pharmacies. Id. at 36–38. More specifically, Mr. Mapes advised that eighty percent of U.S. "pharmacies * * * are buying less than 5,000 dosages of hydrocodone in a month's time," and that "in a typical retail pharmacy," controlled substances might amount to between five and twenty percent of the pharmacy's purchases" with the other eighty to ninety percent of its purchases being non-controlled drugs. Id. at 37. Mr. Mapes also advised Respondent that as a distributor it was required to maintain effective controls against diversion. Id. at 39–40.

Mr. Mapes later discussed with Mr. Goodrich and Ms. Gonzales the requirement under Federal Law that for a prescription to be valid, it must be issued in the usual course of medical practice, and "that an internet questionnaire alone is not sufficient to legally prescribe controlled substances." Id. at 42–43; see also 21 CFR 1306.04(a). Mr. Mapes also discussed the factors that are necessary to establish a bonafide doctor-patient relationship. These include that a patient has a medical complaint, that a history be taken of the patient, that a physical exam be conducted, and that there be a nexus between the complaint, the history, the exam and the drug being prescribed. Id. at 42–43, 45–46; GX 61, at 13.

Mr. Mapes also provided Mr. Goodrich and Ms. Gonzales with several examples of illegal internet pharmacies. Tr. at 48–49. In one of the examples, which involved a Florida pharmacy, the pharmacy's purchases of phentermine had doubled in a five month period from approximately 200,000 to 400,000 units and "one hundred percent of the drugs purchased by [the] pharmacy were controlled substances." GX 61, at 10; Tr. 49. In another example, the pharmacy was located in an industrial warehouse and sold only hydrocodone and alprazolam (a schedule IV controlled substance), which it purchased in large quantities. Tr. 49; GX 61, at 11. In the final example, the pharmacy had advised the distributor that they were doing business over the Internet. Tr. 50. The pharmacy did not, however, have a VIPPS certification, made frequent large purchases of hydrocodone and various benzodiazepines, and ninety-nine percent of the drugs it ordered were controlled substances. Id.; GX 61, at 12.

Mr. Mapes informed Mr. Goodrich and Ms. Gonzales that "a pattern of drugs being distributed to pharmacies [which] are diverting controlled substances demonstrates a lack of effective controls against diversion by the distributor" and could lead to the revocation of the distributor's registration. Tr. 51. Mr. Mapes further advised "that any distributor who was selling controlled substances that are being dispensed outside the course of professional practice must stop that distribution immediately." Id.

Mr. Mapes also discussed with Respondent's representatives whether it could ship an order which it had reported as suspicious. Id. at 57. Mr.

[6] Additional DEA personnel were on the call including Group Supervisor (GS) Lisa Young and Diversion Investigator (DI) Cynthia Hooks of the DEA Riverside Office. GX 49.

[7] The document also included the data (discussed earlier) regarding the average hydrocodone purchases over a four month period of pharmacies in Florida and nationwide, as well as the average purchases by the "Targeted Internet Pharmacies." GX 45, at 8.

[8] *Direct Sales Co., Inc.* v. *United States*, 319 U.S. 703 (1943); *United States* v. *Moore*, 423 U.S. 122 (1975).

[9] EZRX, LLC, 69 FR 63178 (2004); *RX Network of South Florida, LLC*, 69 FR 62093 (2004).

[10] Published at 66 FR 21181 (2001).

Mapes advised that even if Respondent reported the order, the company still had to make the decision as to whether to ship the order. Id. at 57–58; GX 61, at 9. Moreover, Respondent's personnel asked DEA whether it should stop shipping controlled substances to the internet pharmacies. Tr. 79, 119–20, 342–43. DEA personnel told Mr. Goodrich and Ms. Gonzales that it cannot tell a distributor whether a particular order is legitimate or not, GX 61, at 9; and that whether to ship was "a business decision," Tr. 79; but that Respondent "had an obligation to ensure that the products [it] distributed were used for legitimate medical purposes." Id. 343.

Following the meeting, Respondent continued to distribute large quantities of hydrocodone to numerous internet pharmacies including the six pharmacies that DEA officials specifically referred to as "targeted." For instance, in August 2006, Respondent distributed "in excess of 1.2 million" dosage units of hydrocodone to Accumed. Id. at 341.

Mr. Goodrich cited several reasons to justify Respondent's decision to continue shipping hydrocodone to Accumed. First, he stated that DEA "did not instruct us to cease shipments" and thus Respondent did not "have distinct direction." Id. at 343–44. Second, Mr. Goodrich asserted that Respondent was conducting due diligence. Id. at 343. Third, Mr. Goodrich did not believe that Accumed was acting illegally. Id. at 345.

In August 2006, Respondent also shipped large quantities of hydrocodone to the other internet pharmacies which DEA officials had referred to as "targeted." It shipped 1,246,560 dosage units to Medipharm, 506,340 units to Avee, 185,940 units to Bi-Wise, and 399,070 units to Universal. Respondent also shipped large quantities to other entities which it had identified as internet pharmacies. See Resp. Ex. 52.

Moreover, Respondent continued to make large shipments of hydrocodone to many of these pharmacies until either its registration was immediately suspended or the pharmacies' registrations were suspended. For example, it shipped Medipharm 1.45 million dosage units in September 2006 and just over 1 million dosage units in October 2006; it shipped Accumed 1.56 million dosage units in November 2006; it shipped Avee 2.11 million dosage units in November 2006; and it shipped Discount over 500,000 dosage units in both October and November 2006.

Following the July 2006 conference call, Respondent did undertake additional measures to investigate the business activities of the pharmacies it had identified as filling prescriptions issued through the internet. On July 31, 2006, Mr. Goodrich wrote the Executive Director of the Florida State Board of Pharmacy identifying nineteen pharmacies located in the Tampa Bay area which, as a result of the DEA conference call and "additional research" conducted by Respondent, had led it to "question whether or not these pharmacies are operating legitimately." Resp. Ex. 49, at 1–2. Respondent thus requested that the Florida Board "provide additional information to enable us to qualify the legitimacy of these customers." Id. at 2.

By letter dated August 14, 2006, the Executive Director of the Florida Board responded. Resp. Ex. 50. In the letter, the Executive Director wrote that "[t]he Board of Pharmacy can verify for you that these particular pharmacies do have active community pharmacy licenses in the state of Florida. Id. The Executive Director further advised that "only one of these licenses [sic] has been disciplined by the Florida Board," that pharmacy being Avee, and enclosed a copy of the Board's final order pertaining to it.[11] Id. The letter, however, offered no specific information regarding the legitimacy of the various pharmacies' activities. See id.

On August 15, 2006, Mr. Goodrich sent out a six-page questionnaire to seventeen of the pharmacies including all of the pharmacies which DEA had described as "targeted." Resp. Ex. 51. The questionnaire noted that Respondent was conducting a "due diligence review of our business relationship" which had been prompted by four factors: (1) An "[e]xtremely high percentage of controlled substance purchases vs. non controlled substance purchases," (2) "[e]xtremely high volume of controlled substance dosage units," (3) "[i]dentification of your operation as an internet pharmacy," and (4) "[i]dentification of your pharmacy filling prescriptions based on telemedicine." Id. The questionnaire then stated that Respondent "has a responsibility to insure [sic] that all medications we distribute are used for legitimate medical purposes, much in the same way that your pharmacy has an obligation to ensure that every prescription you fill is a result of a valid medical examination by an authorized prescriber." Id.

The document asked a variety of questions. The first question asked the pharmacies to indicate the "overall percentage of controlled substances filled by [the] pharmacy," and to list their other suppliers. Id. The second question was prefaced with the observation that "[t]he volume of controlled substances purchased by your pharmacy far exceeds the 'average' quantity of controlled substances purchased by pharmacies nationwide." Id. at 2. The questionnaire then asked the pharmacy to "provide an explanation for the volume of your controlled substance purchases." Id.

The next set of questions began by noting that "[y]our pharmacy has been identified as an 'internet pharmacy,'" and that "both the FDA and DEA have raised concerns citing the potential for abuse." Id. at 2. The questions then asked the pharmacy to provide the "percentage of prescriptions filled by your pharmacy [that] originate from the Internet," to "list the website identifying your pharmacy," to describe how "a patient provides prescriptions to your pharmacy," and to indicate how patients pay for their prescriptions. Id. at 2–3.

Later, the questionnaire observed that the "[u]se of the internet in a medical practice has raised many issues in regards to the issuance of a prescription, including, but not limited to, ensuring the validity of medical examinations, the establishment of a 'bona fide' doctor/patient relationship and the appropriateness of treatment where the physician is located in a different jurisdiction from the patient's residence." Id. at 4. The questionnaire then asked a series of questions regarding how the pharmacies performed their "due diligence on prescriptions issued by doctors who use the internet in the course of their medical practice." Id. These included asking the pharmacy to "list the web sites identifying the physicians who most commonly issue prescriptions filled by your pharmacy," whether the pharmacy verified the physician's state license and DEA registrations, and whether the pharmacy verified that the physician was "also authorized to practice medicine in the state in which the patient is located." Id. The questionnaire also asked whether the pharmacy had a protocol to ensure that "prescriptions issued through an internet-assisted encounter constitute[d] a valid medical exam." Id.

Next, the questionnaire observed that "a preponderance of prescription orders issued by a physician for the same

[11] According to the materials, Avee was sanctioned because it shipped hydrocodone to a person in Tennessee when it did not hold a Tennessee license authorizing it to dispense to residents of that State. See Resp. Ex. 50. Avee entered into a stipulation with the State under which it was fined $2,000 and required to pay $719.95 as costs. See id. Avee did, however, retain its Florida license.

products in the same prescription quantities" was indicative of "potential prescription abuse" and asked the pharmacy to attach its "policies and procedures that address prescription abuse." Id. at 5. Finally, the questionnaire noted that "[m]any states have adopted laws and regulations pertaining to internet prescribing" that mandate "direct contact between the doctor and patient and the requisite physical exam(s)." Id. The questionnaire thus asked the pharmacy to "list those states [it had] identified that allow the filling of prescriptions issued without a face-to-face encounter between the physician and the patient." Id.[12]

Upon receiving the questionnaires, which Respondent sent by certified mail, the pharmacies responded in a variety of ways. Some, such as Bi-Wise, did not respond at all. See Resp. Ex. 58. Others, such as CRJ and YPM, failed to answer questions or indicated "N/A." See Resp. Ex. 59 & 71. Others such as Accumed completed the questionnaire maintaining that they were not internet pharmacies, indicated "N/A" when asked to list the websites of the physicians who wrote the prescriptions they filled, and answered affirmatively that they had a protocol to ensure that the prescriptions were issued pursuant to a valid medical exam. Resp. Ex. 54. Likewise, Duane's stated that zero percent of the prescriptions it filled originated on the internet, that it had retained counsel to implement a strict compliance program to ensure that the prescriptions it filled were valid, and indicated "N/A" where asked to list the websites of the physicians who were commonly issuing the prescriptions that it filled. Res. Ex. 61.

Some of the pharmacies provided information which Respondent deemed adequate but which clearly suggested that the prescriptions were illegal. For example, Respondent deemed Grand Pharmacy's response adequate. See ALJ at 24 (FOF 81). Yet in a letter, Grand's owner/president indicated that "[a]ll doctors Grand deal with require a current physical done in a physician's presence. All doctors Grand deal with have a physical *or extended phone dialogue* with the patient to establish the diagnosis and need for the medication." Resp. Ex. 63, at 2 (emphasis added). It is noteworthy that Grand's response did not say that the physical was performed by the prescribing physician, what constituted a "current physical," or that the doctors prescribing on the basis of a telephone call were the same doctors that had performed the physical exam. Notwithstanding the suspicious nature of the information, Mr. Goodrich deemed the answers satisfactory and did not inquire further, see Resp. Ex. 64; Respondent continued to ship large quantities of hydrocodone to Grand.

The questionnaires completed by the Medicine Shoppe and Medicom, which apparently were owned by the same person, were of similar nature. For example, while the Medicine Shoppe's questionnaire indicated that it was "not an internet pharmacy," and that only one to two percent of the prescriptions it filled originated on the internet, it also indicated the name of a website used by the "physicians who most commonly issue prescriptions filled by [the] pharmacy." Resp. Ex. 65, at 2–4. Furthermore, in answer to the question of whether the pharmacy verified that the physicians were "authorized to practice medicine in the state [where] the patient is located," the Medicine Shoppe stated: "No. The doctor[s] makes the consult from [the] state in which they are licensed." Id. at 4.

The Medicom questionnaire indicated that "[w]e are not [an] internet pharmacy; I receive Rx from doctors who have spoken [to] patients, discussed therapy, and also reviewed entire medical history." Resp. Ex. 66, at 2. The questionnaire also indicated that it received prescriptions "via telemedicine," and included the names of three websites used by physicians whose prescriptions the pharmacy was filling. Id. at 3–4. Furthermore, when asked whether the pharmacy verified that the physicians were "authorized to practice medicine in the state in which the patient is located," Medicom likewise stated: "No. The doctor makes the consultation from the state they are licensed" in.[13] Id. at 4.

Mr. Goodrich deemed both the Medicine Shoppe and Medicom's responses to be adequate. ALJ at 24–25 (FOFs 82 & 83). Notwithstanding the suspicious nature of their responses, Respondent continued to ship large quantities of hydrocodone to both pharmacies.

The Medipharm and Universal questionnaires were prepared by the same attorney, who had previously served as an Assistant State Attorney. See Resp. Exs. 67 & 69. Both questionnaires indicated that the pharmacies were "not an 'internet pharmacy,'" and that zero percent of the prescriptions originated on the internet. Resp. Exs. 67 at 2, 69 at 2. Both questionnaires indicated "N/A" where asked to "list the websites identifying the physicians who most commonly issue prescriptions filled by your pharmacy." Resp. Exs. 67 at 4, 69 at 4. Moreover, both questionnaires indicated that the pharmacies had "retained counsel to prepare and implement a strict compliance program to ensure compliance with the applicable rules and regulations for prescription practice in each of the states in which [the pharmacy] is licensed and transacts business." Id. The questionnaires also indicated that the pharmacies "routinely verif[ied]" that the doctors were "authorized to practice medicine in the state in which the patient is located." Id. Finally, both pharmacies stated that they did "not fill prescriptions where the patient has not had a face-to-face encounter with a physician."[14] Resp. Ex. 67, at 5; Resp. 69, at 5.

United's questionnaire, which was submitted more than five weeks after Respondent's deadline, stated that it was "not an internet pharmacy" and that "[r]egulations regarding physicians requiring a face-to-face consultation is an issue of compliance for the physician and the relevant medical board." Resp. Ex. 70. With respect to whether United verified that the physicians were authorized to practice medicine in the States where their patients were located, the pharmacy gave the non-responsive answer that "We are advised by the prescribing physician that they are authorized to practice medicine for their patients." Id. Finally, in answering the question as to whether United had a protocol to ensure that the prescriptions were issued pursuant to a valid medical exam, the pharmacy stated: "United has a policy, through a signed affidavit, as well as providing us with recent medical history for the patient file, that

[12] In a letter dated August 15, 2006, Mr. Goodrich transmitted a copy of the questionnaire to the DEA Diversion Group Supervisor and advised that he had requested that the pharmacies respond "by the end of the month." Resp. Ex. 52. Mr. Goodrich further wrote that "[i]f we do not receive a response, we will cease business with that particular company." Id.

[13] Both the Medicine Shoppe and Medicom included logs showing that the pharmacies had reviewed medical records pertaining to internet prescriptions and a form letter the pharmacy represented as sending to the physicians and which the physicians were supposedly required to sign and return to the pharmacies. See, e.g., Resp. Ex. 66. The record does not establish whether these two pharmacies actually sent the letter and whether the physicians signed it.

[14] On November 2, 2006, the DEA Riverside Group Supervisor met with Mr. Goodrich at Respondent's facility to discuss Respondent's criteria and procedures for determining whether to ship to internet pharmacies. Tr. 102–03. During the meeting, Medipharm was specifically discussed. Id. at 104. According to the testimony of the Group Supervisor, Mr. Goodrich stated that "Medipharm * * * had a comprehensive compliance program, and * * * he ha[d] determined that they were innocent until proven guilty." Id.; see also ALJ at 29 (FOF 98).

the physician meets the standards noted. However, that being the case, we are not required [to determine] whether or not the physician has an internet or in-office encounter with his patient." Id. United further stated that it was "not aware that it is a commonly accepted practice in the pharmacy industry, that the pharmacy verify the type of consultation a physician has with a patient." Id.

United also included a December 2005 report by Mudri Associates regarding the pharmacy's compliance with the CSA.[15] The report specifically noted that "[a] doctor expecting to have his prescriptions filled by [United] can anticipate having to complete an extensive background questionnaire. This background consists of samples of writing along with a signed acknowledgement pertaining to a notification of [United's] adherence to fulfilling their corresponding responsibilities with the physician." Id. According to the report:

The physician is contacted and asked to acknowledge that there *[sic]* practice subscribes to sound medical judgment criteria, such as valid patient medical complaints, extensive physician interview and consultation, in-person patient examination, or supervision and/or direction of an examination by a consulting medical professional, documented in a patient file, along with the appropriateness of medications based upon this physician/patient relationship.

Id. Respondent deemed United's response adequate. ALJ at 25 (FOF 84).

Avee submitted its questionnaire nearly a month late. Resp. Ex. 55. Avee admitted that controlled substances comprised ninety percent of the prescriptions it filled and answered "N/A" to the question "What percentage of prescriptions filled by your pharmacy originate on the internet." Id. at 1–2. Avee further maintained that it was not an internet pharmacy but rather a "mail order pharmacy," and that it did not know what percentage of the physicians whose prescriptions it filled used the internet in the course of their medical practice. Id. at 3–4. Where asked to identify the websites of the physicians who were "most commonly issu[ing the] prescriptions filled by your pharmacy," Avee wrote "N/A." Id. at 4. Where asked if it verified that the prescribing physician was "authorized to practice medicine in the state in which the patient is located," Avee wrote: "where the doctor is located." Id.

[15] According to the stipulated facts, Mr. Mudri is a retired DEA Diversion Investigator.

Upon reviewing Avee's questionnaire, Mr. Goodrich wrote back to it noting that he "was surprised that your responses to our questionnaire did not support the observations I made on site," and added that he was "curious if your business model has changed in the past six months." Resp. Ex. 56. Mr. Goodrich further noted that he was "unable to reconcile the information provided on our questionnaire with the information observed during a visit to [its] facility." Id. Mr. Goodrich then indicated that he wished to visit Avee again and requested that it provide "a current overview of [its] internal due diligence protocols." Id.

In an undated letter, Avee outlined its compliance procedures and provided Mr. Goodrich with a copy of a letter regarding prescribing practices which it claimed it sent to the physicians whose prescriptions it filled. Resp. Ex. 57. Avee maintained that it required that this letter be signed annually by the physician and that it also conducted site visits at the physician's offices. Id. at 2. In its letter to the physicians, Avee listed the four elements of a legitimate doctor/patient relationship. Id. at 5.

While the pharmacy accurately stated the four elements, the letter further added that "[t]o these, Avee would add an opportunity for the prescribing practitioner and patient, via some means, to confer." Id. (emphasis added). Avee further maintained that "[i]t is not a requirement that the prescribing physician himself/herself took the history or performed the physical examination, as long as the prescribing practitioner *had full and meaningful access to the medical history and physical examination, and an opportunity to confer with the patient.*" Id. (emphasis added).

Avee's letter to its physicians clearly raised a substantial question as to the legality of the prescriptions it was filling and conflicted with information that DEA had previously provided Respondent regarding the requirements to establish a legitimate doctor-patient relationship. Indeed, it indicated that Avee's practices remained the same as Mr. Goodrich had observed during his February 2006 visit when he noted that the pharmacy filled "prescriptions from various sources, *including internet-connected medical providers who provide patient assessments and diagnosis through unconventional practice models.*" GX. 20 (emphasis added). Here again, Respondent continued to ship large quantities of controlled substances to Avee and did so up until December 6, 2006, when the immediate suspension order was served.

As a result of the surveys, Respondent stopped shipping controlled substances to Bi-Wise, CRJ and YPM. ALJ at 25 (FOF 86). Even then, however, Respondent did not stop accepting orders from these entities until October 20, 2006, and did not stop shipping to them until October 27, 2006, nearly two months after the completed questionnaires were due. Id.; see also Gov. Ex. 36 (memorandum dated December 20, 2006, from Respondent's counsel to DEA attorney regarding discontinued pharmacy customers); Resp. Ex. 52 (questionnaire at p.6).

Moreover, Respondent's own evidence indicates that it never sent a questionnaire to Discount Mail Meds (a/k/a Liddy's), see Resp. Ex. 52, at 2, and there is no completed questionnaire from it. See Resp. Exs. 51–72. Respondent, however, continued to sell large quantities of hydrocodone to Discount and sold it more than 500,000 dosage units a month in both October and November 2006.

Finally, there is no evidence that Respondent ever received a completed questionnaire from Medcenter and Medichem. See Resp. Exs. 54–72; ALJ at 24–25 (Stipulated FOFs 77–86). Respondent nonetheless continued to supply Medcenter with large quantities until November 16, 2006, when the latter's registration was immediately suspended. It also continued to supply Medichem with large quantities of hydrocodone through November 2006.

Respondent also adopted a policy under which it would, effective on December 15, 2006, cease distributing controlled substances to those pharmacies whose DEA registrations had not been automatically renewed but were continued on a day-to-day basis for a period of more than two months. Accordingly, on November 17, 2006, Mr. Goodrich wrote Avee, United, and Universal, notifying them of the policy and its effective date. See Resp. Exs. 77, 78, 79. Between the date of this letter and December 5, 2006 (the day before service of the Immediate Suspension), Respondent supplied Avee with more than 1.8 million dosage units of hydrocodone. ALJ at 7 (FOF 21). Moreover, between the date of its letter and November 30, 2006, Respondent supplied Universal with 150,210 dosage units. ALJ at 10 (FOF 31). Finally, from November 21, 2006 through December 5, 2006, Respondent supplied United with 158,280 dosage units of hydrocodone. ALJ at 14 (FOF 45).[16]

[16] The parties also stipulated that between January and May 2006, Respondent stopped accepting orders from seven other pharmacies based

Continued

As a result of the surveys, in October 2006, Respondent updated its customer profile questionnaire for potential pharmacy customers. Id. at 26 (FOF 88). On this questionnaire, Respondent required potential customers to disclose information related to the prescriptions the pharmacy was dispensing including whether "they [were] the result of an internet- or telephone-based medical encounter." Resp. Ex. 75. Respondent also required the pharmacy's responsible officer to attest to the validity of the information it provided. Id.

Relatedly, in October 2006, Respondent revised its standard operating procedures (SOP) pertaining to the sale of controlled substances to pharmacy customers. ALJ 26 (FOF 88). The SOP adopted the requirement that Respondent's pharmacy customers certify whether they knowingly filled prescriptions that arose out of an internet or telephone-based medical encounter. Resp. Ex. 76. It also directed that "[i]f [a] pharmacy affirms that they fill prescriptions of this nature, they will be required to provide details of the compliance program they have adopted to ensure that these prescriptions are legal and valid." Id. The SOP further noted that "[c]ustomers with significant purchases of controlled substances, significant activity in mail-order dispensing or with significant amounts of telemedicine dispensing will be subject to on-site assessments within four months after being accepted as a customer." Id. at 2.

Respondent's Failure to Report Suspicious Orders

Under federal regulations, a registrant must "design and operate a system to disclose to the registrant suspicious orders of controlled substances"; suspicious orders must be reported to the local Field Division Office upon discovery by the registrant. 21 CFR 1301.74(b). Under the regulation, "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Id.[17]

While the record establishes that Respondent had worked with a DEA DI to develop a system for detecting and reporting suspicious orders, ALJ at 20 (FOF 64), the system had been created when most of Respondent's customer base was comprised of physicians. Tr. 739. Moreover, no one from Respondent contacted the DI to discuss its decision to supply internet pharmacies and the criteria and procedures that should be used to determine whether the pharmacies' orders were suspicious. Id. at 741.

Under Respondent's procedures, a monthly report was generated which identified those customers purchasing controlled substances and the percentage of controlled versus non-controlled drugs purchased by the customer. Resp. Ex. 109, ¶ 25.2. If a customer's monthly purchases of controlled substances deviated by "over 150%" from the customer's average monthly percentage of controlled substance purchases for the preceding six months, it was then subject to further review. Id. at ¶ 25.3.

Under Respondent's system, "[i]f no customers [were] deemed suspicious," it would send DEA "a report stating 'no suspicious activity' for the period." Id. at ¶ 25.6. Moreover, twice a year, Respondent sent to DEA "a list of the largest purchasers of controlled substances." Id. at ¶ 25.8. The customers on this list were not "reported as having suspicious purchases." Id. According to Mr. Goodrich's testimony, Respondent did not have a procedure in place to monitor and detect excessive purchases on a monthly basis. Tr. 397–98.

Respondent sent DEA e-mails reporting that it had "no suspicious activity to report" for the months of December 2005 (GX 9), January 2006 (GX 10), March 2006 (GX 11), and April 2006 (GX 12). In addition to the exhibits, testimony establishes that "Respondent did not report any suspicious orders through the month of December 2006," ALJ at 36 (FOF 129, citing Tr. 95–96), even though the Florida internet pharmacies were purchasing quantities that greatly exceeded the average amount of hydrocodone (6,000 dosage units per month) purchased by a traditional brick-and-mortar retail pharmacy. GX 45, at 8; Tr. 608.

Respondent, however, twice provided the DEA Riverside Field Office with a report listing its top purchasers of controlled substances. See Resp. Ex. 46, 47, & 48. The first of these, which Mr. Goodrich e-mailed to the DEA Riverside office on February 13, 2006, covered the period June through December 2005. See Resp. Ex. 46. The report included Avee, Medipharm and Accumed, indicated the date the pharmacies had become customers,[18] the number of bottles of controlled substances the pharmacies had ordered, and the percentage of prescription drugs ordered by the pharmacies that were controlled substances. See id.

Mr. Goodrich provided the second report to DEA at the July 17, 2006 conference call. ALJ at 23 (FOF 72). This report covered the period December 2005 through June 2006, and included Medipharm, Accumed, Avee, United, Medichem, Bi-Wise, Medicom, Discount, Universal, Medcenter, CRJ, and Woody Pharmacy. See Resp. Ex. 47. The report likewise listed the date the pharmacies had become customers, the total amount of controlled substances ordered, and the percentage of prescription drugs ordered that were controlled substances. See id. Of the aforementioned pharmacies, the lowest percentage of controlled substances ordered was ninety-eight percent by CRJ. See id. Almost all of the above pharmacies had ordered only controlled substances. See id. Finally, the list did not include several of Respondent's recently acquired customers including Grand Pharmacy and the Medicine Shoppe. See id.

At the hearing, Mr. Goodrich acknowledged that "an unusual quantity could be a determining factor" in deciding whether an order must be reported as suspicious. Tr. 490. Mr. Goodrich further admitted that some of the orders received by Respondent were of an unusual size. Id. Moreover, Mr. Goodrich further testified that following the July 17, 2006 conference call with DEA, Respondent did not report any of the orders placed by the Florida-based pharmacies to be suspicious because "[w]e considered [all of the pharmacies] suspicious at that point." Tr. 424.

On cross-examination, Mr. Robert Schwartz, who became Respondent's Chief Operating Officer on September 26, 2006, was asked a series of hypothetical questions based on the evidence in the case regarding the reporting of suspicious orders. Tr. 953–57. Mr. Schwartz testified that while he had previously worked in senior management positions at major pharmaceutical distributors such as H.D. Smith and Barnes Wholesale, he could not recall a pharmacy ordering 800,000 dosage units of hydrocodone in a month. Id. at 953. Mr. Schwartz also testified that an order for 2.1 million dosage units of the drug was "a lot of hydrocodone" and should be reported as suspicious because, based on his experience at Barnes, it was not

on "the cessation of their" registrations by DEA. ALJ at 25 (FOF 86).

[17] The parties also stipulated that every month since July 2002, Respondent had submitted ARCOS reports regarding its distributions of schedule III controlled substances including hydrocodone to the ARCOS Unit at DEA headquarters. ALJ at 18 (FOF 58)

[18] According to the document, Medipharm had become a customer on December 7, 2005; Accumed and Avee became customers on December 19, 2005, and December 21, 2005, respectively. See Resp. Ex. 46.

consistent with what pharmacies ordered. Id. at 953–54. Similarly, Mr. Schwartz admitted that various changes in a pharmacy's ordering history (such as those which occurred here) would be suspicious and should be reported to DEA. Id. at 954–57.

The ALJ further found that Mr. Schwartz "provided credible testimony concerning two possible justifications for the Respondent's sharp rise in the sale of hydrocodone products in August of 2006." ALJ at 38 (FOF 135 (citing Tr. 930)). The first reason given was that there are "year-end inventory shortages" from the manufacturers and thus "wholesalers begin 'to buy extra product from manufacturers in August, building up our inventories for the year-end," and pharmacies "buy extra inventory at this time." Id. The second reason was the State of Florida's implementation of its requirement, effective July 1, 2006, that "pedigree must be passed by each distributor who is not a manufacturer, before each distribution of a drug and provided to each person who receives the drug." ALJ at 38–39 (FOF 137). Respondent met the pedigree requirements, and the developer of the software it used issued a press release announcing that Respondent was compliant with Florida law. See id.; Resp. Ex. 105.

Respondent, however, introduced no evidence that it contacted any of its pharmacy customers that increased their purchases between July and August 2006 to determine if they had done so for either reason. Tr. 487. As Mr. Goodrich testified, he did not "know that the pedigree program had a direct impact on the hydrocodone that we distributed to our pharmacy customers." Id. at 488. In fact, only seven of the pharmacies increased their purchases of hydrocodone from July to August 2006. During this period, four of the pharmacies actually decreased their hydrocodone purchases from Respondent and the remaining three purchased roughly the same amount. Relatedly, Mr. Goodrich admitted that Respondent did not even "develop a [suspicious orders] policy that specifically addressed the pharmacy customers until September of 2006." ALJ at 34 (FOF 119).

Furthermore, the orders of the Florida-based internet pharmacies were suspicious from the beginning because of their large size, their frequency, and the fact that controlled substances constituted the overwhelming percentage (and frequently 100 percent) of the products being purchased. See ALJ at 36–37 (FOF 130–132); see also Resp. Exs. 46 & 47. Even if Respondent had contacted the seven pharmacies and determined that they had increased their orders for either of the above reasons, their orders were still suspicious and subject to reporting. And as Mr. Goodrich testified, following the July 17, 2006 conference, he considered all of the Florida-based pharmacies to be suspicious. Tr. 424.

Respondent's Corrective Actions and Post-Suspension Conduct

The ALJ also made several findings regarding corrective actions instituted by Respondent. First, the ALJ found credible the testimony of Mr. Schwartz that on December 5, 2006, the day before the immediate suspension order was served on Respondent, he and its owner, Mr. John Sempre, had determined that it should stop supplying the Florida-based internet pharmacies. ALJ at 40 (citing Tr. 938–39).

Mr. Schwartz also testified that if Respondent regained its registration, he and not Mr. Goodrich, would be responsible for reviewing suspicious order reports before they were submitted to DEA. Tr. 1027. Moreover, Mr. Schwartz was to "have ultimate authority" to accept or reject any new customer seeking to purchase controlled substances. ALJ at 41 (citing Tr. 1027). Finally, Respondent entered into an agreement with SynTegra, L.L.C., to review its procedures for monitoring and reporting suspicious orders to DEA. Resp. Ex. 102.

After the immediate suspension of its registration, Respondent continued to receive orders for controlled substances which it forwarded on to Pharmapac, a competitor, for filling. Tr. 184–87, GX 63. Under the "Sold To" line on the Pharmapac invoices, typically the name of the individual practitioner who ordered the controlled substances was listed above Respondent's name and address. See GX 63, at 281–351. However, on the invoices "Ship To" line, the invoices contained the individual practitioner's name and address. See id. The invoices also included a label which stated: "Please send payment to: SOUTHWOOD PHARMACEUTICALS, INC., 60 Empire Drive, Lake Forest, CA 92630." See id.

On February 1, 2007, Respondent Mr. Schwartz wrote a letter to Respondent's customers indicating that it had "mistakenly placed a sticker on these invoices directing payment to Southwood Pharmaceuticals." Resp. Ex. 107. The letter instructed Respondent's customers that the sticker be disregarded and that payment should be made directly to Pharmapac at its address. Id.

The ALJ found that "Respondent processed an extensive number of orders for controlled substances in January of 2007," and that "Respondent did receive payment from many of these customers consistent with the invoices dated during January of 2007." ALJ at 44 (FOF 157) (citing GX 63). During the hearing, however, the parties stipulated that "[i]t was not [Respondent's] intent to retain any payment submitted to or through Southwood by [its] customers, in connection with orders forwarded to and filled by Pharmapac." Tr. 1030. Moreover, the Government introduced no evidence establishing that Pharmapac is not registered with DEA to manufacture or distribute controlled substances.

Discussion

Section 304(a) of the Controlled Substances Act provides that "[a] registration * * * to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render [its] registration under section 823 * * * inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). As relevant here, Congress directed that the following factors be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. 823(d). These factors are considered in the disjunctive. I may rely on any one or a combination of factors and give each factor the weight I deem appropriate in determining whether to revoke a registration or to deny a pending application for renewal of a registration. See Green Acre Farms, Inc., 72 FR 24607, 24608 (2007); ALRA Laboratories, Inc., 59 FR 50620, 50621 (1994). Moreover, I am "not required to

make findings as to all of the factors." *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

The Government bears the burden of proving that Respondent's continued registration would be inconsistent with the public interest. 21 CFR 1301.44(e). If, however, the Government establishes a prima facie case, the burden shifts to Respondent to show why its continued registration would not be inconsistent with the public interest. See Gregory D. Owens, 67 FR 50461, 50464 (2002).

In this case, I conclude that factors one, five and six establish that Respondent's continued registration would "be inconsistent with the public interest." 21 U.S.C. 823(d). Indeed, Respondent "concedes that the Government has established a prima facie case * * * that [its] continued registration may be inconsistent with the public interest." Resp. Proposed Findings of Fact and Conclusions of Law (hereinafter, Resp. Br.) at 31. Respondent maintains, however, that the record "encompasses sufficient examples of mitigation and ongoing remediation by" it to compel the conclusion that revoking its registration "would be inconsistent with the public interest." Id. For the reasons set forth below, I conclude otherwise and will order the revocation of Respondent's registration and the denial of its pending renewal application.

Factors One and Five—Maintenance of Effective Controls Against the Diversion of Controlled Substances Into Other Than Legitimate Channels and Respondent's Past Experience in Distributing Controlled Substances

Under DEA regulations, all "registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 CFR 1301.71(a). A registrant is further required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and is required to "inform the [DEA] Field Division Office * * * in his area of suspicious orders when discovered by the registrant." Id. 1301.74(b). As explained below, the record establishes that Respondent failed repeatedly to comply with both requirements.

Respondent's Distributions of Hydrocodone and Due Diligence Efforts

Beginning in December 2005, Respondent distributed massive quantities of hydrocodone, a highly abused drug and schedule III controlled substance, to entities which, notwithstanding their various assertions to Mr. Goodrich, were nothing more than drug pushers operating under the patina of legitimate authority. Respondent's due diligence measures " which initially involved nothing more than verifying a pharmacy's DEA registration and state license—were wholly deficient.

As the record demonstrates, Respondent sold Medipharm in excess of 1.75 million units of hydrocodone in the months of December 2005 and January 2006, before Mr. Goodrich even visited this entity to inquire into the nature of its business. Likewise, during the months of December 2005 and January 2006, Respondent sold more than 1.55 million dosages units of hydrocodone to Avee and 476,000 dosage units of the drug to Accumed before Mr. Goodrich even visited these entities. It also sold large quantities of hydrocodone to Medichem and Bi-Wise before Mr. Goodrich visited them. As Mr. Goodrich admitted, Respondent had "no" process in place to determine the nature of a potential customer's business before it sold to them.

Moreover, during the February on-site visits with the above entities, Mr. Goodrich received substantial information which raised serious doubt as to the legality of their business practices. As the evidence demonstrates, Mr. Goodrich determined that Medipharm had a "mail order business [with] ties to internet pharmacy," GX 16, that Accumed had "ties to the internet," GX 17, and that Medichem was mailing prescriptions out-of-state and had "some ties to the internet community." GX 18.

At Avee, Mr. Goodrich found that it "provide[d] mail order fulfillment of prescriptions from various sources, *including internet-connected medical providers who provide patient assessments and diagnosis through unconventional practice models,*" with *"[m]any of these prescriptions* [being] *connected to pain management therapies involving the prescription of controlled substances."* GX 20 (emphasis added). Avee's management also discussed with Mr. Goodrich a visit earlier that day by agency investigators and their concern as to "the validity of the doctor-patient relationship that formed the basis *of the digital diagnosis that resulted in a prescription for controlled substances being submitted to Avee for filling."* Id. (emphasis added). Moreover, in his testimony, Mr. Goodrich admitted that he knew as early as his visit to Avee that "[s]ome of the prescriptions [it] filled were not the result of physical contact between the doctor and the patient," Tr. 348, and that Avee had also provided him with the names of two websites that were the source of the prescriptions it filled. Id. at 351–52.

The evidence further establishes that notwithstanding that he did not "know [] much about this telemedicine thing," id. at 354, Mr. Goodrich did not order that Respondent's shipments to these pharmacies be stopped. Indeed, following the visits, Respondent shipped even larger monthly quantities of hydrocodone to some of the pharmacies. Furthermore, Mr. Goodrich testified that he did not assess whether Avee was operating illegally, claiming that he did not think he could "make that assessment." Tr. 359. Indeed, Respondent remained disinterested in determining whether the Florida-based pharmacies were lawfully filling prescriptions until after the July 17, 2006, conference call with DEA officials.[19]

Notwithstanding that Mr. Goodrich had reason to know that the Florida-based internet pharmacies were not filling lawful prescriptions, Respondent proceeded to supply large quantities of hydrocodone to an additional eleven internet pharmacies (most of which were located in the Tampa Bay area) including United, Medicom, Discount, Universal, Medcenter, CRJ, Grand, Medicine Shoppe, Duane's, Woody, and Elite. Moreover, notwithstanding the large quantities that these pharmacies ordered, Mr. Goodrich apparently did not deem it necessary to conduct site visits to inquire into the nature of their businesses and whether they were filling lawful prescriptions. See, e.g., Resp. Br. at 34–35 (discussing "steps taken by Mr. Goodrich to ascertain that [Respondent's] pharmacy customers in Florida were not diverting controlled substances," and noting only Goodrich's Feb. 8, 2006 site visits and the August 2006 pharmacy questionnaires). Moreover, Respondent continued to supply the pharmacies, notwithstanding that they were ordering hydrocodone in quantities that far exceeded what its traditional retail pharmacy customers ordered, that Respondent had information that controlled substances comprised between 98 and 100 percent

[19] It is true that Mr. Goodrich testified that he visited the DEA Diversion Control website in early 2006. However, he testified that he received most of the information about prescriptions during the July 2006 conference call. Tr. 357. Neither Mr. Goodrich nor any other witness for Respondent claimed to have reviewed the DEA April 2001 policy statement on prescribing controlled substances over the internet prior to it being provided to him by DEA officials. Moreover, Respondent makes no claim that following the February visits it consulted legal counsel to determine the legality of the prescribing practices of the Florida pharmacies.

of the prescription drugs being ordered by these entities, and that as Mr. Goodrich explained, these entities "were a different type of a customer than what we'd been used to dealing with." Tr. 319.

Respondent contends that it is "unfair" to compare what Mr. Goodrich learned during the site visits through his "lay inquiry" with what a DEA Diversion Investigator learned, "armed as she was by two decades of diversion investigation experience, search warrants, and a team of armed agents carrying intimidating badges." Resp. Br. 35. The record demonstrates, however, that even without a warrant, a badge and a gun, Mr. Goodrich was able to obtain from Avee substantial information indicating that its practices were illegal and already subject to DEA's scrutiny. He was also able to obtain information from several other pharmacies which suggested that further inquiry was warranted as they were engaged in practices similar to those of Avee. Moreover, Respondent's argument ignores that it sold to numerous additional internet pharmacies without even conducting site visits.

Furthermore, even after DEA presented information to it—on the proverbial silver platter—that Respondent's Florida-based internet pharmacy customers were likely engaged in illegal activity and even specifically mentioned that six of its customers were "targeted," Respondent continued to distribute extraordinarily large quantities of hydrocodone to these pharmacies.

To Medipharm, an entity described as a target of an investigation, in August 2006, Respondent distributed 1.25 million dosage units of hydrocodone. In September 2006, Respondent distributed to Medipharm 1.45 million dosage units of the drug, and in October 2006, more than 1 million dosage units. Furthermore, Respondent distributed an additional 538,000 dosage units to Medipharm during the first half of November 2006, at which time Medipharm's registration was suspended.

To Accumed, another of the targeted pharmacies, in August 2006, Respondent sold approximately 1.268 million dosage units of hydrocodone. While in September and October 2006, Respondent's hydrocodone sales to Accumed declined to approximately 503,000 and 394,000 dosage units respectively, in November 2006, Respondent sold 1.56 million dosage units to it.

As for Avee, which was also identified as a target, in August 2006, Respondent sold 506,430 dosage units of hydrocodone, an amount that was more than five times the previous month's sale. In September 2006, Respondent sold Avee approximately 696,000 dosage units; in October, it sold Avee 537,900 dosage units; and in November, it sold Avee 2.11 million dosage units.[20]

It is true that following the July 17, 2006 conference call, Respondent attempted to perform additional due diligence. More specifically, Mr. Goodrich requested information from the Florida Board of Pharmacy as to whether the pharmacies were operating legitimately. The Florida Board, however, only provided information as to the licensure status of the pharmacies. Resp. Ex. 50.

On August 15, 2006, Respondent also sent out a questionnaire to its internet pharmacy customers. It is true that Respondent did eventually cease shipping controlled substances to three of the pharmacies (Bi-Wise, CRJ and YPM) because these pharmacies either failed to respond (Bi-Wise) or gave inadequate responses on their questionnaires (CRJ and YPM). But even with respect to these pharmacies, Respondent did not cut off its shipments to them until late October 2006, nearly two months after its own deadline for completing the questionnaires, and sold them large quantities of hydrocodone notwithstanding that the pharmacies had failed to comply with Respondent's request for additional information.

It is also true—as Respondent contends—that two of the pharmacies (Medipharm and Universal) submitted questionnaires which were "prepared by an apparently reputable attorney," Resp. Br. 35, and which indicated that the pharmacies had "retained counsel to * * * implement a strict compliance program to ensure compliance with the applicable rules and regulations for prescription practice in each of the states in which" the pharmacies did business. Resp. Ex. 67, at 4; Resp. Ex. 69, at 4. These questionnaires further stated that the pharmacies "routinely verif[ied]" that the doctors were "authorized to practice medicine in the state in which the patient is located." Resp. Ex. 67, at 4; Resp. Ex. 69, at 4.

These two pharmacies further indicated, however, that they did "not fill prescriptions where the patient has not had a face-to-face encounter with a physician." Resp. Ex. 67, at 5, Resp. Ex. 69, at 5 (emphasis added). Notably, the latter statement did not say that the patients had a face-to-face encounter with the prescribing physician.

I need not decide whether it was reasonable for Respondent to continue shipping controlled substances to Medipharm and Universal in light of the ambiguous statements they provided and the massive quantities of controlled substances they were ordering. Even if it was, Respondent ignores the numerous instances in which it continued to ship to other pharmacies which had provided ample information casting serious doubt as to the validity of their activities.[21]

For example, Respondent continued shipping hydrocodone to Grand Pharmacy deeming its response to be adequate. Yet Grand stated that "[a]ll doctors Grand deal with have a physical *or extended phone dialogue with the patient to establish the diagnosis and need for the medication.*" Resp. Ex. 63, at 2 (emphasis added). While this answer should have stood out like a swollen thumb, Mr. Goodrich deemed Grand's answers adequate and Respondent continued to ship large quantities of controlled substances to it.

The Medicine Shoppe's questionnaire indicated the name of a website used by the "physicians who most commonly issue prescriptions filled by [the] pharmacy." Resp. Ex. 65, at 4. Moreover, the pharmacy answered the question of whether it verified that the physicians were "authorized to practice medicine in the state where the patient is located," stating: "No. The doctor makes the consult from the state in which they are licensed." Id. at 4.

Medicom—which apparently was owned by the same person who owned the Medicine Shoppe—stated that it was not an internet pharmacy. The pharmacy added, however, that it "receive[d] Rx from doctors who have spoken [to] patients, discussed therapy, and also reviewed entire medical history." Resp. Ex. 66, at 2. Notably, Medicom did not maintain that the prescriptions were issued by the physicians pursuant to a face-to-face encounter with the patients. Moreover, the questionnaire indicated that the pharmacy received prescriptions "via telemedicine" and named three websites used by physicians whose prescriptions the pharmacy filled. Id., at 2 & 4. Finally, when asked whether it verified that the physicians were authorized to practice medicine in the states where the patients were located,

[20] Respondent also continued to ship large quantities of hydrocodone to Universal, another pharmacy which was identified as "targeted." In August, it shipped 399,070 dosage units to Universal; in September, 340,500 dosage units; in October, 453,690 dosage units; and in November, 330,600 dosage units.

[21] Likewise, the answers submitted by Duane's appeared to be in order even if they were false.

Medicom answered: "No. The doctor makes the consultation from the state they are licensed" in. Id. at 4.

Here again, Mr. Goodrich deemed both the Medicine Shoppe and Medicom's responses to be adequate despite the obvious indications that they were not filling lawful prescriptions and Respondent continued to ship hydrocodone to both pharmacies. Most significantly, in September 2006, it shipped 164,000 dosage units to Medicom; in October, it shipped 375,690 dosage units to Medicom; and in November, it shipped 385,000 dosage units to the pharmacy.

Avee, another of the identified targets, sent its questionnaire in nearly a month late. On its questionnaire, Avee indicated that it was not an internet but rather a "mail order pharmacy." Resp. Ex. 55, at 4. It also answered "N/A" to the questions which asked what percentage of the prescriptions it filled originated on the internet and to identify the websites used by the physicians who were commonly issuing the prescriptions it filled. Resp. Ex. 55, at 2 & 4.

I acknowledge that Mr. Goodrich then undertook further inquiry to determine whether Avee had changed its business model and requested additional information regarding its due diligence protocols. Resp. Ex. 56. Avee wrote back including a copy of a letter it claimed to have sent to the physicians who issued the prescriptions it filled. Resp. Ex. 57. As found above, while that letter correctly stated the four elements of a legitimate doctor/patient relationship, it also stated that "[t]o these, Avee would add an opportunity for the prescribing practitioner and patient, *via some means, to confer.*" Id. at 2 [22] (emphasis added). Moreover, the letter maintained that "[i]t is not a requirement that the prescribing physician himself/herself took the history or performed the physical examination, as long as the prescribing practitioner had full and meaningful access to the medical history and physical examination, and *an opportunity to confer with the patient.*" Id. (emphasis added).

In short, Avee had not changed its practices from the time of the February 2006 on-site visit, when Mr. Goodrich noted that the pharmacy filled "prescriptions from various sources, *including internet-connected medical providers who provide patient assessments and diagnosis through unconventional practice models.*" GX 20 (emphasis added). Respondent nonetheless continued to ship large quantities of hydrocodone to Avee.

[22] This is page 5 of the exhibit.

Indeed, in September 2006, Respondent shipped 695,800 dosage units to Avee, in October, it shipped 537,900 dosage units to Avee, and in November, it shipped 2.11 million dosage units to the pharmacy.

Accumed, another of the "targeted pharmacies," represented in its questionnaire that it was "not an internet pharmacy," and that zero percent of the prescriptions it filled originated on the internet. Resp. Ex. 54, at 2–3. It also indicated "N/A" where asked to list the websites used by the "physicians who most commonly issue prescriptions filled by your pharmacy." Id. at 4. Notwithstanding the inconsistency between Accumed's answers and Mr. Goodrich's finding during the February site visit that the pharmacy had "ties to the internet," GX 17, there is no evidence that Mr. Goodrich undertook any additional investigation to determine whether it was filling legitimate prescriptions.

Here again, Respondent continued to sell extraordinary quantities of hydrocodone to the pharmacy. More specifically, in August 2006, Respondent sold Accumed 1.267 million dosage units; in September, it sold 503,020 dosage units; in October, it sold 393,610 dosage units; and in November, it sold more than 1.56 million dosage units.

Finally, Respondent produced no evidence that it ever received responses from Medcenter, Discount Mail Meds (a/k/a Liddy's), and Medichem. See Resp. Exs. 54–72; ALJ at 24–25 (Stipulated FOF 77–86). Moreover, Respondent's evidence suggests that it did not even send a questionnaire to Discount Mail Meds. See Resp. Ex. 52, at 2.

Respondent nonetheless continued to distribute large quantities of hydrocodone to Medcenter until November 16, 2006, when the pharmacy's registration was suspended. More specifically, Respondent sold Medcenter 378,000 dosage units in September, 608,000 dosage units in October, and approximately 314,000 dosage units in the first half of November.

Respondent also distributed large quantities of hydrocodone to Discount and Medichem until the immediate suspension of its registration on December 6, 2006. Between August and November 2006, Respondent sold Medichem at least 216,000 dosage units each month. During the same period, the lowest amount Respondent sold to Discount was 292,720 dosage units in August. Moreover, in October and November, Respondent sold to Discount more than 500,000 dosage units each month.

Accordingly, I conclude that even after being advised by agency officials that its internet pharmacy customers were likely engaged in illegal activity, Respondent failed miserably to conduct adequate due diligence. Notwithstanding the breadth of information provided during the conference call, Respondent did not stop selling to any of its internet pharmacy customers while it investigated the legitimacy of their businesses activities.

Moreover, even when some of the pharmacies provided information indicating that the prescriptions they filled were likely illegal, Respondent continued to distribute large quantities of hydrocodone to them. Indeed, the only instances in which Respondent stopped supplying a pharmacy pursuant its "due diligence" program was when one pharmacy (Bi-Wise) entirely failed to submit the questionnaire and when two other pharmacies (CRJ and YPM) answered nearly every question with a dash or "N/A." Furthermore, Respondent failed to even send a questionnaire to one of the pharmacies and continued to ship to two pharmacies which apparently never submitted a completed questionnaire.

In short, the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was the likely diversion of millions of dosage units of hydrocodone. Indeed, it is especially appalling that notwithstanding the information Respondent received from both this agency and the pharmacies, it did not immediately stop distributing hydrocodone to any of the pharmacies. Moreover, in several cases, Respondent actually distributed even larger quantities of the drug to them. As one of the DIs testified regarding Respondent's distribution of 2.1 million dosage units to Avee in November 2006, "[t]his is an obscene amount of drugs." Tr. 617. The term "obscene" also fairly describes Respondent's experience in distributing hydrocodone to all of its internet pharmacy customers.[23]

[23] Respondent attempts to excuse its conduct on the ground that it repeatedly asked DEA officials whether it should stop selling to the pharmacies only to be told by DEA officials that they could not tell them whether or not to sell because that was a business decision. Resp. Br. 33. Several courts have held, however, that DEA has no authority under the CSA to tell a distributor whether to sell or not. *See PDK Labs Inc.*, v. *Ashcroft*, 338 F.Supp.2d 1, 14 (D.D.C. 2004).

Respondent also faults the July 2006 presentation by agency personnel as "[s]easoned with antiquated case law and dense, professional material," and asserts that it had "little pedagogic value." Resp. Br.

Respondent's Failure to Report Suspicious Orders

The record further demonstrates that Respondent repeatedly failed to report any of its sales to the Florida-based internet pharmacies as suspicious orders even though, as the ALJ concluded, the purchases by these customers "fell within the regulatory definition of suspicious orders." ALJ at 49. From its first distribution of hydrocodone products in December 2005 through its last in December 2006, not once did Respondent report a suspicious order.

Moreover, Respondent failed to report these distributions notwithstanding (1) that the Florida-based pharmacies were ordering massive quantities of hydrocodone, quantities which greatly exceeded what Respondent sold to traditional retail pharmacies, and (2) that controlled substances typically constituted all but a miniscule percentage of the prescriptions drugs being ordered by the Florida-based pharmacies. For example, between December 7 and December 31, 2005 (a three-and-a-half week period), Respondent distributed approximately 817,000 dosage units of hydrocodone to Medipharm. This amount was 109 times the amount of hydrocodone that Respondent typically sold in a month to its retail pharmacy customers. Moreover, controlled substances comprised 98 percent of Medipharm's purchases of prescriptions drugs from Respondent.

Notwithstanding this information, Respondent did not deem Medipharm's purchases to be suspicious. It did not report any of Medipharm's subsequent purchases as suspicious even though the pharmacy never purchased less than 703,000 dosage units of hydrocodone in a month and purchased more than a million dosage units of this drug in six different months. Moreover, even though between December 2005 and June 2006, controlled substances constituted 99% of Medipharm's prescription drug purchases from it and was specifically identified as a targeted pharmacy, Respondent never reported the purchases as suspicious.

As another example, between December 21st and 31st, 2005, Avee purchased approximately 346,000 dosage units of hydrocodone from Respondent. Just as in the case of Medipharm, this amount—which involved only ten days of purchases—greatly exceed Respondent's average monthly sale of hydrocodone to a traditional pharmacy. Moreover, while Avee was only a customer for ten days during the seven-month period of June through December 2005, Avee nonetheless made Respondent's list (ranking eighth) of its largest purchasers of controlled substances. See Resp. Ex. 46. Moreover, controlled substances constituted 100 percent of Avee's purchases of prescription drug products from Respondent. Id.

Here again, Respondent did not report any of Avee's purchases as suspicious. It did not do so after Mr. Goodrich acquired information during the February site visit indicating that Avee was engaged in the filling of illegitimate prescriptions. Nor did it do so even after the July 2006 conference call when DEA officials informed Respondent that it was a targeted pharmacy. It did not do so even in November 2006, when it distributed more than 2.1 million dosage units of hydrocodone to Avee.

Moreover, as it obtained additional Florida based customers, who proceeded to order excessive quantities of hydrocodone, Respondent never reported any of these pharmacies' orders as suspicious. To the contrary, on various occasions, it submitted e-mails to DEA field personnel affirmatively stating that it had reviewed its customer's purchases of controlled substances and had "no suspicious activity to report." See GX 9 (Dec. 2005); GX 10 (Jan. 2006); GX 11 (Mar. 2006); GX 12 (April 2006).

Respondent contends that "[t]he [G]overnment's focus on [its] failure to report orders as suspicious in early 2006 is a red herring." Resp. Br. 34. Respondent argues that its failure to file suspicious order reports was not the result of any intent to mislead and points to the fact that in February 2006, it submitted a report that identified Medipharm, Avee and Accumed as among its largest purchasers of controlled substances. Id. Respondent also argues that by filing reports with DEA's ARCOS unit "it alerted the DEA to Southwood's commerce with internet pharmacies." Id.

Even if Mr. Goodrich had no intent to mislead by submitting these negative reports, Respondent still violated the regulation by failing to report suspicious orders. That some of the pharmacies were identified on the two reports Respondent submitted listing its largest purchasers of controlled substances (which Respondent submitted in February and July 2006), does not excuse its failure to comply with the regulation. Those reports did not comply with the regulation for several reasons.

First, they were not timely submitted. See 21 CFR 1301.74(b) (requiring reporting of "suspicious orders when discovered by the registrant"). Indeed, many of the pharmacies had been purchasing extraordinary quantities of hydrocodone for months by the time Respondent submitted its July 2006 report. Second, the reports did not list several of the internet customers—even though they had purchased large quantities—either because they had only recently become customers (as in the case of Grand Pharmacy and the Medicine Shoppe), or because the pharmacy had only purchased hydrocodone from Respondent for a limited time (as in the case of Elite).

Nor does Respondent's filing of ARCOS reports excuse its failure to report suspicious orders. The ARCOS reporting requirement and the suspicious orders reporting requirement serve two different purposes. While ARCOS provides the Agency with information regarding trends in the diversion of controlled substances, the reports need not be submitted until fifteen days after the end of the reporting period. In contrast, as explained above, a suspicious order must be reported "when discovered by the registrant." 21 CFR 1301.74(b). The suspicious orders reporting requirement exists to provide investigators in the field with information regarding potential illegal activity in an expeditious manner. Respondent's compliance with the ARCOS reporting requirement is thus not a substitute for its failure to report suspicious orders.[24]

Accordingly, I further conclude that Respondent repeatedly violated federal

at 34. The Supreme Court's decision in *United States* v. *Moore*, 423 U.S. 122 (1975), however, remains good law. As for the purportedly "dense, professional materials," these documents were typically no more than a handful of pages in length and surely capable of being understood by a person of reasonable intelligence. See GX 61. Indeed, based on the questionnaire Mr. Goodrich prepared, it seems clear that he understood the requirements for a valid prescription and legitimate doctor/patient relationship even if he chose to ignore the information provided by many of the pharmacies. See Resp. Ex. 52.

I further note, however, that the Agency had no obligation to conduct the July 2006 briefing. In any event, in April 2001, the Agency published in the **Federal Register** a guidance document explaining the potential illegality under existing law of the activities engaged in by Respondent's internet pharmacy customers. *See Dispensing and Purchasing Controlled Substances over the Internet*, 66 FR 21181 (2001).

[24] Finally, Mr. Goodrich testified that the reason Respondent did not file the reports even after being told during the July 2006 conference call of the highly suspicious nature of the activities of the Florida-based pharmacies was that the pharmacies were already under investigation. Respondent's awareness of an ongoing investigation does not, however, excuse its failure to report its customers' continued suspicious orders. Indeed, such information might well enable the agency to complete its investigation.

regulations by failing to report suspicious orders. 21 CFR 1301.74(b). As explained above, the record also clearly establishes that Respondent's experience in distributing controlled substances is characterized by recurring distributions of extraordinary quantities of controlled substances to entities which then likely diverted the drugs by filling prescriptions which were unlawful. Moreover, Respondent's due diligence measures were wholly inadequate to protect against the diversion of the drugs. Respondent's failure to maintain effective controls against diversion and its experience in distributing controlled substances thus support the conclusion that its continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4).

Factor Six—Other Factors Relevant to and Consistent With Public Health and Safety

Respondent "concedes that the Government has established a prima facie case * * * that [its] continued registration may be inconsistent with the public interest." Resp. Br. 31. Respondent contends, however that there is sufficient evidence "of mitigation and ongoing remediation by [it] to compel a conclusion that to revoke its registration would be inconsistent with the public interest." Id. (citations omitted).

More specifically, Respondent argues that its "cooperation with and responsiveness to * * * DEA [should] also be considered in evaluating whether [its] continued registration is in keeping with the public interest." Id. at 37. Respondent maintains that it has undertaken several remedial measures "to prevent the occurrence of further violations," and that therefore, a sanction less than revocation is warranted. These measures include: (1) The development of a new SOP "to more rapidly detect suspicious orders"; (2) placing its new COO "in charge of DEA compliance"; (3) retaining a consultant to audit its compliance efforts; and (4) working with the consultant "to develop a means of interdicting suspicious orders of controlled substances before they are shipped." Resp. Br. 36.

The ALJ agreed with Respondent. According to the ALJ, "Respondent has worked with * * * DEA throughout its registration," and had "worked closely with local DEA diversion investigators to establish systems to control against the diversion of controlled substances." Id. at 54–55. The ALJ also noted that Respondent had "consistently submitted" ARCOS reports without any deficiencies noted. Id. at 54.

Addressing the issue of its responsiveness to the Agency, the ALJ noted that Respondent attempted to obtain information from the Florida Board, that it sent questionnaires to the pharmacies and developed a new customer profile to evaluate new accounts, and that it adopted a policy under which it stopped filling orders placed by pharmacies whose registrations had been continued on a day-to-day basis but not renewed. Id. at 59–60.

The ALJ also explained that "Respondent continues to demonstrate a willingness to bring its business practices into compliance with DEA regulations," and noted that its new COO "has a firmer grasp [of] these regulatory requirements." Id. at 61. Reasoning that Respondent had "kept an open dialogue with the DEA and has attempted to come into compliance with the DEA's regulations," and had not previously been subject to enforcement action, the ALJ concluded that revocation of its "entire * * * registration is too severe a remedy" even though Respondent had "irresponsibly sold" what she described as "egregious quantities" of hydrocodone to the Florida internet pharmacies. Id. at 62.

I disagree with both Respondent and the ALJ. As for Respondent's view, its "circumstances" do not "compare favorably with [those of] registrants" whose registrations have not been revoked, but rather, subjected to lesser sanctions. See Resp. Br. 36. As for the ALJ's view that Respondent had kept "an open dialogue," the record amply establishes that Respondent is not a good listener.

For support, Respondent cites my decision in Joy's Ideas, 70 FR 33195 (2005), where I noted that the registrant had taken "aggressive actions to improve her" accountability systems. Id. at 33198. Notwithstanding that the registrant "may have been an unknowing and unintentional contributor" to the methamphetamine problem, I still revoked her registration based on evidence that large amounts of the products she distributed were being diverted. Id. at 33198–99. The case thus does not support Respondent for two reasons: (1) I revoked the registration in Joy's Ideas notwithstanding the mitigating evidence, and (2) here, Respondent had reason to know that it was contributing to the diversion of hydrocodone through most, if not all, of the pharmacies it supplied.

Respondent also cites Service Pharmacy, Inc., 61 FR 10791 (1996), which noted that a registrant's adherence to the terms of a consent order it had entered into with state authorities supported its being allowed to maintain its DEA registration. Respondent argues by analogy that its "cooperation with and responsiveness to * * * DEA [should] also be considered in evaluating whether [its] continued registration is [consistent] with the public interest." Resp. Br. 37.

I agree that Respondent's level of cooperation and responsiveness to DEA should be considered in determining the appropriate sanction. It is true that there is some evidence of Respondent's having been a cooperative registrant as to some issues involving its responsibilities under the CSA. In particular, Respondent worked with a diversion investigator to develop a suspicious orders reporting system (although it was developed for a different customer base). There was also no evidence of Respondent's non-compliance with the CSA prior to its decision to supply internet pharmacies.

On the other hand, even were I to completely ignore Respondent's conduct during the period between December 2005, when it started supplying the pharmacies, and the July 2006 conference call, the record further demonstrates that it did not adequately respond to the information DEA provided it in July 2006. As explained above, Respondent did not cut off any of the pharmacies until more than three months after being informed of the potential illegality of the pharmacies' activities. Indeed, it did not even enforce the deadline it set in its questionnaire.

Moreover, while some of the responses to the questionnaires were either false or were cleverly prepared by a wordsmith, in a number of other instances the responses contained information—which Respondent then ignored—that clearly suggested that the pharmacy was filling invalid prescriptions. Finally, Respondent continued to sell large quantities to many of the pharmacies—including those specifically identified as targeted—up until the suspension of either the pharmacy's registration or its own registration. Contrary to Respondent's view, the entire body of evidence regarding its cooperation and responsiveness does not support its continued registration.

While finding that "Respondent continues to fail to adequately protect against diversion of hydrocodone products," ALJ at 59, the ALJ nonetheless concluded that to revoke its entire registration would be "too severe a remedy," presumably because there was "no evidence of [its] improper

handling of any other controlled substances." Id. at 62. The ALJ, however, offered no explanation as to why Respondent's procedures were nonetheless sufficient to entrust it with authority to distribute other controlled substances.

To the extent the ALJ's recommendation was based on the lack of evidence showing that Respondent improperly handled other controlled substances, the ALJ erred. The Government is not required to prove that multiple categories of the drugs Respondent distributed were diverted in order to sustain the revocation of its entire registration. Rather, proof that a single category of a drug it distributed was diverted is enough to support the revocation of Respondent's entire registration.[25]

The ALJ apparently was persuaded by the various measures undertaken by Respondent to bring itself into compliance. Among these was Respondent's hiring of its new COO. According to the ALJ, the new COO is "an experienced officer who will be making the final decisions concerning * * * Respondent's compliance measures," and this hiring "operates as an increased level of protection of the public interest and [its] compliance with DEA regulations in its business practices." ALJ at 62. The ALJ also noted that Respondent had voluntarily agreed "to cease selling controlled substances to Internet pharmacies." Id. at 63. Relatedly, Respondent points to its retaining of a consultant to audit its DEA compliance efforts and to develop a means of interdicting suspicious orders before they are shipped.

As for Respondent's hiring of its new COO, the record establishes that Mr. Schwartz commenced his duties on September 26, 2006. Mr. Schwartz was thus the COO for more than two months before the immediate suspension order was served. Yet during this period, Respondent continued to distribute extraordinary quantities of hydrocodone to numerous internet pharmacies. Moreover, with respect to some of the pharmacies, it actually distributed increasing quantities culminating with the 2.1 million dosage units it sold to Avee in November 2006.

In his testimony, Mr. Schwartz claimed that he did not become aware of Respondent's sales to the internet pharmacies and DEA's interest in the matter until on or about November 2, 2006, when DEA investigators visited Respondent and again met with its employees including Mr. Goodrich.[26] Mr. Schwartz testified that it took "a couple of days" for him to be given the notebook which DEA investigators had provided to Respondent before the July conference call and review it, and that on December 5, 2007—approximately four weeks later—he and Mr. Sempre (Respondent's owner) came to the decision to cease doing business with the Florida pharmacies.

While the ALJ credited Mr. Schwartz's testimony, I decline to give any weight to Respondent's stroke-of-midnight decision in determining the appropriate sanction. See, e.g., *Vico Products Co., Inc.*, v. *NLRB*, 333 F.3d 198, 211 (D.C. Cir. 2003). As an initial matter, I note that it should not have taken five weeks for Mr. Schwartz to even become aware of Respondent's sales to the internet pharmacies. Moreover, given the information Mr. Schwartz claims to have reviewed and his extensive experience in the industry, it should not have taken another four weeks to decide to stop selling to these entities.

Most importantly, the decision must be considered in light of the evidence that for nearly a year prior to it, Respondent distributed millions of dosage units of hydrocodone products to entities which were likely diverting the drugs. Moreover, Respondent continued to distribute hydrocodone to the pharmacies following at least two meetings in which DEA investigators discussed the questionable practices of these pharmacies. As the Seventh Circuit has noted, "[a]n agency rationally may conclude that past performance is the best predictor of future performance." *ALRA Laboratories, Inc.*, v. *DEA*, 54 F.3d 450, 452 (7th Cir. 1995). In short, Respondent's decision is too little, too late, to persuade me that it can be entrusted with a registration.

Nor does the other evidence Respondent presented regarding its remedial efforts persuade me that a sanction less than revocation is warranted. Respondent's distribution of 44 million dosage units of hydrocodone which were likely diverted caused extraordinary harm to the public health and safety. Moreover, the record establishes that Respondent had reason to know that the hydrocodone it distributed was likely being diverted.

As the record demonstrates, for nearly a year, Respondent repeatedly supplied these drug pushers with large quantities of hydrocodone. Respondent commenced supplying the pharmacies showing little interest in determining whether they were engaged in lawful activity. Moreover, Respondent continued to supply the pharmacies even after being advised by this Agency of the likely illegality of their activities. Finally, while Respondent eventually undertook some inquiries, it then frequently ignored the information it obtained from the pharmacies themselves, which indicated that they were likely filling unlawful prescriptions, and continued to supply most of them.

Given the scope of Respondent's conduct and the harm it caused, I decline to accept its assertions of reform. I therefore conclude that this factor also supports the conclusion that Respondent's continued registration "is inconsistent with the public interest." 21 U.S.C. 823(d). Finally, for the same reasons which led me to order the immediate suspension of Respondent's registration, I further hold that this order shall be effective immediately. See 21 CFR 1316.67.

* * * * *

My determination is based on the reasons set forth above, and those reasons are sufficient by themselves to support the revocation of Respondent's registration. There is, however, an additional consideration, which, while not necessary to decide this case, bears mentioning. Specifically, to allow Respondent to maintain its registration—even subject to the conditions as proposed by the ALJ and/or Respondent—would create a perverse incentive. A precedent which ignores how irresponsibly a registrant has acted and allows it to maintain its registration based on its claim of having reformed its business practices, could well prompt other registrants to ignore their obligations under the Act and sell massive quantities of controlled substances to diverters.

I acknowledge that proceedings under sections 303 and 304 of the CSA are non-punitive. *See Samuel S. Jackson* 72 FR 23848, 23853 (2007); *Leo R. Miller*, 53 FR 21931, 21932 (1988). Relatedly, DEA precedent holds that a proceeding under these provisions ' "is a remedial measure, based upon the public interest and the necessity to protect the public

[25] As for the Government's exception, when a party intends to rely on evidence contained in a CD–ROM, it has the obligation to prepare a summary setting forth what the data contained therein show. That summary must be prepared and served on opposing counsel along with a copy of the CD–ROM in advance of the hearing. It is not the responsibility of the ALJ or this Office to plumb the depths of such an exhibit to determine what the data show. Moreover, such evidence should not be admitted into the record unless the proponent of the exhibit establishes an adequate foundation for its admission by identifying and authenticating the exhibit; this must be done even if opposing counsel do not object to its admission.

[26] As Mr. Schwartz testified, "when a regulatory agency is on-site * * * everybody in the company knows about it. Word travels quickly." Tr. 937.

from those individuals who have misused * * * their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be [en]trusted with the responsibility carried by such a registration.'" *Jackson*, 72 FR at 23853 (quoting *Miller*, 53 FR at 21932).

Neither *Jackson* nor any other agency decision holds, however, that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be revoked. Moreover, even when a proceeding serves a remedial purpose, an administrative agency can properly consider the need to deter others from engaging in similar acts. *Cf. Butz* v. *Glover Livestock Commission Co., Inc.*, 411 U.S. 182, 187 (1973). Consideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest, see 21 U.S.C. 801, and the broad grant of authority conveyed in the CSA's statutory text, which authorizes the revocation of a registration when a registrant has committed acts that render its "registration * * * inconsistent with the public interest," id. 824(a)(4), and specifically directs the Attorney General to consider "such other factors as may be relevant to and consistent with the public health and safety." Id. 823(d)(6).

As noted by a recent study of the National Center on Addiction and Substance Abuse (CASA), "the abuse of controlled prescription drugs in America now eclipses abuse of all illicit drugs combined, except marijuana." GX 3 (Declaration of Joseph T. Rannazzisi). According to the CASA study, "between 1992 and 2003, abuse of controlled prescription drugs grew at a rate twice that of marijuana abuse, five times greater than cocaine abuse, and 60 times greater than heroin abuse." Id. Relatedly, CASA has found that the number of "controlled prescription drug-related visits to emergency rooms has increased three and a half times more than heroin-related visits and four times more than visits linked to cocaine abuse." Id. Moreover, "between 1994 and 2002, emergency department reports of hydrocodone * * * overdoses increased by 170 percent." Id.

Equally alarming are the results of the National Institute of Drug Abuse (NIDA) 2004 survey of eighth, tenth and twelfth grade school children. According to the survey, "9.3 percent of twelfth graders reported using Vicodin, a brand name Schedule III controlled substance containing hydrocodone, without a prescription in the previous year." Id.

Illegitimate internet sites play an increasingly large and disturbing role in facilitating the growth of prescription drug abuse. Id. at 1–2.; *see also William R. Lockridge*, 71 FR 77791 (2006). Because these websites allow a person to obtain a controlled substance based on a prescription which is issued outside of a legitimate doctor/patient relationship and the safeguards that relationship provides, "[a]nyone—including children—can easily obtain highly addictive controlled substances online." GX 3, at 2.

As stated above, these websites and the pharmacies that fill the prescriptions issued by them, are nothing more than drug pushers operating under the patina of legitimate authority. Cutting off the supply sources of these pushers is of critical importance in protecting the American people from this extraordinary threat to public health and safety. In accomplishing this objective, this Agency cannot do it all itself. It must rely on registrants to fulfill their obligation under the Act to ensure that they do not supply controlled substances to entities which act as pushers. And to make clear, because of the threat to public safety posed by the diversion of controlled substances through the internet, the deterrent value of a sanction is an appropriate consideration in proceedings brought under sections 303 and 304 of the CSA.

Order

Pursuant to the authority vested in me by 21 U.S.C 823(d) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, RS0204898, issued to Southwood Pharmaceuticals, Inc., be, and it hereby is, revoked. I further order that the pending application of Southwood Pharmaceuticals, Inc., for renewal of its registration be, and it hereby is, denied. Moreover, for the same reasons which led me to conclude that Respondent's continued registration constituted an imminent danger to public health and safety, this order is effective immediately.

Dated: June 22, 2007.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF LABOR

Employment and Training Administration

Special Guidelines for Processing H–2B Temporary Labor Certification in Tree Planting and Related Reforestation Occupations

AGENCY: Employment & Training Administration, Department Of Labor.

ACTION: Notice.

SUMMARY: This notice updates procedures for State Workforce Agencies and ETA National Processing Centers to process H–2B labor certification applications in tree planting and related reforestation occupations.

SUPPLEMENTARY INFORMATION:

I. References

Immigration and Nationality Act (INA) section 101(a)(15)(H)(ii)(b); 20 Code of Federal Regulations (CFR) Parts 652 and 655; 8 CFR 214.2(h)(6); **Federal Register** Notice, Vol. 70, No. 137, pps. 41430–41438; Migrant and Seasonal Agricultural Worker Protection Act, 29 U.S.C. 1801, *et seq.*; 29 CFR part 500; and Training and Employment Guidance Letter (TEGL) 21–06, Procedures for H–2B Temporary Labor Certification in Non-Agricultural Occupations.

II. Background

The H–2B nonimmigrant program permits employers to hire foreign workers to come to the United States (U.S.) and perform temporary non-agricultural services or labor on a one-time, seasonal, peakload, or intermittent basis. The H–2B visa classification requires the Secretary of Homeland Security to consult with appropriate agencies before admitting H–2B nonimmigrants. Homeland Security regulations require the intending employer first to apply for a temporary labor certification from the Secretary of Labor advising the Department of Homeland Security's United States Citizenship and Immigration Services (USCIS) as to whether qualified U.S. workers are available and whether the alien's employment will adversely affect the wages and working conditions of similarly employed U.S. workers, or a notice that such certification cannot be made, prior to filing an H–2B visa petition with USCIS.

However, in December 2004, the Department opened two new National Processing Centers (NPCs), one each located in Atlanta and Chicago. These Centers have been designated to process

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Opioid Treatment Guidelines

Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain

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Abstract: Use of chronic opioid therapy for chronic noncancer pain has increased substantially. The American Pain Society and the American Academy of Pain Medicine commissioned a systematic review of the evidence on chronic opioid therapy for chronic noncancer pain and convened a multidisciplinary expert panel to review the evidence and formulate recommendations. Although evidence is limited, the expert panel concluded that chronic opioid therapy can be an effective therapy for

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carefully selected and monitored patients with chronic noncancer pain. However, opioids are also associated with potentially serious harms, including opioid-related adverse effects and outcomes related to the abuse potential of opioids. The recommendations presented in this document provide guidance on patient selection and risk stratification; informed consent and opioid management plans; initiation and titration of chronic opioid therapy; use of methadone; monitoring of patients on chronic opioid therapy; dose escalations, high-dose opioid therapy, opioid rotation, and indications for discontinuation of therapy; prevention and management of opioid-related adverse effects; driving and work safety; identifying a medical home and when to obtain consultation; management of breakthrough pain; chronic opioid therapy in pregnancy; and opioid-related polices.

Perspective: ***Safe and effective chronic opioid therapy for chronic noncancer pain requires clinical skills and knowledge in both the principles of opioid prescribing and on the assessment and management of risks associated with opioid abuse, addiction, and diversion. Although evidence is limited in many areas related to use of opioids for chronic noncancer pain, this guideline provides recommendations developed by a multidisciplinary expert panel after a systematic review of the evidence.***

Key words: Clinical practice guideline, opioids, opioid analgesics, risk assessment, monitoring, chronic pain.

Editor's Note: The American Pain Society and the American Academy of Pain Medicine present this first of 3 articles in this 3-part report as a guideline for opioid treatment of noncancer pain.

Opioid analgesics are widely accepted for the treatment of severe acute pain and chronic pain related to active cancer or at the end of life. In contrast, the use of chronic opioid therapy (COT, see Appendix B, Glossary) to treat other types of chronic pain remains controversial. Chronic pain is defined by the *International Association for the Study of Pain* as "pain that persists beyond normal tissue healing time, which is assumed to be three months."[59] Chronic pain may occur in the context of numerous diseases and syndromes.[51,134] For the purposes of this guideline, all chronic pain disorders outside of cancer pain or pain at end of life are collectively labeled "chronic noncancer pain" (CNCP). CNCP conditions, including common conditions such as back pain, osteoarthritis, fibromyalgia, and headache, are extremely prevalent and account for very large costs. For back pain alone, total health care expenditures in 2004 and 2005 were estimated at $85 to $100 billion.[75] CNCP is a leading cause of disability[16,128] and can have deleterious effects on ability to work, functional status and other quality of life domains.

There are numerous treatments for CNCP and a comprehensive assessment is needed in every case to guide therapeutic decision making. Some patients with CNCP are appropriate for focused therapy with a small number of modalities. Patients with more complex cases, including those with disabling CNCP, tend to experience better outcomes if they are managed using a comprehensive approach that integrates strategies to improve pain with those that address the functional impairment and psychosocial factors that are often associated with CNCP.[88] Whether the plan of care is limited or is designed to be more comprehensive, opioid therapy may be a useful component of the management plan.[30,132] However, the selection of patients for an opioid trial, and decisions about chronic opioid therapy (COT), must weigh potential benefits of opioids against the risk of significant harms, including a wide range of adverse effects as well as adverse outcomes associated with abuse (refer to Appendix B, Glossary for definition) potential.

Opioid prescriptions have increased substantially over the last 20 years,[14,90] in part due to a growing consensus that opioid therapy is appropriate for some patients with CNCP.[132] An increase in prescription opioid misuse (see Glossary) and mortality associated with opioid use has also been observed, affecting adolescent and adults of all ages.[9] Clinicians and regulators must jointly seek a balanced approach to opioid use, acknowledging the legitimate medical need for opioids in some patients with CNCP, while concurrently recognizing the serious public health problem of abuse (see Appendix B, Glossary), addiction (see Appendix B, Glossary) and diversion (see Appendix B, Glossary), and implement procedures to reduce these risks.

The American Pain Society (APS), in partnership with the American Academy of Pain Medicine (AAPM), commissioned a multidisciplinary panel to develop evidence-based guidelines on COT for adults with CNCP. These recommendations are based on a systematic evidence review also commissioned by the APS and AAPM.[19]

Methods

Panel Composition

The APS and AAPM convened a multidisciplinary panel of 21 experts to review the evidence and formulate recommendations (see Appendix 1 for list of panel members). Two co-chairs (P.F. and G.F.) were selected by the APS and AAPM to lead the panel, which also included the Chair of the APS Clinical Practice Guidelines Committee (C.M.) and the APS Director of Clinical Guidelines Development (R.C.).

Target Audience and Scope

The intent of the guideline is to provide evidence-based recommendations for use of COT for CNCP in

both primary care and specialty settings. The target audience is all clinicians who provide care for adults with CNCP, including cancer survivors with chronic pain due to their cancer or its treatment. Management of cancer pain, pain at end of life, acute pain, postsurgical pain, labor pain, or CNCP in children and adolescents is outside the scope of this guideline. Separate APS guidelines address management of sickle cell pain[5] and cancer pain.[83]

Funding and Conflicts of Interest

Funding for the guideline was provided by the APS. The guideline was approved by the APS and AAPM, but the content of the guideline is the sole responsibility of the authors and panel members. All panelists were required to disclose conflicts of interest within the preceding 5 years at all face-to-face meetings and before submission of the guideline for publication, and recused themselves from votes if a conflict was present. Conflicts of interest of the authors and panel members are listed in Appendix 1.

Evidence Review

This guideline is informed by an evidence review conducted at the Oregon Evidence-based Practice Center and commissioned by APS and AAPM.[19] The panel developed the key questions, scope, and inclusion criteria used to guide the evidence review. Literature searches were conducted through November 2007. Investigators reviewed 8,034 abstracts from searches for systematic reviews and primary studies from multiple electronic databases, reference lists of relevant articles, and suggestions from expert reviewers. A total of 14 systematic reviews and 57 primary studies (not included in previously published systematic reviews) were included in the evidence report.[19]

Grading of the Evidence and Recommendations

The panel used methods adapted from the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group to rate the recommendations included in this guideline.[52] Each recommendation received a separate grade for the strength of the recommendation (strong or weak) and for the quality of evidence (high, moderate, or poor) (Appendix 2). In general, a strong recommendation is based on the panel's assessment that potential benefits of following the recommendation clearly outweigh potential harms and burdens. Given the available evidence, most clinicians and patients would choose to follow a strong recommendation. A weak rating is based on more closely balanced benefits to harms or burdens, or weaker evidence. Decisions to follow a weak recommendation could vary depending on specific clinical circumstances or patient preferences and values. For grading the quality of a body of evidence that supports a recommendation, we considered the type, number, size, and quality of studies; strength of associations or effects; and consistency of results among studies.[52]

Guideline Development Process

The guideline panel met in person on three occasions between September 2006 and January 2008. At the first meeting, the panel developed the scope and key questions used to guide the systematic evidence review. At the second meeting, the panel reviewed the results of the evidence review and drafted initial potential recommendation statements. In between the second and third meetings, panelists participated in a multi-stage Delphi process, in which the draft recommendations were ranked and revised. At each stage of the Delphi process, the lowest-ranked recommendations were eliminated. At the third meeting, the final set of recommendations and recommendation grades were finalized and approved. Although a two-thirds majority was required for a recommendation to be approved, unanimous agreement was achieved on all but two recommendations (5.2 and 5.3 each had 2 panelists voting against). After the third meeting, the guideline was written by various panel members and drafts distributed to the panel for feedback and revisions. Over twenty external peer reviewers were solicited for additional comments. After another round of revisions and panel approval, the guideline was submitted to the APS and AAPM Executive Committees for approval.

The APS intends to update its clinical practice guidelines regularly. This guideline and the evidence report used to develop it will be reviewed and updated by 2012, or earlier if critical new evidence becomes available.

Recommendations

1. Patient Selection and Risk Stratification

Recommendations

1.1 Before initiating COT, clinicians should conduct a history, physical examination and appropriate testing, including an assessment of risk of substance abuse, misuse, or addiction (strong recommendation, low-quality evidence).

1.2 Clinicians may consider a trial of COT as an option if CNCP is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh or are likely to outweigh potential harms (strong recommendation, low-quality evidence).

1.3 A benefit-to-harm evaluation including a history, physical examination, and appropriate diagnostic testing, should be performed and documented before and on an ongoing basis during COT (strong recommendation, low-quality evidence).

Proper patient selection is critical and requires a comprehensive benefit-to-harm evaluation that weighs the potential positive effects of opioids on pain and function against potential risks. Thorough risk assessment and stratification is appropriate in every case. This approach is justified by estimates of aberrant drug-related behaviors (see Appendix B, Glossary), drug abuse, or misuse

in patients with CNCP, which range from 0% to 50%, depending on the population evaluated and methods used to define and identify these outcomes.[57] Risk stratification pertaining to outcomes associated with the abuse liability of opioids—misuse, abuse, addiction and diversion—is a vital but relatively undeveloped skill for many clinicians.[96] However, all clinicians prescribing opioids should be knowledgeable about risk factors for opioid abuse and methods for assessing risk. Assessment of risks for opioid-associated adverse effects also should be performed, given their high prevalence.[86]

A thorough history and physical examination, including an assessment of psychosocial factors and family history, is essential for adequate risk stratification. Implicit in the recommendation to conduct a comprehensive benefit-to-harm analysis is the recognition that an opioid trial may not be appropriate. Clinicians should obtain appropriate diagnostic tests to evaluate the underlying pain condition, and should consider whether the pain condition may be treated more effectively with nonopioid therapy rather than with COT. For example, COT generally would not be appropriate before a trial of an anticonvulsant for trigeminal neuralgia,[7] a disease-modifying antirheumatic drug for rheumatoid arthritis,[27] a corticosteroid for polymyalgia rheumatica,[118] or various abortive and prophylactic therapies for migraine headache.

Reliable evidence on methods to accurately assess the potential benefits of COT is limited. However, randomized trials that demonstrate the benefits of COT are most applicable to patients with moderate or more severe pain who have not responded to nonopioid therapies.[42,63] Presence of poorly-defined pain conditions, a likely somatoform disorder, or unresolved compensation or legal issues may predict poorer response to all therapies, including COT.[103,114] Although neuropathic and non-neuropathic pain conditions appear in general to respond similarly to COT,[42,63,86] evidence that demonstrates the efficacy of COT for conditions with strong psychosocial contributors such as some types of chronic low back pain,[74] daily headache,[119] and fibromyalgia[48] is sparse. There is insufficient evidence to recommend use of an intravenous opioid trial to predict likelihood of benefit from COT.[63]

The factor that appears to be most strongly predictive of drug abuse, misuse, or other aberrant drug-related behaviors after initiation of COT is a personal or family history of alcohol or drug abuse.[28,35,60,72,85,111] Younger age and presence of psychiatric conditions are also associated with aberrant drug-related behaviors in some studies.[28,35,60,84,111] Preexisting constipation, nausea, pulmonary disease, and cognitive impairment probably predict risk for opioid-related adverse effects, though no studies have adequately evaluated the utility of these factors for use in risk stratification.

Clinicians should consider a trial of COT for CNCP when potential benefits are likely to outweigh risks, and there is no alternative therapy that is likely to pose as favorable a balance of benefits to harms. For example, a patient who is 60 years old, has chronic disabling osteoarthritis pain despite nonopioid therapies, and whose history reveals no significant psychiatric comorbidities, major medical comorbidities, or personal or family history of drug abuse or addiction would be assessed as having high potential benefits from COT relative to potential risks. COT could be prescribed to this patient in most clinical settings with routine monitoring (see Section 5). In contrast, a patient who is 30 years old with fibromyalgia and recent intravenous drug abuse would have high potential risks relative to benefits. COT in this context requires intensive structure, monitoring, and management by professionals with expertise in both addiction medicine and pain medicine and should be undertaken only if risks can be adequately managed (see Section 6). The selection of patients between these two extremes requires careful assessment and characterization of patient risk and structuring of care to match risk (see Section 5). In patients with a history of substance abuse or a psychiatric comorbidity, this may require assistance from persons with expertise in managing pain, addiction or other mental health concerns (see Section 6), and in some cases opioids may not be appropriate or should be deferred until the comorbidity has been adequately addressed.

Screening tools that assess the potential risks associated with COT based on patient characteristics are likely to be helpful for risk stratification, though more validation and prospective outcome studies are needed to understand how their use predicts and affects clinical outcomes. Tools that appear to have good content, face, and construct validity include the Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1 (Appendix 3),[10] the revised SOAPP (SOAPP-R),[12] the Opioid Risk Tool (ORT) (Appendix 4),[138] and the Diagnosis, Intractability, Risk, Efficacy (DIRE) instrument (Appendix 5).[4] DIRE is clinician-administered and is designed to assess potential efficacy as well as harms. The SOAPP Version 1, SOAPP-R and ORT are patient self-report questionnaires that assess risk of aberrant drug-related behaviors.

2. Informed Consent and Opioid Management Plans

Recommendations

2.1 When starting COT, informed consent should be obtained. A continuing discussion with the patient regarding COT should include goals, expectations, potential risks, and alternatives to COT (strong recommendation, low-quality evidence).

2.2 Clinicians may consider using a written COT management plan to document patient and clinician responsibilities and expectations and assist in patient education (weak recommendation, low-quality evidence).

Clinicians should inform patients about the risks and benefits associated with COT before initiating a trial of therapy.[30] In patients already on COT, clinicians should periodically review risks and benefits of therapy. Patients should be counseled about the potential for common opioid-related adverse effects (eg, constipation, nausea, sedation) as well as other serious risks (eg, abuse, addiction, overdose). Potential risks of long-term or high-dose

COT (eg, hyperalgesia (see Appendix B, Glossary), endocrinologic or sexual dysfunction) should also be discussed, though more evidence is needed to better understand and quantify these risks.[24,25,73,82] The goal of the consent process is to assist patients to make appropriate medical decisions that are consistent with their preferences and values. In some states, clinicians are required to document this discussion, though specific requirements vary.[95] A sample informed consent form is shown in Appendix 6.

It is important for clinicians to discuss a COT management plan before initiating a course of treatment and on an ongoing basis while patients are on therapy.[30] The COT management plan includes goals of therapy, how opioids will be prescribed and taken, expectations for clinic follow-up and monitoring (see Section 5), alternatives to COT, expectations regarding use of concomitant therapies, and potential indications for tapering or discontinuing COT, which may include failure to make progress toward therapeutic goals, intolerable adverse effects, or repeated or serious aberrant drug-related behaviors.[2] Patients should be counseled that opioids may be just one part of a multimodal treatment plan (see Section 9) to reduce pain intensity and improve quality of life, especially functional capacity. To avoid unrealistic patient expectations regarding likely benefits, patients should be counseled that total pain relief with COT is rare. Indeed, trials suggest that improvement averages less than 2 to 3 points on a 0 to 10 scale.[42,63]

Although evidence is lacking about the most effective methods to convey the COT management plan, written documentation can help clarify the plan with the patient, the patient's family, and other clinicians who may become involved in the patient's care. For patients at higher risk for misuse of opioid analgesics, use of clear written guidelines may be particularly helpful to reinforce expectations about the appropriate and safe use of opioids. Though the content of written COT management plans vary,[34] provisions may include: Obtaining opioids from one prescriber, filling opioids prescriptions at one designated pharmacy, random urine drug screens, office visits at a specified minimum interval, use of pill counts, limited prescriptions (in weekly or biweekly instead of monthly amounts) and enumeration of behaviors that may lead to discontinuation of opioids. However, there is insufficient evidence to guide specific recommendations on which provisions to include. A sample COT management plan is shown in Appendix 7.

There is increasing awareness that theft from medicine cabinets is a major source of diverted opioids. All patients should be encouraged to lock their medications (eg, using a medicine safe). Guidance is available on best methods for disposing of opioids.[89]

3. Initiation and titration of COT

Recommendations

3.1 Clinicians and patients should regard initial treatment with opioids as a therapeutic trial to determine whether COT is appropriate (strong recommendation, low-quality evidence).

3.2 Opioid selection, initial dosing, and titration should be individualized according to the patient's health status, previous exposure to opioids, attainment of therapeutic goals, and predicted or observed harms (strong recommendation, low-quality evidence). There is insufficient evidence to recommend short-acting versus long-acting opioids, or as-needed versus around-the-clock dosing of opioids.

An initial course of treatment with opioids for CNCP should be viewed as a short-term, therapeutic trial lasting from several weeks to several months. The decision to proceed with COT should be intentional and based on careful consideration of outcomes during the trial. Outcomes to consider include progress toward meeting therapeutic goals, presence of opioid-related adverse effects, changes in the underlying pain condition, changes in psychiatric or medical comorbidities, and the identification of aberrant drug-related behaviors, addiction, or diversion (see Section 5 on monitoring). In most cases, the therapeutic trial includes individualization of the dose through incremental dose escalations, as long as no serious harms are present. In patients who experience mild or moderate opioid-related adverse effects, a longer trial may be indicated because some adverse effects decrease with longer exposure. Some adverse effects can be managed with additional therapies (see Section 8). Suspected aberrant drug-related behaviors require further evaluation and action (see Section 6).

In patients who are opioid-naïve, or have modest previous opioid exposure, opioids should be started at a low dose and titrated slowly, to decrease risk of opioid-related adverse effects. However, there is insufficient evidence to recommend specific optimal starting doses and methods of dose titration. In general, opioid doses should be individualized based on risk for adverse outcomes and responses to therapy. Some patients, such as frail older persons or those with comorbidities, may benefit from more cautious initiation and titration of therapy. Short-acting opioids are probably safer for initial therapy since they have a shorter half-life and may be associated with a lower risk of inadvertent overdose. However, there is no direct evidence from randomized trials that demonstrates that any one opioid is superior to any other for initial therapy (see Section 4 for issues regarding methadone).[17] There is also insufficient evidence to guide recommendations for use of short-acting versus long-acting opioids,[17] or as-needed versus around-the-clock dosing. Proposed benefits of transitioning to long-acting opioids with around-the-clock dosing include more consistent control of pain, improved adherence and lower risk of addiction or abuse, though well-conducted studies have not examined these benefits.

4. Methadone

Recommendation

4.1 Methadone is characterized by complicated and variable pharmacokinetics and pharmacodynamics

and should be initiated and titrated cautiously, by clinicians familiar with its use and risks (strong recommendation, moderate-quality evidence).

Use of methadone for CNCP has increased dramatically.[15] However, few trials have evaluated benefits and harms of methadone for CNCP.[17] In addition, a number of epidemiologic studies suggest an increased rate of methadone-associated deaths in the United States.[15,44,76,91] QTc prolongation and cardiac arrhythmias may occur in patients on methadone, particularly at higher doses, or with concomitant use of drugs that interact with methadone or that themselves prolong QTc.[21,23,68]

Clinicians who prescribe methadone should be familiar with its clinical pharmacology and associated risks. Methadone has a very long and highly variable half-life, which necessitates careful titration to avoid delayed adverse events, such as overdose. Although the half-life of methadone is usually estimated at 15 to 60 hours, in some reports the half-life is as high as 120 hours.[71] In a patient for whom the methadone half-life is 60 hours, it would take almost 12 days on a stable dose of methadone to approach a steady state (5 half-lives). Methadone should therefore be started at low doses and titrated slowly. Based on panel consensus, a safe starting dose in most opioid-naïve patients is 2.5 mg every 8 hours, with dose increases occurring no more frequently than weekly. In older patients or those with renal or hepatic comorbidities, less frequent dosing and more cautious dose titration are recommended.

In opioid-tolerant patients, conversion to methadone should be performed cautiously. Equianalgesic dose ratios for methadone relative to other opioids are variable and can range from 0.1% to 10% morphine equivalents (lower at higher doses). In patients on lower doses of other opioids, safe starting doses of methadone may be similar to those used for opioid-naïve patients. Starting methadone doses should generally not exceed 30 to 40 mg a day even in patients on high doses of other opioids. Several algorithms are available for converting from other opioids to methadone, though there is insufficient evidence to recommend a particular method, and much of the evidence is derived from studies of patients with cancer.[49,69,112] Because of its long half-life and variable pharmacokinetics, the panel recommends that methadone not be used to treat breakthrough pain or as an as-needed medication.

5. Monitoring

Recommendations

5.1 Clinicians should reassess patients on COT periodically and as warranted by changing circumstances. Monitoring should include documentation of pain intensity and level of functioning, assessments of progress toward achieving therapeutic goals, presence of adverse events, and adherence to prescribed therapies (strong recommendation, low-quality evidence).

5.2 In patients on COT who are at high risk or who have engaged in aberrant drug-related behaviors, clinicians should periodically obtain urine drug screens or other information to confirm adherence to the COT plan of care (strong recommendation, low-quality evidence).

5.3 In patients on COT not at high risk and not known to have engaged in aberrant drug-related behaviors, clinicians should consider periodically obtaining urine drug screens or other information to confirm adherence to the COT plan of care (weak recommendation, low-quality evidence).

Clinicians should periodically reassess all patients on COT. Regular monitoring of patients once COT is initiated is critical because therapeutic risks and benefits do not remain static and can be affected by changes in the underlying pain condition, presence of coexisting disease, or changes in psychological or social circumstances. Monitoring is essential to identify patients who are benefiting from COT, those who might benefit more with restructuring of treatment or receiving additional services such as treatment for addiction, and those whose benefits from treatment are outweighed by harms. Insufficient evidence exists to guide precise recommendations on appropriate monitoring intervals. However, risk stratification (see Section 1) is useful for guiding the approach to monitoring. In patients at low risk for adverse outcomes and on stable doses of opioids, monitoring at least once every three to six months may be sufficient. Patients who may need more frequent or intense monitoring, at least for a period of time after initiation of therapy or changes in opioid doses, include those with a prior history of an addictive disorder, those in an occupation demanding mental acuity, older adults, patients with an unstable or dysfunctional social environment, and those with comorbid psychiatric or medical conditions. For patients at very high risk for adverse outcomes, monitoring on a weekly basis may be a reasonable strategy.

Monitoring that involves regular, repeated evaluations and addresses a variety of domains is likely to be more informative than infrequent, narrowly focused evaluations. Although there is insufficient evidence for specific recommendations about how to monitor patients on COT, there is general agreement that monitoring should routinely include assessment and documentation of pain severity and functional ability, progress toward achieving therapeutic goals, and presence of adverse effects.[98] In addition, clinicians should routinely carry out a thorough clinical assessment for presence of aberrant drug-related behaviors, substance use, and psychological issues. Because patient self-report may be unreliable for determining amount of opioid use, functionality, or aberrant drug-related behaviors,[31,67,110] pill counts, urine drug screening , family member or caregiver interviews, and use of prescription monitoring program data can be useful supplements. Although evidence is lacking on the accuracy and effects on clinical outcomes of formal screening instruments for identification of aberrant drug-related behaviors, use of tools with strong content, face and construct validity, such as the PADT (Appendix 8)[97,98] and COMM (Appendix 9)[11] are

recommended as an efficient method of assessment and documentation.

Periodic urine drug screening can be a helpful tool to monitor patients on COT.[65] Urine drug screening is likely to result in a higher yield in patients with risk factors for drug abuse or diversion. However, targeted (nonuniversal) urine drug screening will miss some proportion of patients who engage in aberrant drug-related behaviors, as predictors of such behaviors are relatively weak.[18] Random urine drug screens may be more informative than scheduled or routine testing, as patients may change behaviors when they expect to be tested, though there are no studies comparing these approaches. Although evidence on accuracy of urine drug screening to identify aberrant drug-related behaviors or diversion is lacking, and no evidence exists that demonstrates that screening improves clinical outcomes, absence of prescribed opioids or presence of unprescribed opioids or illicit drugs can be a marker for problematic issues that would not be apparent without urine drug screening.[67] Interpretation of urine drug screen results is a challenge, and requires an understanding of opioid drug metabolism, pharmacokinetics and limits of laboratory testing methods.[8] In fact, urine drug screen results usually do not suggest a definitive course of action, but rather should be interpreted in the context of individual patient circumstances.[55] Clinicians should consider a differential diagnosis for abnormal urine drug screen results, including drug abuse or addiction, self-treatment of poorly controlled pain, psychological issues, or diversion (which may be suggested by absence of prescribed opioids).

6. High-Risk Patients

Recommendations

6.1 Clinicians may consider COT for patients with CNCP and history of drug abuse, psychiatric issues, or serious aberrant drug-related behaviors only if they are able to implement more frequent and stringent monitoring parameters. In such situations, clinicians should strongly consider consultation with a mental health or addiction specialist (strong recommendation, low-quality evidence).

6.2 Clinicians should evaluate patients engaging in aberrant drug-related behaviors for appropriateness of COT or need for restructuring of therapy, referral for assistance in management, or discontinuation of COT (strong recommendation, low-quality evidence).

CNCP is common in patients with suspected aberrant drug-related behaviors, psychosocial comorbidities, and history of substance abuse.[115,129] Use of COT is challenging in these patients because they are more vulnerable to drug misuse, abuse, and addiction. In some patients, such as those actively using illicit drugs, potential benefits are outweighed by potential risks, and COT should not be prescribed outside of highly controlled and specialized settings (such as an opioid treatment program with directly observed therapy). In other patients, potential benefits of COT may outweigh potential risks. Although evidence is lacking on best methods for managing such patients, potential risks may be minimized by more frequent and intense monitoring compared with lower risk patients (see Section 5), authorization of limited prescription quantities, and consultation or co-management with persons who have expertise in addiction or mental health issues. In settings where local access to specialists is limited, clinicians may need to consider alternative methods (such as telemedicine or web-based resources) for obtaining consultative services, though there is no evidence evaluating risks and benefits compared with traditional face-to-face consultation. Clinicians should also be aware of and use prescription monitoring programs if they are available in their area of practice, as they can help identify patients who obtain drugs from multiple sources.[62]

The occurrence of aberrant drug-related behavior always suggests the need for re-evaluation, and perhaps a change in therapy. However, aberrant drug-related behaviors vary in seriousness. Clinicians should formulate a differential diagnosis when evaluating suspected aberrant drug-related behaviors (see Section 5).[41] The response to aberrant drug-related behavior reflects a clinical judgment about its seriousness, its cause or causes, the likelihood that behaviors of this type will recur, and the clinical context. Although evidence to guide optimal management strategies is lacking, anecdotal experience of panel members suggests that patients who are not assessed as being at high risk and engage in a relatively nonserious aberrant behavior, such as one or two episodes of unauthorized opioid escalations, can often be managed with patient education and enhanced monitoring. Patients who are repeatedly nonadherent and patients who engage in more serious aberrant behaviors (such as use of cocaine, use of unprescribed opioids, or obtaining opioids from multiple outside sources) may require consultation or referral (if not already done), major restructuring of therapy, and in many cases discontinuation of COT (see Section 7). In one study, four or more previous aberrant drug-related behaviors were a strong predictor of a current substance use disorder.[35] Patients who report a subjective sense of losing control regarding opioid use may also require restructuring of therapy, as this may predict future aberrant drug-related behaviors.[139] Patients who meet criteria for a substance use disorder should be referred for treatment of this serious comorbidity.

Restructuring of therapy may include more frequent or intense monitoring strategies, temporary or permanent tapering of opioid doses, or the addition of psychological therapies or other nonopioid treatments. In patients with opioid addiction who require ongoing pain treatment and do not respond to nonopioid analgesic interventions, structured opioid agonist treatment with methadone or buprenorphine by a licensed program may be an appropriate option. COT must be discontinued in patients who are known to be diverting opioids or in those engaging in seriously aberrant behaviors (such as injecting an oral formulation). Patients whose COT is to be discontinued may require referral or

consultation for assistance with opioid detoxification and management of withdrawal (see Section 7).

7. Dose Escalations, High-Dose Opioid Therapy, Opioid Rotation, and Indications for Discontinuation of Therapy

Recommendations

7.1 When repeated dose escalations occur in patients on COT, clinicians should evaluate potential causes and reassess benefits relative to harms (strong recommendation, low-quality evidence).

7.2 In patients who require relatively high doses of COT, clinicians should evaluate for unique opioid-related adverse effects, changes in health status, and adherence to the COT treatment plan on an ongoing basis, and consider more frequent follow-up visits (strong recommendation, low-quality evidence).

7.3 Clinicians should consider opioid rotation when patients on COT experience intolerable adverse effects or inadequate benefit despite dose increases (weak recommendation, low-quality evidence).

7.4 Clinicians should taper or wean patients off of COT who engage in repeated aberrant drug-related behaviors or drug abuse/diversion, experience no progress toward meeting therapeutic goals, or experience intolerable adverse effects (strong recommendation, low-quality evidence).

Management of treatment-refractory patients on high doses of COT is challenging. Although progressively higher opioid doses may improve symptom control in some patients, repeated dose escalations can also be a marker for a substance use disorder or diversion. In some patients, repeated dose escalations may have limited utility because of adverse effects, the lack of incremental benefit with higher doses, or other factors. Theoretically, opioids have no maximum or ceiling dose, but there is little evidence to guide safe and effective prescribing at higher doses and there is no standardized definition for what constitutes a "high" dose. By panel consensus, a reasonable definition for high dose opioid therapy is >200 mg daily of oral morphine (or equivalent), based on maximum opioid doses studied in randomized trials[42,63] and average opioid doses observed in observational studies.[105] Some studies suggest that hyperalgesia,[1,20] neuroendocrinologic dysfunction,[25,70] and possibly immunosuppression[113,116] may be more likely at higher opioid doses, though more evidence is needed to define these risks, their relationship to dose, and their relationship to clinical outcomes.

Clinicians should carefully reassess (see Section 5) all patients on COT who have repeated dose escalations. When opioid doses reach 200 mg daily of morphine (or equivalent), more frequent and intense monitoring is often appropriate, to sufficiently inform the decision to continue therapy or consider additional dose escalations. Opioid treatment may require restructuring (including weaning or discontinuation of COT) if assessments indicate reduced analgesia, function, or quality of life; aberrant drug-related behaviors; or the presence of intolerable adverse effects.

Opioid rotation (switching from one opioid to another opioid) is a potential strategy for patients on COT who experience intolerable adverse effects or inadequate benefit despite dose increases. The theory behind opioid rotation is based on concepts of incomplete cross-tolerance to the analgesic and nonanalgesic effects across opioids and a high degree of individual variation in response to different opioids. This could potentially lead to a better balance of benefits to harms when one opioid is changed to another.[80,108] However, well-designed studies that evaluate the benefits and harms of opioid rotation are lacking, and available studies in patients with CNCP show inconsistent results.[38-40] There is also insufficient evidence to guide specific recommendations for performing opioid rotation. Dose conversion tables and rotation protocols are available[102] and generally suggest that a switch to a new drug should be accompanied by a moderate (usually 25% to 50%) reduction in the calculated equianalgesic dose. However, this method does not apply to cases in which patients are being rotated to methadone (see Section 4).

Patients should be tapered or weaned off COT when they engage in serious or repeated aberrant drug-related behaviors or diversion, experience intolerable adverse effects, or make no progress toward meeting therapeutic goals. Although there is insufficient evidence to guide specific recommendations on optimal strategies, a taper or wean can often be achieved in the outpatient setting in patients without severe medical or psychiatric comorbidities. When available, opioid detoxification in a rehabilitation setting (outpatient or inpatient) can be helpful, especially for patients unable to reduce their opioid dose in a less structured setting. When aberrant drug-related behaviors are a continuing issue, the clinician may need to enforce weaning efforts. If the aberrant behaviors are thought to be due to addiction, addiction treatment resources should be made available and continued follow-up arranged to provide both support for nonopioid pain management and to motivate the patient to seek treatment for addiction.

Symptoms of opioid withdrawal can be very unpleasant, but are generally not life threatening. Approaches to weaning range from a slow 10% dose reduction per week to a more rapid 25% to 50% reduction every few days. Evidence to guide specific recommendations on the rate of reduction is lacking, though a slower rate may help reduce the unpleasant symptoms of opioid withdrawal.[22,109,131] Factors that may influence the rate of reduction include the reason driving the decision to discontinue COT, presence of medical and psychiatric comorbidities, the starting dose, and the occurrence of withdrawal symptoms as the process is initiated. Anecdotal clinical experience of panel members suggests that at high doses (eg, over 200 mg/d of morphine or equivalent), the initial wean can be more rapid. The rate of dose reduction often must be slowed when relatively low daily doses, such as 60 to 80 mg daily of morphine (or equivalent), are reached, due to occurrence

of more withdrawal symptoms. Patients weaned from COT because of lack of effectiveness may report improvements in well-being and function without any worsening in pain,[3] though other patients may experience pain hypersensitivity during opioid withdrawal.[1] Clinicians should continue to treat patients who are withdrawn from COT for their painful condition as well as for substance use or psychiatric disorders.

8. Opioid-Related Adverse Effects

Recommendation

8.1 Clinicians should anticipate, identify, and treat common opioid-associated adverse effects (strong recommendation, moderate-quality evidence).

An important goal of any COT management plan is to maintain a favorable balance of benefits relative to harms. Anticipation and treatment of opioid-associated adverse effects reduce the likelihood that patients will discontinue COT due to intolerable adverse effects, and may allow use of higher opioid doses if needed for uncontrolled pain.

Constipation is one of the most common opioid-related adverse effects.[86] Most patients develop some degree of constipation after opioid initiation or dose increases, and resolution of constipating effects of opioids often does not occur with continued exposure. In older adults or other patients with additional reasons to develop constipation, we recommend routinely considering initiation of a bowel regimen before the development of constipation. Though most evidence is anecdotal, bowel regimens including increased fluid and fiber intake, stool softeners, and laxatives are often effective. There is insufficient evidence to recommend oral opioid antagonists to prevent or treat opioid-induced bowel dysfunction in persons with CNCP, though randomized trials suggest some potential benefits over placebo.[100,137]

Nausea or vomiting is another common opioid-associated adverse effect that tends to diminish over days or weeks of continued opioid exposure. A number of antiemetic therapies, in both oral and rectal forms, are available to treat nausea or vomiting.

Sedation or clouded mentation after opioid initiation also tends to wane over time. When initiating or changing doses of opioids, patients should be counseled about driving and work and home safety (see Section 10). In addition, patients should be counseled on effects and risks of concomitant exposure to other drugs and substances with sedating effects. There is insufficient evidence to recommend specific pharmacologic therapies for persistent opioid-related sedation.

Chronic use of sustained-release oral opioids for CNCP was associated with hypogonadism and decreased levels of dehydroepiandrosterone sulfate in several cross-sectional studies.[24-26] Patients should be tested for such hormonal deficiencies if they report symptoms consistent with their presence, such as decreased libido, sexual dysfunction, or fatigue. Insufficient evidence exists to recommend routine monitoring of asymptomatic patients on COT for CNCP for hormonal deficiencies, or to guide specific treatment approaches if a deficiency is identified.

Other common opioid-related adverse effects include pruritus and myoclonus. Effective treatment strategies for either condition are largely anecdotal. Respiratory depression may occur when initial opioid doses are too high, opioids are titrated too rapidly, or opioids are combined with other drugs that are associated with respiratory depression or that may potentiate opioid-induced respiratory depression (such as benzodiazepines). Patients with sleep apnea or other underlying pulmonary conditions may be at higher risk for respiratory depression and opioids should be initiated and titrated carefully.

9. Use of Psychotherapeutic Cointerventions

Recommendation

9.1 As CNCP is often a complex biopsychosocial condition, clinicians who prescribe COT should routinely integrate psychotherapeutic interventions, functional restoration, interdisciplinary therapy, and other adjunctive nonopioid therapies (strong recommendation, moderate-quality evidence).

CNCP is often a complex condition that may involve biological, psychological, and environmental factors.[88] When pain is accompanied by comorbidities, impaired function, or psychological disturbances, COT is likely to be most effective as part of multimodality treatment that addresses all of these domains. Clinicians should routinely integrate therapies that target the psychosocial and functional factors that contribute to or are affected by CNCP.

Cognitive-behavioral therapy is the best-studied psychological therapy and is consistently shown to be effective for CNCP.[56,78,87,92,133] It often focuses on helping patients cope with chronic pain to improve function. Other potentially beneficial psychological therapies include progressive relaxation, biofeedback, and other techniques.[133] Functional restoration with specific behavioral interventions, pain education, and simulated or actual physical tasks in a supervised environment may enhance function and improve strength, endurance, flexibility, and cardiovascular fitness.[121] Interdisciplinary or multidisciplinary pain management approaches coordinate physical, vocational, or psychological components and are provided by at least two health care professionals with different clinical backgrounds, and may be the best method for providing multimodality therapy for the highly disabled CNCP patient.[36,53,64] The intensity and content of interdisciplinary therapy varies widely, but most involve an exercise program and some type of psychological therapy. More intensive interdisciplinary programs tend to be more effective than less intensive programs.[53] Barriers to obtaining interdisciplinary therapy include high costs, limited availability in the United States, and frequent lack of insurance coverage. In addition, patients are more likely to benefit if highly

motivated to participate, because interdisciplinary rehabilitation generally requires a high degree of engagement and commitment of time and effort.

10. Driving and Work Safety

Recommendation

10.1 Clinicians should counsel patients on COT about transient or lasting cognitive impairment that may affect driving and work safety. Patients should be counseled not to drive or engage in potentially dangerous activities when impaired or if they describe or demonstrate signs of impairment (strong recommendation, low-quality evidence).

Opioids may cause somnolence, clouded mentation, decreased concentration, and slower reflexes or incoordination, especially when initiating therapy, increasing doses, or when opioids are taken with other drugs or substances that affect the central nervous system.[86,101,126] These effects could impair patients' abilities to drive or work safely. However, epidemiologic studies suggest that motor vehicle accidents, fatalities, and citations for impaired driving are not disproportionally associated with opioid use.[32,33] Other studies indicate that patients who initiate opioids or are on COT perform similarly to patients not on COT on standardized driving tests.[13,43,45,79,117] Shortcomings of the evidence include a reliance on cross-study comparisons (eg, rates of opioid use in persons involved in motor vehicle accidents compared with estimates of opioid use in the general population), use of simulated and other controlled driving tests that may not completely mirror real-world driving conditions, and probable selection bias, as patients experiencing central nervous system opioid-related adverse effects are probably less likely to drive or to participate in studies that evaluate driving ability. No studies have evaluated the effects of COT on work safety.

As a public health measure and for the individual patient's safety, clinicians should counsel all patients initially prescribed COT not to drive or engage in potentially dangerous work or other activities when impaired. Patients should be educated about the greater risk of impairment when starting opioid therapy, when increasing doses, and when taking other drugs or substances that may have central nervous effects, including alcohol. Clinicians should counsel patients not to drive or engage in potentially dangerous activities if they describe or demonstrate signs of impairment, and should refer to state laws regarding physician-reporting requirements to local authorities in these situations. In the absence of signs or symptoms of impairment, no evidence exists to suggest that patients maintained on COT should be restricted from driving or engaging in most work activities. Some studies suggest that COT may improve cognitive functioning due to better control of pain.[61,130] However, clinicians should be aware that certain professions (such as bus drivers and pilots) may be subject to additional regulations and laws regarding use of opioids.

11. Identifying a Medical Home and When to Obtain Consultation

Recommendations

11.1 Patients on COT should identify a clinician who accepts primary responsibility for their overall medical care. This clinician may or may not prescribe COT, but should coordinate consultation and communication among all clinicians involved in the patient's care (strong recommendation, low-quality evidence).

11.2 Clinicians should pursue consultation, including interdisciplinary pain management, when patients with CNCP may benefit from additional skills or resources that they cannot provide (strong recommendation, moderate-quality evidence).

Studies show that patients do better when they have continuous access to a clinician who provides comprehensive care for the large majority of their health care needs and who coordinates care when the services of other health care professionals are needed.[127] Having a clinician who accepts primary responsibility for their overall medical care is likely to be particularly important for patients with CNCP, as they use health care services more frequently[122] and have more comorbidities[136] than those without CNCP. US adults with a primary care clinician, rather than a specialist, as their main health care provider had 33% lower costs of care and were 19% less likely to die at a given age compared with a matched cohort, after adjusting for demographic and health characteristics.[37] Having a primary care clinician is a powerful predictor of longevity.[124]

The attributes of effective primary care were described recently in a model known as the patient-centered primary care medical home.[99] With their multiple and complex health care needs, patients with CNCP require the coordinated and comprehensive services offered through a medical home. The medical home model does not necessarily require the primary care clinician to prescribe and monitor COT. In fact, patients with CNCP may need additional or special services that may not be available in their medical home. In such cases, consultation with other professionals is essential. In particular, pain centers that provide access to an array of pain therapies and specialists trained to assess, prescribe, and monitor COT can be highly valuable. Nonetheless, the primary care clinician should continue to coordinate consultation and communication among all clinicians involved in the patient's treatment.

12. Breakthrough Pain

Recommendation

12.1 In patients on around-the-clock COT with breakthrough pain, clinicians may consider as-needed opioids based upon an initial and ongoing analysis of therapeutic benefit versus risk (weak recommendation, low-quality evidence).

Patients prescribed stable doses of around-the-clock COT for CNCP frequently experience periods of increased

pain (ie, breakthrough pain).[6,106] Breakthrough pain (see Appendix B, Glossary) should be assessed separately from the baseline pain, and can be related to progression of the underlying condition, or a new or unrelated pain condition. Appropriate evaluation of breakthrough pain may require additional diagnostic testing, follow-up visits, or consultation in order to identify the etiology of the pain or the factors precipitating it. Management of breakthrough pain should include consideration of specific therapies directed at the cause of the pain or the precipitating factors, or nonspecific symptomatic therapies intended to lessen the impact of breakthrough pain when it occurs.

There is insufficient evidence to guide recommendations regarding optimal treatment strategies for breakthrough pain in patients with CNCP. Limited evidence from short-term trials suggest that short-acting or rapid onset, as-needed opioids may be effective in this setting, but more studies are needed to evaluate the long-term benefits and harms of this strategy, and to compare effects of different short-acting or rapid onset opioids.[104,125] Clinicians should weigh carefully the potential benefits versus risks when considering the addition of an as-needed opioid for treatment of breakthrough pain, and consider both nonopioid drug therapies and nonpharmacologic treatments as other options. Although there is no evidence on the risk of aberrant drug-related behavior in relation to the availability of medication prescribed for breakthrough pain, it is reasonable to assume that access to a short-acting drug may increase the risk of such behavior in those already engaging in them or at high risk to do so. In patients at low risk for aberrant drug-related behaviors, a trial of an as-needed opioid with routine follow-up and monitoring may be a reasonable strategy. In patients at higher risk for aberrant drug-related behaviors, a trial of an as-needed opioid should only occur in conjunction with more frequent monitoring and follow-up. In all cases, clinicians should carefully assess for aberrant drug-related behaviors and progress toward meeting therapeutic goals, and periodically reassess relative benefits to risks of the as-needed opioid to make appropriate decisions regarding continuation of this therapy.

13. Opioids in Pregnancy

Recommendation

13.1 Clinicians should counsel women of childbearing potential about the risks and benefits of COT during pregnancy and after delivery. Clinicians should encourage minimal or no use of COT during pregnancy, unless potential benefits outweigh risks. If COT is used during pregnancy, clinicians should be prepared to anticipate and manage risks to the patient and newborn (strong recommendation, low-quality evidence).

Managing CNCP in pregnant women is challenging. COT in this setting affects at least two patients, one of whom (the fetus) is unable to consent to treatment. In addition, due to the paucity of research that has been done, or is likely to be done for ethical reasons, it is difficult to evaluate benefits and risks of COT in pregnancy. Most of the literature on pregnancy and opioids has focused on women in methadone maintenance treatment, or women who used opioids for analgesia during labor, rather than COT for CNCP.

Although there are survey data that associate the use of COT during pregnancy with adverse newborn outcomes including low birth weight, premature birth, hypoxic-ischemic brain injury, and neonatal death,[54] it is difficult to separate effects of opioid use from other maternal factors that may contribute to these adverse newborn outcomes.[29] Other neonatal complications associated with maternal opioid use include prolonged QT syndrome and opioid withdrawal syndrome. The risks of adverse neonatal outcomes may be lower when women are on methadone for chronic pain management rather than for opioid dependence treatment.[123] Higher doses of antenatal methadone in tolerant mothers do not seem to increase complication rates.[77]

Given potential risks of opioids during pregnancy, clinicians should counsel women about risks and benefits of COT and recommend minimal or no use of opioids unless potential benefits outweigh risks (eg, severe disabling pain only controllable with opioids). Clinicians who care for pregnant women on COT must be prepared to address the additional risks. While antenatal harms may be difficult to predict and prevent, opioid withdrawal can be expected in up to half of newborns of opioid-dependent mothers. If the mother is receiving COT at or near the time of delivery, a professional who is experienced in the management of neonatal withdrawal should be available.

14. Opioid Policies

Recommendation

14.1 Clinicians should be aware of current federal and state laws, regulatory guidelines, and policy statements that govern the medical use of COT for CNCP (strong recommendation, low-quality evidence).

Surveys show that clinicians have a poor or limited understanding of the laws, regulations, and other policies that govern the prescribing, dispensing, or administration of controlled substances, including opioid analgesics.[46,107] Little research has been conducted to determine the extent that clinicians' knowledge of policies impacts healthcare practice and patient care.[47] However, clinicians are more vulnerable to regulatory investigation or discipline if they fail to comply with practice standards or regulations. Clinicians who prescribe COT for CNCP should be aware of the substantial policy changes that have occurred in recent years, and take steps to understand their responsibilities under federal and state laws, regulations, and other governmental policies that govern such practice. Resources are available to provide clinicians with information regarding opioid-prescribing policies in all 50 states and the District of Columbia.[93-95]

Conclusions

Use of COT for CNCP has been steadily increasing for 2 decades. Guidelines based on the best available

evidence and developed by multidisciplinary panels of experts are critical for promoting the effective and safe use of COT for CNCP. Although evidence is limited, an expert panel convened by APS and AAPM concludes that COT can be an effective therapy for carefully selected and monitored patients with CNCP. However, opioids are also associated with potentially serious harms, including opioid-related adverse effects and outcomes related to the abuse potential of opioids. The guidelines presented in this document are based on the underlying assumption that safe and effective therapy requires clinical skills and knowledge in both the principles of opioid prescribing and on the assessment and management of risks associated with opioid abuse, addiction, and diversion.

Although these guidelines are based on a systematic review of the evidence on COT for CNCP, the panel identified numerous research gaps. In fact, the panel did not rate any of its 25 recommendations as supported by high quality evidence. Only 4 recommendations were viewed as supported by even moderate quality evidence. Nonetheless, the panel came to unanimous consensus on almost all of its recommendations. Optimally balancing benefits and risks of COT for CNCP is dependent on careful patient evaluation and structuring of opioid therapy to accommodate identified risk, appropriate initiation and titration of COT, regular and comprehensive monitoring while on COT, and anticipation and management of opioid-related adverse effects. Other areas of strong consensus include recommendations to use therapies targeting psychosocial factors and to identify a medical home for all chronic pain patients. Critical research gaps are present in methods for providing informed consent, effective components of opioid management plans, balancing risks and benefits of high-dose opioid therapy, utility of opioid rotation, and treatment of breakthrough pain. More research is also needed on how policies that govern prescribing and use of COT affect clinical outcomes.

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Note: Clinical practice guidelines are "guides" only and may not apply to all patients and all clinical situations. As part of a shared decision making approach, it may be appropriate for the clinician to inform a patient that a particular recommendation may not be applicable, after considering all circumstances pertinent to that individual.

Supplementary Data

Supplementary data accompanying this article is available online at www.jpain.org, www.sciencedirect.com, and at doi:10.1016/j.jpain.2008.10.008. The supplementary data include Appendices 1–9.

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Appendix A

American Pain Society and American Academy of Pain Medicine Opioids Guidelines Panel Members; Discipline and Affiliation

Director, APS Clinical Guidelines Project, Roger Chou, MD – Internal Medicine, Oregon Health and Sciences University – Oregon Evidence-based Practice Center.

Co-chairs: Gilbert J. Fanciullo, MD, MS – Anesthesiology/Pain Medicine, Dartmouth-Hitchcock Medical Center, Department of Anesthesiology, Pain Management Center.

Perry G. Fine, MD, Anesthesiology/Pain Medicine and Palliative Care, University of Utah, Pain Research Center.

Chair, APS Clinical Practice Guidelines Committee: Christine Miaskowski, RN, PhD, FAAN, Registered Nurse/Pain Medicine, University of San Francisco, Department of Physiological Nursing.

Panel: Jeremy A. Adler, MS, PA-C, Physician Assistant, Pacific Pain Medicine Consultants.

Jane C. Ballantyne, MD, Anesthesiology/Pain Medicine, Massachusetts General Hospital, Department of Anesthesia and Critical Care.

Pamela Davies, MS, ARNP, Nurse Practitioner/Pain Medicine, Seattle Cancer Care Alliance (Formerly Internal medicine, Veterans Affairs Medical Center, Seattle).

Marilee I. Donovan, PhD, RN, Registered Nurse/Pain Medicine, Kaiser Permanente Northwest, Pain Management Clinic.

David A. Fishbain, MD, FAPA, Psychiatry/Pain Medicine, University of Miami, School of Medicine, Neurological Surgery and Anesthesiology.

Kathy M. Foley, MD, Neurology/Pain Medicine and Palliative Care, Memorial Sloan-Kettering Cancer Center, Pain and Palliative Care Service, Department of Neurology.

Jeffrey Fudin, BS, PharmD, DAAPM, Clinical Pharmacy, Samuel S. Stratton Department of Veterans Affairs Medical Center, and Albany College of Pharmacy & Health Sciences.

Aaron M. Gilson, PhD, Health Policy, University of Wisconsin Paul P. Carbone Comprehensive Cancer Center, Pain and Policy Studies Group.

Alexander Kelter, MD, Public Health, California Department of Health Services, Epidemiology and Prevention for Injury Control (EPIC) Branch (retired 2005).

Alexander Mauskop, MD, FAAN, Neurology, New York Headache Center, State University of New York, Downstate Medical Center.

Patrick G. O'Connor, MD, MPH, Internal Medicine, Yale University School of Medicine and Yale-New Haven Hospital, Section of General Internal Medicine.

Steven D. Passik, PhD, MA, Psychology/Addiction, Memorial Sloan-Kettering Cancer Center, Department of Psychiatry and Behavioral Sciences.

Gavril W. Pasternak, MD, PhD, Neuropharmacology, Memorial Sloan-Kettering Cancer Center, Laboratory of Molecular Neuropharmacology.

Russell K. Portenoy, MD, Neurology/Pain Medicine and Palliative Care, Beth Israel Medical Center, Department of Pain Medicine and Palliative Care.

Ben A. Rich, JD, PhD, Law/Ethics, University of California, Davis, School of Medicine, Division of Bioethics.

Richard G. Roberts, MD, JD, FAAFP, FCLM, Family Practice, University of Wisconsin, School of Medicine and Public Health.

Knox H. Todd, MD, MPH, FACEP, Emergency Medicine, Beth Israel Medical Center - Pain and Emergency Medicine Institute.

Appendix B. Glossary

Term	*Definition*
Aberrant drug-related behavior	A behavior outside the boundaries of the agreed on treatment plan which is established as early as possible in the doctor-patient relationship.[50]
Abuse	Any use of an illegal drug, or the intentional self-administration of a medication for a nonmedical purpose such as altering one's state of consciousness, for example, getting high.[66]
Addiction	A primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.[120]
Breakthrough pain	Transient or episodic exacerbation of pain that occurs in patients with pain that is otherwise considered stable but persistent[81]
Chronic opioid therapy	Daily or near-daily use of opioids for at least 90 days, often indefinitely (adapted from Von Korff et al).[135]
Diversion	The intentional transfer of a controlled substance from legitimate distribution and dispensing channels.[66]
Hyperalgesia	An increased response to a stimulus which is normally painful.[58]
Misuse	Use of a medication (for a medical purpose) other than as directed or as indicated, whether willful or unintentional, and whether harm results or not.[66]
Physical dependence	A state of adapation manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.[120]
Tolerance	A state of adapation in which exposure to a drug induces changes that result in a diminution of one or more opioid effects over time.[120]

Appendix 1. List of Panel Members and Conflict of Interest Statements

Director, APS Clinical Guidelines Project

Roger Chou, MD

Oregon Health & Sciences University - Oregon Evidence-based Practice Center

- No conflicts to report

Co-chairs

Gilbert J. Fanciullo, MD, MS

Dartmouth-Hitchcock Medical Center - Deptartment of Anesthesiology, Pain Management Center

Fee Income:

- Medtronic: Research grant; Speaker, Consultant
- Janssen: Research support
- Teva Pharmaceuticals: Expert Witness
- Pfizer: Educational support for Fellows in Dartmouth Fellowship Program

Perry G. Fine, MD

University of Utah - Pain Research Center

Fee Income:

- Combined honoraria income (exceeding $10,000) from serving on advisory boards related to opioid analgesics for Alpharma, Cephalon, Endo Pharmaceuticals, GlaxoSmithKline, Lilly, Merck, NIH, Ortho-McNeil (J & J), Purdue Pharma, and Wyeth
- Total income of above sources over last three years estimated at $30,000

Ownership interests:

- 17,500 shares in ZARS Pharma, a privately owned company that develops opioid delivery systems

Chair, APS Guidelines

Christine Miaskowski, PhD, RN, FAAN

University of San Francisco - Department of Physiological Nursing

Fee Income:

- Consultant/Speaker' Bureaus for Anesta, Cephalon, Endo,GlaxoSmithKline, Merck, and Pricara

Panel

Jeremy A. Adler, MS, PA-C

Pacific Pain Medicine Consultants

Fee Income:

- Advisory Board member: Alpharma
- Speaker's Bureau: Alpharma, Elan, Endo, Pfizer, and Victory pharmaceutical companies

Jane C. Ballantyne, MD

Massachusetts General Hospital - Department of Anesthesia and Critical Care

Fee Income:

- Harvard International Outreach in Geneva & Bern, Switzerland – 4 weeks sponsored by Novartis, August 2005
- Evidence Base of Acute Pain Management Panel of Experts – results published in *Anesthesia & Analgesia*, sponsored by Orthopedic Review, November 2005
- Hydromorphone Expert Panel/Advisory – sponsored by Endo Pharmaceuticals, May 2006
- Harvard Medical School received $1,500, 000 from Purdue Pharma used to sponsor research and education programs at Massachusetts General Hospital Pain Unit

Appendix 1. Continued

Pamela Davies, MS, ARNP
Seattle Cancer Care Alliance
Fee Income:
- Received honorarium payments from Alpharma and Endo Pharmaceuticals for work as Clinical Advisor
- Received honorarium from Endo Pharmaceuticals for work at University of Washington, School of Nursing Continuing Education
- Total of all honoraria in last 3 years: approximately $5,000

Marilee I. Donovan, PhD, RN
Kaiser Permanente Northwest - Pain Management Clinic
Employment:
- Manager of Kaiser-Permanente Northwest region Pain Management Clinic
- Application for ROI to develop predictors of addiction
- Department accepts test equipment from vendors who then sell department equipment and supplies for interventional pain management procedures
- Consultant to JCAHO re: pain standards
- Clinical lead for outcomes process for Kaiser-Permanente Chronic Pain Guidelines

David A. Fishbain, MD, FAPA
University of Miami - School of Medicine, Neurological Surgery and Anesthesiology
- No conflicts to report

Kathy M. Foley, MD
Memorial Sloan-Kettering Cancer Center - Pain & Palliative Care Service, Department of Neurology
- No conflicts to report

Jeffrey Fudin, BS, PharmD, DAAPM
Samuel S. Stratton Department of Veterans Affairs Medical Center, and Albany College of Pharmacy & Health Sciences
Fee Income:
- Speakers Bureaus for Advisory Boards: Abbott (less than $10,000), Alpharma (less than $10,000), Calloway Labs, Janssen, and Pricara (division of Ortho-McNeil)
- Janssen: Research support
- Teva Pharmaceuticals: Expert Witness

Appendix 1. Continued

Aaron M. Gilson, PhD
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center - Pain & Policy Studies Group
Fee Income:
- Consulting responsibilities for the American Cancer Society
- Honorarium payment for presentations at the Pharmacy Society of Wisconsin and the Federation of State Medical Boards of the U.S., and from Janssen Pharmaceuticals.
- The Pain & Policy Studies Group at The University of Wisconsin receives unrestricted educational grants from Alpharma, Endo Pharmaceuticals, and Purdue Pharma

Research Funding:
- Robert Wood Johnson Foundation, Federation of State Medical Boards of the U.S.
- Research projects at the Pain & Policy Studies Group at The University of Wisconsin are funded by grants from the American Cancer Society, Susan B. Komen for the Cure, U.S. Cancer Pain Relief Committee, and through a cooperative agreement with the Lance Armstrong Foundation
- Project funding is pending for R03 project at the Pain & Policy Studies Group

Alexander Kelter, MD
California Department of Health Services - Epidemiology & Prevention for Injury Control (EPIC) Branch (retired 2005)
- No conflicts to report

Alexander Mauskop, MD, FAAN
New York Headache Center
State University of New York, Downstate Medical Center
- No conflicts to report

Patrick G. O'Connor, MD, MPH
Yale University School of Medicine and Yale-New Haven Hospital - Section of General Internal Medicine
- No conflicts to report

Steven D. Passik, PhD, MA
Memorial Sloan-Kettering Cancer Center - Department of Psychiatry and Behavioral Sciences
Fee Income:
- Consultant/Speaker' Bureaus for Alpharma, Cephalon, Endo, King, Ligand, Lilly, and, Pricara pharmaceutical companies
- Honoraria for speaking on pain/addiction and risk management from Ligand, Cephalon, Endo, Alpharma, Purdue, and Mallinckrodt pharmaceutical companies

Research Funding:
- Have received grant/research support from Cephalon, Lilly, Amgen, Janssen, and Ligand companies

Gavril W. Pasternak, MD, PhD
Memorial Sloan-Kettering Cancer Center - Laboratory of Molecular Neuropharmacology
Fee Income:
- Consultant/Scientific Advisory Boards for Sarentis, Traxon, EpiCept, Limmerick, and QrxPahrma companies
- Honoraria from Adolor, Endo, Cephalon, and Ortho-McNeill pharmaceutical companies

Research Funding:
Have received grant/research support from Sarentis for preclinical evaluation of drug candidates

Appendix 1. Continued

Russell K. Portenoy, MD
Beth Israel Medical Center - Department of Pain Medicine & Palliate Care
Fee Income:
- Consulting agreements with an extensive list of pharmaceutical companies, estimated to work with 4-5 within three year period (complete list available upon request)

Research Funding:
- Department at Beth Israel Medical Center has received research funding in amounts ranging from less than $10,000 to over $100,000 funding from several pharmaceutical companies, foundations, and other sources (complete list available upon request)

Ben A. Rich, JD, PhD
University of California, Davis - School of Medicine, Division of Bioethics
Fee Income:
- Speaker honoraria payments from Purdue Pharma, PharmaCon, Pharmacia/Pfizer
- Expert consultant/review payment from Purdue Pharma

Richard G. Roberts, MD, JD, FAAFP, FCLM
University of Wisconsin - School of Medicine and Public Health
Fee Income:
- Advisor Board membership payments (less than $10,000 each) from Endo, Ortho-McNeill, and Pfizer

Knox H. Todd, MD, MPH, FACEP
Beth Israel Medical Center - Pain and Emergency Medicine Institute
Fee Income:
- Consulting payments from Johnson & Johnson, Alpharma, ALZA, and Ortho-McNeill pharmaceutical companies

Research Funding:
- Board of Director member for the American Chronic Pain Association, which has received research funding from Cephalon

Appendix 2. Grading Evidence and Recommendations (GRADE)

Grading evidence and recommendations - operationalization of GRADE methods[52]

High-quality Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least two consistent, higher-quality randomized controlled trials*, or multiple, consistent observational studies with no significant methodological flaws showing large effects).
Moderate-quality Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial* with >100 subjects; two or more higher-quality trials* with some inconsistency; at least two consistent, lower-quality trials*, or multiple, consistent observational studies with no significant methodological flaws showing at least moderate effects).
Low-quality Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher quality studies, important flaws in study design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

*Or prospective studies on risk prediction or studies of diagnostic accuracy when appropriate

Appendix 3. Risk Assessment Tool – Screener and Opioid Assessment for Patients with Pain (SOAPP)

Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0 - 14Q

The Screener and Opioid Assessment for Patients with Pain (SOAPP) ® Version 1.0 is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP® version 1.0 is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. Version 1.0 -14Q is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Preliminary reliability data (coefficient α) from 175 patients chronic pain patients
- Preliminary validity data from 100 patients (predictive validity)
- Simple scoring procedures
- 14 items
- 5 point scale
- <8 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP® is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP® is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP® scores to decide on a particular patient's treatment.
- The SOAPP® is **NOT** intended for all patients. The SOAPP® should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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Appendix 3. Continued

SOAPP® Version 1.0-14Q

Name: _____ Date: _____

The following are some questions given to all patients at the Pain Management Center who are on or being considered for opioids for their pain. Please answer each question as honestly as possible. This information is for our records and will remain confidential. Your answers alone will not determine your treatment. Thank you.

Please answer the questions below using the following scale:

0 = Never, 1 = Seldom, 2 = Sometimes, 3 = Often, 4 = Very Often

1. How often do you have mood swings?	0 1 2 3 4
2. How often do you smoke a cigarette within an hour after you wake up?	0 1 2 3 4
3. How often have any of your family members, including parents and grandparents, had a problem with alcohol or drugs?	0 1 2 3 4
4. How often have any of your close friends had a problem with alcohol or drugs?	0 1 2 3 4
5. How often have others suggested that you have a drug or alcohol problem?	0 1 2 3 4
6. How often have you attended an AA or NA meeting?	0 1 2 3 4
7. How often have you taken medication other than the way that it was prescribed?	0 1 2 3 4
8. How often have you been treated for an alcohol or drug problem?	0 1 2 3 4
9. How often have your medications been lost or stolen?	0 1 2 3 4
10. How often have others expressed concern over your use of medication?	0 1 2 3 4

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Appendix 3. Continued

0 = Never, 1 = Seldom, 2 = Sometimes, 3 = Often, 4 = Very Often

11. How often have you felt a craving for medication?	0 1 2 3 4
12. How often have you been asked to give a urine screen for substance abuse?	0 1 2 3 4
13. How often have you used illegal drugs (for example, marijuana, cocaine, etc.) in the past five years?	0 1 2 3 4
14. How often, in your lifetime, have you had legal problems or been arrested?	0 1 2 3 4

Please include any additional information you wish about the above answers. Thank you.

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Appendix 3. Continued

Scoring Instructions for the SOAPP® Version 1.0-14Q

To score the SOAPP® V.1- 14Q, simply add the ratings of all the questions:

A score of 7 or higher is considered positive.

Sum of Questions	SOAPP® Indication
> or = 7	+
< 7	-

What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP® generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP® is at different cutoff values. These values suggest that the SOAPP® is a sensitive test. This confirms that the SOAPP® is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 7 or higher will identify 91% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 7 is .90, which means that most people who have a negative SOAPP® are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP® score (at a cutoff of 7) is nearly 3 times (2.94 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 7 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP® score suggests the patient is really at low-risk, while a high SOAPP® score will contain a larger percentage of false positives (about 30%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

SOAPP® Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 7 or above	.91	.69	.71	.90	2.94	.13
Score 8 or above	.86	.73	.75	.86	3.19	.19
Score 9 or above	.77	.80	.77	.80	3.90	.28

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Appendix 4. Risk Assessment Tool – Opioid Risk Tool (ORT)

Date _____

Patient Name _____

OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. Age (Mark box if 16 – 45)		[ ]	1	1
4. History of Preadolescent Sexual Abuse		[ ]	3	0
5. Psychological Disease	Attention Deficit Disorder Obsessive Compulsive Disorder Bipolar Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
TOTAL		[ ]		

Total Score Risk Category Low Risk 0 – 3 Moderate Risk 4 – 7 High Risk ≥ 8

Reproduced with permission from Lynn Webster[137]

Appendix 5. Risk Assessment Tool - Score Diagnosis, Intractability, Risk Efficacy (D.I.R.E.)

D.I.R.E. Score: Patient Selection for Chronic Opioid Analgesia

For each factor, rate the patient's score from 1-3 based on the explanations in the right hand column

Score	Factor	Explanation
	Diagnosis	1 = Benign chronic condition with minimal objective findings or no definite medical diagnosis. Examples: fibromyalgia, migraine headaches, non-specific back pain. 2 = Slowly progressive condition concordant with moderate pain, or fixed condition with moderate objective findings. Examples: failed back surgery syndrome, back pain with moderate degenerative changes, neuropathic pain. 3 = Advanced condition concordant with severe pain with objective findings. Examples: severe ischemic vascular disease, advanced neuropathy, severe spinal stenosis.
	Intractability	1 = Few therapies have been tried and the patient takes a passive role in his/her pain management process. 2 = Most customary treatments have been tried but the patient is not fully engaged in the pain management process, or barriers prevent (insurance, transportation, medical illness). 3 = Patient fully engaged in a spectrum of appropriate treatments but with inadequate response.
	Risk	(R= Total of P+C+R+S below)
	Psychological:	1 = Serious personality dysfunction or mental illness interfering with care. Example: personality disorder, severe affective disorder, significant personality issues. 2 = Personality or mental health interferes moderately. Example: depression or anxiety disorder. 3 = Good communication with clinic. No significant personality dysfunction or mental illness.
	Chemical Health:	1 = Active or very recent use of illicit drugs, excessive alcohol, or prescription drug abuse. 2 = Chemical coper (uses medications to cope with stress) or history of CD in remission. 3 = No CD history. Not drug-focused or chemically reliant.
	Reliability:	1 = History of numerous problems: medication misuse, missed appointments, rarely follows through. 2 = Occasional difficulties with compliance, but generally reliable. 3 = Highly reliable patient with meds, appointments & treatment.
	Social Support:	1 = Life in chaos. Little family support and few close relationships. Loss of most normal life roles. 2 = Reduction in some relationships and life roles. 3 = Supportive family/close relationships. Involved in work or school and no social isolation.
	Efficacy score	1 = Poor function or minimal pain relief despite moderate to high doses. 2 = Moderate benefit with function improved in a number of ways (or insufficient info- hasn't tried opioid yet or very low doses or too short of a trial). 3 = Good improvement in pain and function and quality of life with stable doses over time.

_____Total score = D + I + R + E

Score 7-13: Not a suitable candidate for long-term opioid analgesia
Score 14-21: Good candidate for long-term opioid analgesia

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Appendix 6. Sample Informed Consent form

Consent for Chronic Opioid Therapy

A consent form from the **American Academy of Pain Medicine**

Dr. _____ is prescribing opioid medicine, sometimes called narcotic analgesics, to me for a diagnosis of _____.

This decision was made because my condition is serious or other treatments have not helped my pain.

I am aware that the use of such medicine has certain risks associated with it, including, but not limited to: sleepiness or drowsiness, constipation, nausea, itching, vomiting, dizziness, allergic reaction, slowing of breathing rate, slowing of reflexes or reaction time, physical dependence, tolerance to analgesia, addiction and possibility that the medicine will not provide complete pain relief.

I am aware about the possible risks and benefits of other types of treatments that do not involve the use of opioids. The other treatments discussed included:

_____

_____

_____

I will tell my doctor about all other medicines and treatments that I am receiving.

I will not be involved in any activity that may be dangerous to me or someone else if I feel drowsy or am not thinking clearly. I am aware that even if I do not notice it, my reflexes and reaction time might still be slowed. Such activities include, but are not limited to: using heavy equipment or a motor vehicle, working in unprotected heights or being responsible for another individual who is unable to care for himself or herself.

I am aware that certain other medicines such as nalbuphine (Nubain ™), pentazocine (Talwin™), buprenorphine (Buprenex™), and butorphanol (Stadol™), may reverse the action of the medicine I am using for pain control. Taking any of these other medicines while I am taking my pain medicines can cause symptoms like a bad flu, called a withdrawal syndrome. I agree not to take any of these medicines and to tell any other doctors that I am taking an opioid as my pain medicine and cannot take any of the medicines listed above.

I am aware that addiction is defined as the use of a medicine even if it causes harm, having cravings for a drug, feeling the need to use a drug and a decreased quality of life. I am aware that the chance of becoming addicted to my pain medicine is very low. I am aware that the development of addiction has been reported rarely in medical journals and is much more common in a person who has a family or personal history of addiction. I agree to tell my doctor my complete and honest personal drug history and that of my family to the best of my knowledge.

Appendix 6. Continued

I understand that physical dependence is a normal, expected result of using these medicines for a long time. I understand that physical dependence is not the same as addiction. I am aware physical dependence means that if my pain medicine use is markedly decreased, stopped or reversed by some of the agents mentioned above, I will experience a withdrawal syndrome. This means I may have any or all of the following: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawal is uncomfortable but not life threatening.

I am aware that tolerance to analgesia means that I may require more medicine to get the same amount of pain relief. I am aware that tolerance to analgesia does not seem to be a big problem for most patients with chronic pain, however, it has been seen and may occur to me. If it occurs, increasing doses may not always help and may cause unacceptable side effects. Tolerance or failure to respond well to opioids may cause my doctor to choose another form of treatment.

(**Males only**) I am aware that chronic opioid use has been associated with low testosterone levels in males. This may affect my mood, stamina, sexual desire and physical and sexual performance. I understand that my doctor may check my blood to see if my testosterone level is normal.

(**Females Only**) If I plan to become pregnant or believe that I have become pregnant while taking this pain medicine, I will immediately call my obstetric doctor and this office to inform them. I am aware that, should I carry a baby to delivery while taking these medicines, the baby will be physically dependent upon opioids. I am aware that the use of opioids is not generally associated with a risk of birth defects. However, birth defects can occur whether or not the mother is on medicines and there is always the possibility that my child will have a birth defect while I am taking an opioid.

I have read this form or have it read to me. I understand all of it. I have had a chance to have all of my questions regarding this treatment answered to my satisfaction. By signing this form voluntarily, I give my consent for the treatment of my pain with opioid pain medicines.

Patient signature _____ Date _____

Witness to above _____

Approved by the AAPM Executive Committee on January 14, 1999.

PHYSICIANS DEDICATED TO RELIEVING PAIN
the AMERICAN ACADEMY *of* PAIN MEDICINE
the voice of pain medicine

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Appendix 7. Sample Medical Agreement

SAMPLE FOR ADAPTATION AND REPRODUCTION ON PHYSICIAN LETTERHEAD

PLEASE CONSULT WITH YOUR ATTORNEY

Long-term Controlled Substances Therapy for Chronic Pain

SAMPLE AGREEMENT

A consent form from the American Academy of Pain Medicine

The purpose of this agreement is to protect your access to controlled substances and to protect our ability to prescribe for you.

The long-term use of such substances as opioids (narcotic analgesics), benzodiazepine tranquilizers, and barbiturate sedatives is controversial because of uncertainty regarding the extent to which they provide long-term benefit. There is also the risk of an addictive disorder developing or of relapse occurring in a person with a prior addiction. The extent of this risk is not certain.

Because these drugs have potential for abuse or diversion, strict accountability is necessary when use is prolonged. For this reason the following policies are agreed to by you, the patient, as consideration for, and a condition of, the willingness of the physician whose signature appears below to consider the initial and/or continued prescription of controlled substances to treat your chronic pain.

1. All controlled substances must come from the physician whose signature appears below or, during his or her absence, by the covering physician, unless specific authorization is obtained for an exception. (Multiple sources can lead to untoward drug interactions or poor coordination of treatment.)
2. All controlled substances must be obtained at the same pharmacy, where possible. Should the need arise to change pharmacies, our office must be informed. The pharmacy that you have selected is:

   _____ phone: _____.
3. You are expected to inform our office of any new medications or medical conditions, and of any adverse effects you experience from any of the medications that you take.
4. The prescribing physician has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your health care for purposes of maintaining accountability.
5. You may not share, sell, or otherwise permit others to have access to these medications.
6. These drugs should not be stopped abruptly, as an abstinence syndrome will likely develop.
7. Unannounced urine or serum toxicology screens may be requested, and your cooperation is required. Presence of unauthorized substances may prompt referral for assessment for addictive disorder.

Appendix 7. Continued

8. Prescriptions and bottles of these medications may be sought by other individuals with chemical dependency and should be closely safeguarded. It is expected that you will take the highest possible degree of care with your medication and prescription. They should not be left where others might see or otherwise have access to them.

9. Original containers of medications should be brought in to each office visit.

10. Since the drugs may be hazardous or lethal to a person who is not tolerant to their effects, especially a child, you must keep them out of reach of such people.

11. Medications may not be replaced if they are lost, get wet, are destroyed, left on an airplane, etc. If your medication has been stolen and you complete a police report regarding the theft, an exception may be made.

12. Early refills will generally not be given.

13. Prescriptions may be issued early if the physician or patient will be out of town when a refill is due. These prescriptions will contain instructions to the pharmacist that they not be filled prior to the appropriate date.

14. If the responsible legal authorities have questions concerning your treatment, as might occur, for example, if you were obtaining medications at several pharmacies, all confidentiality is waived and these authorities may be given full access to our records of controlled substances administration.

15. It is understood that failure to adhere to these policies may result in cessation of therapy with controlled substance prescribing by this physician or referral for further specialty assessment.

16. Renewals are contingent on keeping scheduled appointments. Please do not phone for prescriptions after hours or on weekends.

17. It should be understood that any medical treatment is initially a trial, and that continued prescription is contingent on evidence of benefit.

18. The risks and potential benefits of these therapies are explained elsewhere [and you acknowledge that you have received such explanation].

19. You affirm that you have full right and power to sign and be bound by this agreement, and that you have read, understand, and accept all of its terms.

Physician Signature	Patient Signature
Date	Patient Name (Printed)

Approved by the AAPM Executive Committee on April 2, 2001.

AAPM
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Web site http://www.painmed.org/

Appendix 8. Monitoring Tool – Pain Assessment and Documentation Tool (PADT)

A

PROGRESS NOTE
Pain Assessment and Documentation Tool (PADT™)

Patient Stamp Here

Patient Name: _____ Record #: _____

Assessment Date: _____

Current Analgesic Regimen

Drug name	Strength (eg, mg)	Frequency	Maximum Total Daily Dose

The PADT is a clinician-directed interview; that is, the clinician asks the questions, and the clinician records the responses. The Analgesia, Activities of Daily Living, and Adverse Events sections may be completed by the physician, nurse practitioner, physician assistant, or nurse. The Potential Aberrant Drug-Related Behavior and Assessment sections must be completed by the physician. Ask the patient the questions below, except as noted.

Analgesia

If zero indicates "no pain" and ten indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

1. What was your pain level on average during the past week? (Please circle the appropriate number)

No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be

2. What was your pain level at its worst during the past week?

No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be

3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100%.) _____

4. Is the amount of pain relief you are now obtaining from your current pain reliever(s) enough to make a real difference in your life?
☐ Yes ☐ No

5. **Query to clinician:** Is the patient's pain relief clinically significant?
☐ Yes ☐ No ☐ Unsure

Activities of Daily Living

Please indicate whether the patient's functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient's last assessment with the PADT.* (Please check the box for Better, Same, or Worse for each item below.)

	Better	Same	Worse
1. Physical functioning	☐	☐	☐
2. Family relationships	☐	☐	☐
3. Social relationships	☐	☐	☐
4. Mood	☐	☐	☐
5. Sleep patterns	☐	☐	☐
6. Overall functioning	☐	☐	☐

* If the patient is receiving his or her first PADT assessment, the clinician should compare the patient's functional status with other reports from the last office visit.

(Continued on reverse side)

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Appendix 8. Continued

B

PROGRESS NOTE
Pain Assessment and Documentation Tool (PADT™)

Adverse Events

1. Is patient experiencing any side effects from current pain reliever(s)? ☐ Yes ☐ No

Ask patient about potential side effects:

	None	Mild	Moderate	Severe
a. Nausea	☐	☐	☐	☐
b. Vomiting	☐	☐	☐	☐
c. Constipation	☐	☐	☐	☐
d. Itching	☐	☐	☐	☐
e. Mental cloudiness	☐	☐	☐	☐
f. Sweating	☐	☐	☐	☐
g. Fatigue	☐	☐	☐	☐
h. Drowsiness	☐	☐	☐	☐
i. Other _____	☐	☐	☐	☐
j. Other _____	☐	☐	☐	☐

2. Patient's overall severity of side effects?
☐ None ☐ Mild ☐ Moderate ☐ Severe

Potential Aberrant Drug-Related Behavior
This section must be completed by the physician.

Please check any of the following items that you discovered during your interactions with the patient. Please note that some of these are directly observable (eg, appears intoxicated), while others may require more active listening and/or probing. Use the "Assessment" section below to note additional details.

- ☐ Purposeful over-sedation
- ☐ Negative mood change
- ☐ Appears intoxicated
- ☐ Increasingly unkempt or impaired
- ☐ Involvement in car or other accident
- ☐ Requests frequent early renewals
- ☐ Increased dose without authorization
- ☐ Reports lost or stolen prescriptions
- ☐ Attempts to obtain prescriptions from other doctors
- ☐ Changes route of administration
- ☐ Uses pain medication in response to situational stressor
- ☐ Insists on certain medications by name
- ☐ Contact with street drug culture
- ☐ Abusing alcohol or illicit drugs
- ☐ Hoarding (ie, stockpiling) of medication
- ☐ Arrested by police
- ☐ Victim of abuse

Other: _____

Assessment: (This section must be completed by the physician.)

Is your overall impression that this patient is benefiting (eg, benefits, such as pain relief, outweigh side effects) from opioid therapy? ☐ Yes ☐ No ☐ Unsure

Comments: _____

Specific Analgesic Plan:

- ☐ Continue present regimen — Comments: _____
- ☐ Adjust dose of present analgesic
- ☐ Switch analgesics
- ☐ Add/Adjust concomitant therapy
- ☐ Discontinue/taper off opioid therapy

Date: _____ Physician's signature: _____

Provided as a service to the medical community by Janssen Pharmaceutica Products, L.P. JANSSEN

Appendix 9. Monitoring Tool – Current Opioid Misuse Measure (COMM)

Current Opioid Misuse Measure (COMM)™

The Current Opioid Misuse Measure (COMM)™ is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM™ was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:

- *Signs & Symptoms of Intoxication*
- *Emotional Volatility*
- *Evidence of Poor Response to Medications*
- *Addiction*
- *Healthcare Use Patterns*
- *Problematic Medication Behavior*

The COMM™ will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP®) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM™ examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM™ is:

- A quick and easy to administer patient-self assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM™ is for clinician use only. The tool is not meant for commercial distribution.
- The COMM™ is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM™ scores to decide if and when modifications to particular patient's treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

PainEDU.org

*Reproduced with permission from Inflexxion, Inc.[11] See www.painedu.org for additional information.

Appendix 9. Continued

COMM™

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	O	O	O	O	O
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	O	O	O	O	O
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	O	O	O	O	O
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	O	O	O	O	O
5. In the past 30 days, how often have you seriously thought about hurting yourself?	O	O	O	O	O
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	O	O	O	O	O

PainEDU.org

Appendix 9. Continued

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	O	O	O	O	O

PainEDU.org

Appendix 9. Continued

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
17. In the past 30 days, how often have you had to visit the Emergency Room?	O	O	O	O	O

Appendix 9. Continued

Scoring Instructions for the COMM™

To score the COMM™, simply add the rating of all the questions. A score of 9 or higher is considered a positive

Sum of Questions	COMM Indication
> or = 9	+
< 9	-

As for any scale, the results depend on what cutoff score is chosen. A score that is sensitive in detecting patients who are abusing or misusing their opioid medication will necessarily include a number of patients that are not really abusing or misusing their medication. The COMM™ was intended to over-identify misuse, rather than to mislabel someone as responsible when they are not. This is why a low cut-off score was accepted. We believe that it is more important to identify patients who have only a possibility of misusing their medications than to fail to identify those who are actually abusing their medication. Thus, it is possible that the COMM™ will result in false positives – patients identified as misusing their medication when they were not.

The table below presents several statistics that describe how effective the COMM™ is at different cutoff values. These values suggest that the COMM™ is a sensitive test. This confirms that the COMM™ is better at identifying who is misusing their medication than identifying who is not misusing. Clinically, a score of 9 or higher will identify 77% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 9 is .95, which means that most people who have a negative COMM™ are likely not misusing their medication. Finally, the Positive likelihood ratio suggests that a positive COMM™ score (at a cutoff of 9) is over 2 times (2.26 times) as likely to come from someone who is actually misusing their medication (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 9 will ensure that the provider is least likely to miss someone who is really misusing their prescription opioids. However, one should remember that a low COMM™ score suggests the patient is really at low-risk, while a high COMM™ score will contain a larger percentage of false positives (about 34%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

COMM™ Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 9 or above	.77	.66	.66	.95	2.26	.35

PainEDU.org

News Articles

NEW DATA REVEAL 400% INCREASE IN SUBSTANCE ABUSE TREATMENT ADMISSIONS FOR PEOPLE ABUSING PRESCRIPTION DRUGS
White House Bulletin

WASHINGTON - Today, Gil Kerlikowske, Director of National Drug Control Policy (ONDCP), and Thomas McLellan, Deputy Director of ONDCP, joined Peter Delany, Director of Substance Abuse and Mental Health Services Administration's (SAMHSA) Office of Applied Studies, and Michele M. Leonhart, Acting Administrator of the Drug Enforcement Administration (DEA), to release a new study showing a 400 percent increase in substance abuse treatment admissions for prescription pain relievers. Governor Jack Markell of Delaware and Chris Kennedy Lawford were also in attendance.

The study, Substance Abuse Treatment Admissions Involving Abuse of Pain Relievers 1998-2008, conducted by the SAMHSA, and based on the agency's Treatment Episode Data Set (TEDS) reveals a 400 percent increase between 1998 and 2008 of substance abuse treatment admissions for those aged 12 and over reporting abuse of prescription pain relievers. The increase in the percentage of admissions abusing pain relievers spans every age, gender, race, ethnicity, education, employment level, and region. The study also shows a more than tripling of pain reliever abuse among patients who needed treatment for opioid dependence.

"The TEDS data released today highlights how serious a threat to public health we face from the abuse of prescription drugs", said Gil Kerlikowske, National Drug Policy Director. "The spikes in prescription drug abuse rates captured by this study are dramatic, pervasive, and deeply disturbing."

"The non-medical use of prescription pain relievers is now the second-most prevalent form of illicit drug use in the Nation, and its tragic consequences are seen in substance abuse treatment centers and hospital emergency departments throughout our Nation" said SAMHSA Administrator Pamela S. Hyde, J.D. "This public health threat demands that we follow the President's National Drug Control Strategy's call for an all-out effort to raise awareness of this risk and the critical importance of properly using, storing, and disposing of these powerful drugs."

"The data released today is alarming and shows the tremendous damage being caused by prescription drug abuse all across this country each and every day," said DEA Acting Administrator Michele M. Leonhart. "The effective enforcement of laws regulating the distribution of controlled substances, coupled with their lawful disposal are essential parts of a comprehensive strategy to reduce drug abuse. DEA is committed to being part of the solution, however it will take all of us working together to prevent the tragedies that inevitably come with drug abuse."

"This rise in prescription drug abuse is no surprise to the doctors and law enforcement professionals who see its effects in our communities," said Governor Markell. "We have been focused on making sure that health care professionals have the best tools

available to detect and prevent this kind of abuse before it ruins lives. Delaware's new legislation to authorize a prescription monitoring program is one of those tools and an important component of the President's National Drug Control Strategy."

"Our national prescription drug abuse problem cannot be ignored. I have worked in the treatment field for the last 35 years, and recent trends regarding the extent of prescription drug abuse are startling," said A. Thomas McLellan, Deputy Director of ONDCP. "We must work with prescribers, the pharmaceutical industry, law enforcement, and families to help us fight this scourge."

The National Drug Control Strategy, released in May, outlines several steps to address what Director Kerlikowske calls "the fastest-growing drug problem in the United States"--prescription drug abuse.

They include

* Increasing prescription drug return, take-back, and disposal programs. Prescription drugs that are commonly abused are often found in the family medicine cabinet, and individuals should get rid of unused or expired prescription drugs to prevent diversion and abuse.

* Educating physicians about opiate painkiller prescribing. The Administration's FY 2011 Budget request proposes funding for a program to train prescribers on how to instruct patients in the use and proper disposal of painkillers, to observe signs of dependence, and to use prescription drug monitoring programs to detect when an individual is going from doctor to doctor in search of prescriptions (also called "doctor shopping").

* Expanding prescription drug monitoring programs. Currently, these programs are operating in 34 states. The Administration supports establishment of these programs in every state, and is seeking to ensure new and existing monitoring programs effectively use the data they acquire and share information across state lines.

* Assisting states in addressing doctor shopping and pill mills. Criminal organizations have established thriving businesses of transporting people to states with little regulation to obtain prescription drugs from multiple doctors or from pill mills, which distribute drugs indiscriminately. Federal, state, local, and tribal authorities are working together to address this problem.

* Driving illegal Internet pharmacies out of business.

* Cracking down on rogue pain clinics that do not follow appropriate prescription practices.

The National Drug Control Strategy provides a blueprint for reducing prescription drug abuse. Parents, law enforcement, the medical community, and all levels of government have a role to play in reducing prescription drug abuse.

Later today, Director Kerlikowske will travel to Delaware to attend Governor Markell's bill signing for the Delaware Prescription Drug Monitoring Program.

U.S. can stop some drug sales at 2 CVS stores: judge

Tue, Mar 13 2012

WASHINGTON (Reuters) - The U.S. Drug Enforcement Administration can stop two CVS Caremark Corp pharmacies from selling potentially addictive drugs in a case involving suspected prescription drug abuse, a federal judge ruled on Tuesday.

U.S. District Judge Reggie Walton vacated a temporary restraining order that had blocked the Drug Enforcement Administration (DEA)from acting against the two Florida stores suspected of selling doses of the painkiller oxycodone outside legitimate channels.

Walton stayed his ruling until 10 a.m. (1500 GMT) on Wednesday to give CVS Caremark attorneys time to appeal. But the company appealed later on Tuesday. Further details were not immediately available.

CVS Caremark had asked the judge to impose a preliminary injunction that could have blocked the DEA from taking action until an administrative law judge decided the matter later this year.

Walton said he could find no reason to believe the CVS argument that DEA had acted in an "arbitrary and capricious" manner in ordering sales suspended or that remedial steps taken by CVS were sufficient.

"We are disappointed with today's ruling," CVS said in a statement. "Regardless of today's outcome, we remain committed to working with the DEA to do everything we can to reduce prescription drug abuse."

The litigation stems from the DEA's battle against prescription drug abuse, which has surged in the United States to eclipse abuse of most illicit drugs including heroin and cocaine.

The DEA said in court documents that about 7 million Americans abuse pharmaceuticals made with controlled substances for purposes not related to medicine and that Florida is the center of the growing epidemic.

The federal agency cited state statistics showing a 346 percent increase in overdose deaths related to oxycodone from 2005 to 2010, and an average 11 deaths per day from oxycodone, methadone, hydrocodone, benzodiazepines or morphine.

In a case related to the CVS ruling, Walton last month allowed the DEA to suspend Cardinal Health Inc's license to distribute controlled substances from a Florida facility that serves about 2,700 drug stores or hospitals.

The ruling was later blocked temporarily by a U.S. appeals court. Walton said he expected the appeals court to take the same action on CVS.

The CVS stores are two of four Cardinal customers that DEA has said were inappropriately filling oxycodone prescriptions.

A CVS attorney said the company had stopped oxycodone sales at the two pharmacies. But a Justice Department attorney said suspicious sales had involved other controlled substances.

The DEA charged that between January 2008 and December 2011 the two CVS stores purchased amounts of oxycodone far in excess of normal pharmacy volumes, ignored DEA warnings and addressed the issue only after the DEA acted.

A CVS attorney told the court that the volumes were not out of line for high-volume pharmacies that maintain 24-hour service and argued that remedial steps taken by CVS had eliminated any immediate danger to the community by the time the DEA ordered sales suspended in February.

The case is Holiday CVS LLC v. Justice Department, No. 12-00191.

(Reporting By David Morgan; Editing by Gary Hill)

DEA: Oxycodone orders by pharmacies 20 times average
USA Today.com

Two Florida CVS pharmacies ordered more than 3 million oxycodone pills in 2011, more than 20 times higher than the national average, DEA agents said Monday.

As part of a crackdown on rampant painkiller abuse in Florida, the Drug Enforcement Administration charged a major health care company and the two CVS pharmacies in Sanford, Fla., with violating their licenses to sell the powerful pain pills and other drugs.

"It's a tremendous amount, way beyond what would be for legitimate use," said Mark Trouville, DEA special agent in charge of the Miami Field Division. "We're not talking about a gray area here."

The average pharmacy in the United States ordered about 69,000 oxycodone pills in 2011, the DEA said. The two CVS pharmacies, located less than 6 miles apart, ordered 3 million.

It is the first time the DEA has suspended the license of a chain pharmacy in Florida for its alleged role in the state's prescription drug abuse problem, Trouville said. The DEA had previously targeted pain clinics known as "pill mills" where rogue doctors prescribe thousands of pain pills with only cursory examinations.

"This is absolutely not the end of this investigation," Trouville said. "We knew when we hit the pill mills that pharmacies would be the next issue. We just didn't know chain pharmacies would get into it."

CVS said it took steps with DEA's knowledge to stop filling prescriptions from doctors thought to be prescribing improperly.

"We informed a small number of Florida physicians that CVS/pharmacy will no longer fill the prescriptions they write for Schedule II narcotics," spokeswoman Carolyn Castel said in a written statement. "Distributions of oxycodone to the two Florida stores have decreased by approximately 80% in the last three months compared to the prior three months — we believe in large part due to our action."

On Friday, the DEA on suspended Cardinal Health's controlled substances license at its Lakeland, Fla., distribution center after linking it to high-volume orders of pain pills to four Florida pharmacies, including the two in Sanford. The distribution center services 2,500 pharmacies in Florida, Georgia and South Carolina.

A federal judge temporarily halted the suspension after Cardinal said it would stop supplying the drugs to the four pharmacies. A hearing on the suspension order was set for Feb. 13 in Washington, D.C.

Cardinal CEO George Barrett called the DEA action a "drastic overreaction" and said the company has "extensive processes" to prevent diversion of its pharmaceuticals for illegitimate use. Cardinal's internal controls have flagged more than 160 pharmacies in Florida and 350 pharmacies nationwide for "suspicious order patterns," he said.

"The needs of pharmacies are varied, and higher volumes can be appropriate based on a number of factors, including pharmacy size, hours of operation, patient demographics, and proximity to hospital and surgery centers, nursing homes, cancer clinics and hospice providers," Cardinal said in a statement.

DEA moves against two Florida pharmacies, distributor over pill sales
CNN.com

(CNN) -- Agents from the Drug Enforcement Administration raided two CVS pharmacies in central Florida over the weekend, removing controlled substances and suspending the stores' ability to handle or distribute drugs such as painkillers oxycodone and hydrocodone.
The DEA said that during one year, the two pharmacies -- both in Sanford, Florida -- ordered more than 3 million oxycodone units from a pharmaceutical wholesaler, while a typical pharmacy orders 69,000.

"Each registrant (pharmacy) was filling prescriptions far in excess of legitimate needs of its customers," said DEA Special Agent in Charge Mark Trouville during a press conference Monday in central Florida.

The DEA also has suspended the controlled-substance license of the wholesale distributor, Cardinal Health of Lakeland, Florida, according to Trouville.

"Cardinal Health did not fulfill its due diligence to insure controlled substances were not diverted into other than legitimate channels," Trouville said.

On Friday, Cardinal Health filed and received an emergency injunction from a federal judge in Washington allowing the drug supplier to continue filling orders for other pharmacies.

"We believe the DEA is wrong," said Cardinal Health Chairman and CEO George Barrett in a written statement.

"We strongly disagree with the allegations the DEA has made against our facility and intend to vigorously challenge this action," said Barrett.

The two Sanford pharmacies remain open filling regular prescriptions but they cannot fill prescriptions for controlled substances such as oxycodone, one form of which is the well-known narcotic OxyContin.

CVS said in a written statement that the company is disappointed by the DEA actions but is fully cooperating with the DEA suspension.
"CVS/pharmacy is unwavering in its compliance with and support of the measures taken by federal and state law enforcement officials to prevent drug abuse and keep controlled substances out of the wrong hands," said CVS spokesman Mike DeAngelis.

Hearings on the suspensions will be held but no date has been set.

Trouville said that since the state of Florida moved to crack down on "pill mills" by banning doctors from directly distributing controlled narcotics, pharmacy sales of controlled substances have skyrocketed.

— *Arelis R. Hernández*

DEA agents raid CVS pharmacies

By Arelis R. Hernández
Staff Writer

Federal drug authorities raided two CVS stores in Seminole County on Saturday, removing boxes of medication and other materials from the pharmacies.

CVS spokesman Michael DeAngelis said the raid was related to action a day earlier by the Drug Enforcement Agency against Cardinal Health, which has a drug-distribution center in Lakeland.

The DEA tried to suspend the license of Cardinal Health in order to stop the company from shipping drugs such as oxycodone and hydrocodone from the Lakeland center. But a judge blocked DEA's order.

In a statement released Friday, Cardinal, a billion-dollar pharmaceutical company, said it distributes drugs to more than 2,500 pharmacies in the Southeast, including four pharmacies listed in the DEA's order, that are accused of filling prescriptions for purposes other than for legitimate medical reasons.

Agents on Saturday first raided the CVS pharmacy at 3798 Orlando Drive in Sanford, and then removed boxes from another CVS pharmacy at 5198 W. First St. in Sanford.

About a dozen DEA agents worked for hours at each location packaging items from behind the pharmacy counter while CVS employees went about their business helping customers fill prescriptions.

"We are disappointed that the DEA has taken administrative action to prohibit two CVS/pharmacy stores in Florida from dispensing controlled substances," DeAngelis said in a statement Saturday.

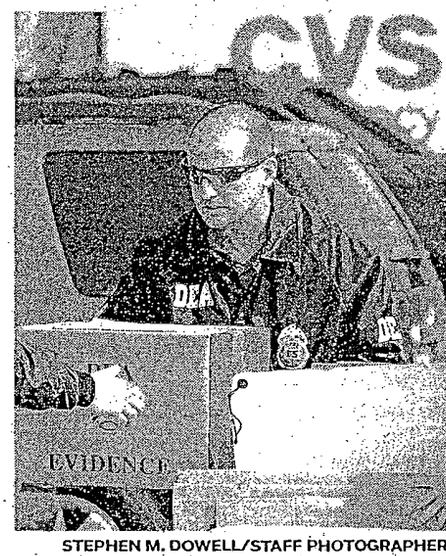
The raids come amid aggressive action by the DEA against businesses accused of dispensing suspicious prescriptions for powerful pain killers and anti-anxiety drugs.

Cardinal Health said it has cooperated with the agency and has stopped shipping to more than 160 Florida pharmacies in the past four years.

"We believe the DEA is wrong," Cardinal chairman and CEO George Barrett said in a statement. He added that the company has "extensive processes to help prevent those medicines from falling in the wrong hands."

CVS also defended its record, describing its compliance with state and federal law enforcement as "unwavering" in order "to prevent drug abuse and keep controlled substances out of the wrong hands."

More than two months ago, the company sent a letter to a small group of Florida doctors telling them that they would no longer fill the prescriptions they write for painkillers and other addictive drugs.



STEPHEN M. DOWELL/STAFF PHOTOGRAPHER
DEA special agent David Melenkevitz removes boxes of prescription painkillers from a Sanford CVS store Saturday.

"While we regret any inconvenience this may cause for our customers, we treat the dispensing of controlled substances with the utmost care and seriousness," CVS said in an email statement to the Orlando Sentinel last month.

At least one doctor on the list filed a defamation suit against CVS, saying the list falsely implied that the physician was acting unethically or illegally.

The pill-mill epidemic in Florida has prompted new laws and beefed-up law enforcement, which officials said last week is having a positive impact.

For example, sales of the painkiller oxycodone dropped 20 percent last year in Florida, the Drug Enforcement Administration said. And the number of powerful narcotic pills sold by Florida pharmacies and doctors dropped from 622 million in 2010 to 498 million last year.

CVS emphasized its role in that effort, saying oxycodone distribution at the two stores raided Saturday have "decreased by approximately 80 percent in the last three months compared to the prior three months — we believe in large part due to our action."

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DEA charges 2 Fla. pharmacies in pill mill probe

Drug wholesaler also under investigation

By Donna Leinwand Leger
USA TODAY

Federal authorities have expanded their crackdown on painkiller abuse, charging a major health care company and two CVS pharmacies in Florida with violating their licenses to sell powerful pain pills and other drugs.

The Drug Enforcement Administration linked Cardinal Health to unusually high shipments of the controlled drugs to four pharmacies.

On Friday, the DEA suspended Cardinal's controlled substances license at its Lakeland, Fla., distribution center, which services 2,500 pharmacies in Florida, Georgia and South Carolina.

A federal judge temporarily halted the suspension the same day after Cardinal, a $1.3 billion company, said it would stop supplying the drugs to the four pharmacies. A hearing on the suspension order was set for Feb. 13 in Washington, D.C.

"We believe the DEA is wrong," CEO George Barrett said on the company's website.

The action comes as the DEA is cracking down on pill mills — rogue doctors and shady pharmacies that divert the highly addictive pills, such as oxycodone, to drug dealers.

"This is still an ongoing investigation," said DEA Special Agent David Melenkevitz, spokesman for the Miami Field Division. "We will be able to provide more information on Monday."

On Saturday, the DEA raided two CVS pharmacies in Sanford, Fla., and suspended their licenses to dispense controlled substances.

CVS said Saturday that it had taken steps with DEA's knowledge to stop filling prescriptions from doctors thought to be prescribing improperly.

"We informed a small number of Florida physicians that CVS/pharmacy will no longer fill the prescriptions they write for Schedule II narcotics," spokeswoman Carolyn Castel said in a written statement. "Distributions of oxycodone to the two Florida stores have decreased by approximately 80% in the last three months compared to the prior three months — we believe in large part due to our action."

In its suspension order, the DEA alleges that Cardinal knew or should have known that the four retail pharmacies had purchased far more drugs than it needed to fulfill legitimate prescriptions.

The company called the DEA action a "drastic overreaction" that would disrupt delivery of critical medications to hospitals and pharmacies.

Cardinal has "extensive processes" to prevent diversion of its pharmaceuticals for illegitimate use, Barrett said. Cardinal's internal controls have flagged more than 160 pharmacies in Florida and 350 pharmacies nationwide for "suspicious order patterns," he said. Barrett said the DEA is holding the company responsible for a part of the supply chain it does not control.

"At the time we filled these orders, the pharmacies held valid state board of pharmacy and DEA licenses," Barrett said in a call to investors Friday. "Pharmaceutical distributors do not influence the manufacture of controlled medicines. We do not write prescriptions. We do not dispense controlled medicines, nor do we license pharmacies. Our role is as a distributor, a critical link in the supply chain between pharmaceutical manufacturers and pharmacies."

Friday's action is the third time in five years the DEA has suspended Cardinal's controlled substances license. In November 2007, the DEA suspended the license for Cardinal's Auburn, Wash., distribution facility for selling 18 million hydrocodone pills in nine months to retail drugstores. The company sold 605,000 pills to one store in Burlington, Wash., over a seven-month period, the DEA said.

Cardinal Health settles drug distribution case
USA Today
May 16, 2012

The DEA suspended Cardinal Health, the country's second largest drug distributor, from selling and shipping powerful painkillers and other drugs from its Lakeland, Fla., facility for two years as part of a settlement reached Tuesday.

The Drug Enforcement Administration sought to revoke Cardinal's license in February, accusing the company of selling excessive amounts - more than 12 million oxycodone pain pills - to four Florida pharmacies over three years. The DEA said the company did not report suspicious orders or visit the chain pharmacies that purchased large amounts of the drugs.

The DEA also suspended controlled substances licenses for two CVS pharmacies in Sanford, Fla., which purchased millions of oxycodone pills from Cardinal. A judge is expected to rule on the CVS case this month.

"Cardinal Health is not above the law," said Joe Rannazzisi, DEA deputy assistant administrator. "With this agreement, it admits that it neglected its vital responsibility to prevent the diversion of controlled substance medications."

While the agreement resolves the licensing issue, the DEA said it may pursue civil penalties, including fines, against the company. The Dublin, Ohio-based company had revenue of more than $100 billion in 2011.

This is the second time the DEA has taken action against Cardinal. In 2008, Cardinal paid a $34 million fine after the DEA accused it of shipping excessive amounts of hydrocodone, another powerful painkiller, to Internet pharmacies. As part of that settlement, the DEA suspended licenses at three distribution facilities for a year.

Cardinal admitted Tuesday it had "inadequate" control over some of its controlled drugs and had not fully complied with the 2008 agreement.

"This agreement allows us to put this matter behind us, and just as important, will clear the way for a more productive dialogue about how we and others in the health care and regulatory community can work together to prevent the abuse and misuse of prescription drugs," Cardinal CEO George Barrett said.

The five-year agreement applies to all 28 of Cardinal's distribution facilities and requires the company to review orders for the controlled drugs, visit pharmacies to look for signs of diversion and hire extra field inspectors for Florida pharmacies.

The Lakeland facility can still distribute non-controlled drugs and medical supplies.

Cardinal Plant Can't Ship Pain Pills

Wall Street Journal

A U.S. appeals court ruled Friday that a Cardinal Health Inc. distribution hub in Florida can't ship prescription painkillers while the company battles a Drug Enforcement Administration move to suspend that facility's license.

While the appeals court recently issued a stay of the DEA's enforcement efforts against Cardinal's Lakeland, Fla., facility, the court Friday said Cardinal hasn't met the "stringent requirements for an injunction." The decision means the Lakeland facility can't ship controlled substances until the appeal is sorted out.

Cardinal, based in Dublin, Ohio, said it activated contingency plans earlier this month "and will continue to endeavor to meet our customers' needs with minimal disruption from our other distribution centers."

The contingency plans involve shipping controlled drugs to customers in the Southeast U.S. from alternative facilities in Mississippi or North Carolina. Analysts have said the plans could add transportation costs to Cardinal and delay deliveries.

The suspension of the DEA license means the Lakeland facility is blocked from shipping controlled medications like the pain drug oxycodone to thousands of pharmacies, hospitals and other health-care providers. Cardinal, the nation's No. 2 drug distributor by sales after McKesson Corp., can still ship noncontrolled medications, which include most prescription drugs, and supplies such as surgical packs.

The DEA also suspended last month the controlled-medication licenses of four Florida pharmacies, including two owned and operated by CVS Caremark Corp. CVS won a temporary, administrative stay on Wednesday to keep dispensing controlled medications after an appeals court denied the pharmacy chain's request for a preliminary injunction.

The DEA took action against the Lakeland facility last month while accusing Cardinal of not doing enough to stop oxycodone abuse. Cardinal has said that it supports the DEA's efforts but also disagreed that it wasn't doing enough.

A U.S. District Court Judge ruled in late February that the government acted properly in trying to cut off shipments of oxycodone from the Lakeland site. Cardinal appealed that ruling in the U.S. Court of Appeals for the District of Columbia Circuit.

DEA searches Fla. Walgreens in painkiller probe

CURT ANDERSON, AP Legal Affairs Writer
Updated 3:01 p.m., Friday, April 6, 2012

MIAMI (AP) — Federal drug agents have searched six Walgreens pharmacies and a company distribution center in Florida as part of an investigation into prescription painkiller drug abuse, U.S. Drug Enforcement Administration officials said Friday.

The distribution center in Jupiter and the six pharmacies — two in Fort Pierce and one each in Hudson, Port Richey, Fort Myers and Oviedo — all showed signs of suspiciously high distribution of the highly addictive drug oxycodone, a DEA investigator wrote in an affidavit for the search warrants.

Such large amounts, investigator Marjorie Milan wrote, indicates "a pharmacy that fills prescriptions issued by physicians at pain clinics and/or a pharmacy which services primarily drug-seeking individuals who abuse the medication."

The searches for pharmacy records conducted Wednesday are the latest in a crackdown by federal and state authorities on "pill mills" and other illegal sources of prescription drugs in Florida, which has become the nation's leading source of oxycodone and similar drugs. The DEA says that prescription drug abuse now exceeds abuse of all illegal drugs combined, except marijuana.

Michael Polzin, a spokesman for Deerfield, Ill.-based Walgreens, said it is cooperating in the investigation.

Earlier this year, the DEA moved to suspend the sale of similar controlled substances at two CVS pharmacies in the Orlando area, and the shipment of them from Cardinal Health Inc.'s Lakeland, Fla.-based center that supplied the stores. A federal appeals court recently upheld those suspensions.

DEA records cited in the Walgreens affidavit show sharp increases in oxycodone purchases at each of the locations. For example, the pharmacy in Fort Myers went from selling 95,800 units of oxycodone in 2009 to more than 2.1 million units in 2011 — good for 67 percent of all the oxycodone purchased by pharmacies in that same zip code in 2011.

In the first two months of this year, the DEA added, 53 Walgreens pharmacies are listed in the agency's top 100 purchasers of oxycodone. In 2009, none were on the list.

Earlier this year, the DEA released figures showing that Florida may be losing its distinction as the nation's leading illicit source for painkillers because of the ongoing law enforcement crackdown and several new laws. Florida also last year began operating a prescription drug tracking system and database aimed at combating illegal diversion of the drugs.

About 85 people, including at least 13 doctors, have been arrested in South Florida over the past year on pill mill-related charges, according to federal prosecutors.

The DEA's prescription drug policy saves many lives
Wall Street Journal
By: Peter Bensinger and Robert L. DuPont

Scott Gottlieb's "The DEA's War on Pharmacies—and Pain Patients" (op-ed, March 23) hardly tells the true story of prescription drug abuse and the government's response. In the current Cardinal Health case, the Drug Enforcement Administration discovered numerous oxycodone transactions that greatly exceeded the "suspicious order" criteria in the law and were not halted or reported to the DEA. Cardinal Health was fined $34 million in 2008 for similar violations.

Last July, the Florida legislature declared a public-health emergency—not because of a shortage of medicine, but because of increased overdose deaths caused by prescription opioids. Last year 25 distributors provided over 570 million dosage units of oxycodone in Florida alone, with Cardinal Health accounting for 25%.

Dr. Gottlieb thinks transferring DEA's responsibilities to the FDA would be a good idea, yet the FDA's record when it comes to regulating controlled substances is not good. In 1996, DEA asked FDA to schedule Soma (carisoprodol), a muscle relaxant abused by opiate addicts. In 2009, 13 years later, the FDA granted permission to schedule the drug. In 2004, the DEA asked the FDA to reschedule hydrocodone products (Vicodin, Lortab, etc.). The FDA responded four years later but did not agree to tighten the controls on what continues to be America's most frequently prescribed opioid associated with significant overdose deaths. A bill currently in Congress, if passed, will accomplish this long overdue action.

Prescription-drug overdose deaths now exceed U.S. motor-vehicle fatalities. The only federal agency that has confronted the unlawful diversion of these drugs is the DEA. Shifting regulatory control from the DEA to the FDA would accomplish nothing, but would add to the problem.

The DEA represents the unspoken interests of tens of thousands of victims harmed or killed each year by prescription drug abuse. The DEA's enforcement actions in Florida are clearly in the public interest, and its regulatory authority should not be diminished, but strongly supported.

Actavis Top 50 Pharmacy
Sales 2010-2012

Top 50 Pharmacies
Sales of Oxycodone 15mg (NDC 52152-0214-02)
2010

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
1	BF7000526	FOOD CITY PHARMACY #674	KNOX	KNOXVILLE	TN	37919	245,000
2	AB9244497	BERNIE'S PHARMACY	ANCHORAGE	ANCHORAGE	AK	99508	213,600
3	FH0853247	HAPPY HARRY'S INC.	SUSSEX	SEAFORD	DE	19973	194,600
4	BH8636598	HEPZIBAH	HILLSBOROUGH	TAMPA	FL	33613	177,300
5	BE6812754	EXPRESS SCRIPTS	BUCKS	BENSALEM	PA	19020	158,300
6	BT7485166	THE WELLNESS PHARMACY INC	DAVIDSON	ANTIOCH	TN	37013	150,000
7	BJ3675456	J & H STORES INC	BROWARD	FORT LAUDERDALE	FL	33309	148,000
8	FJ1305689	JK SERVICES OF SARASOTA LLC	MANATEE	BRADENTON	FL	34202	145,900
9	BS8246349	SAFESCRIPT PHARMACY #6	CABELL	HUNTINGTON	WV	25701	145,400
10	AW3028304	WALGREEN CO.	BREVARD	PALM BAY	FL	32905	138,000
11	FH1151517	HAPPY HARRY'S, INC.	SUSSEX	MILFORD	DE	19963	136,100
12	BW5872494	WALGREEN CO.	SAINT LUCIE	FORT PIERCE	FL	34981	127,900
13	FS0617893	SANDLAKE PHARMACY	ORANGE	ORLANDO	FL	32819	126,600
14	BE8131625	ESI MAIL PHARMACY SERVICE	MARICOPA	TEMPE	AZ	85284	125,500
15	BW1548760	WALGREEN CO.	SEMINOLE	CASSELBERRY	FL	32730	125,500
16	AW1366877	WALGREEN CO.	LEE	FORT MYERS	FL	33907	124,100
17	BP6777532	PROSCRIPT PHARMACY SERVICES, INC	BROWARD	FORT LAUDERDALE	FL	33314	117,400
18	BN9244726	NORWIN PHARMACY	WESTMORELAND	IRWIN	PA	15642	110,200
19	BO9931557	OSBORNE PHARM INC	BROWARD	FORT LAUDERDALE	FL	33317	108,700
20	BH9875026	HAPPY HARRY'S INC.	NEW CASTLE	BEAR	DE	19701	103,400
21	AW5430943	WALGREEN CO.	SARASOTA	SARASOTA	FL	34233	101,100
22	BW3133915	WALGREEN CO.	ORANGE	ORLANDO	FL	32806	99,500
23	BW5039804	WALGREEN EASTERN CO., INC.	STRAFFORD	ROCHESTER	NH	03867	99,000
24	FW0277283	WALGREEN CO.	CALVERT	PRINCE FREDERICK	MD	20678	98,900
25	FP1067164	PERRY DRUG INC.	JOHNSON	LENEXA	KS	66215	97,600
26	BW8910879	WALGREENS MAIL SERVICE, INC.	ORANGE	ORLANDO	FL	32819	96,500
27	FU1700512	UPSTATE PHARMACY CROSS CREEK	GREENVILLE	GREENVILLE	SC	29605	94,700
28	BW5837591	WALGREEN CO.	MILWAUKEE	MILWAUKEE	WI	53222	94,500
29	BH9874810	HAPPY HARRY'S INC.	SUSSEX	LEWES	DE	19958	93,600
30	BW7920413	WALGREEN CO.	BALTIMORE	PARKVILLE	MD	21234	91,500
31	AW6020541	WALGREEN CO.	MANATEE	BRADENTON	FL	34205	90,600
32	AE6893374	ELK PHARMACY INC	SURRY	ELKIN	NC	28621	89,300
33	BL4229515	LOVELACE OUTPATIENT PHARMACY	BERNALILLO	ALBUQUERQUE	NM	87108	88,800
34	BH9874151	HAPPY HARRY'S INC.	NEW CASTLE	NEWARK	DE	19713	88,700

Date Prepared : 04/03/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
35	AM8423080	MANOR PHARMACY	NEW CASTLE	NEW CASTLE	DE	19720	87,600
36	AW6020539	WALGREEN CO.	MANATEE	BRADENTON	FL	34207	86,300
37	BH9875216	HAPPY HARRY'S INC.	SUSSEX	LAUREL	DE	19956	86,000
38	BE6824317	EXPRESS SCRIPTS	SAINT LOUIS	SAINT LOUIS	MO	63134	85,700
39	BW4713992	WALGREEN CO.	PASCO	HUDSON	FL	34667	84,300
40	BP8246236	PHARMCORE INC	BROWARD	HALLANDALE	FL	33009	82,600
41	A97118246	TRU-VALU DRUGS	PALM BEACH	LAKE WORTH	FL	33460	82,500
42	FW0998647	WALGREEN CO	ORANGE	WINTER PARK	FL	32789	82,200
43	BW6561270	WALGREEN CO.	SAINT LUCIE	PORT SAINT LUCIE	FL	34952	82,000
44	BW9643013	WALGREEN CO.	ASHTABULA	ASHTABULA	OH	44004	81,700
45	AG0388238	P & S PHARMACY	SULLIVAN	KINGSPORT	TN	37660	81,600
46	FW1422512	WALGREEN CO.	MATANUSKA SUSITNA	WASILLA	AK	99654	81,400
47	BH9874923	HAPPY HARRY'S INC.	SUSSEX	MILLSBORO	DE	19966	81,200
48	BW3819781	WALGREEN ARIZONA DRUG CO.	MARICOPA	GLENDALE	AZ	85308	80,400
49	BW7169154	WALGREEN CO.	SALT LAKE	SALT LAKE CITY	UT	84118	79,400
50	BW5431084	WAL-MART PHARMACY 10-1242	HENDERSON	HENDERSONVILLE	NC	28792	79,200

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Date Prepared : 04/03/2012
Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 30mg (NDC 52152-0215-02)
2010

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
1	BF7000526	FOOD CITY PHARMACY #674	KNOX	KNOXVILLE	TN	37919	1,360,800
2	BJ3675456	J & H STORES INC	BROWARD	FORT LAUDERDALE	FL	33309	1,079,100
3	BG5677630	GENERIC DEPOT #2 INC	BROWARD	HOLLYWOOD	FL	33026	970,400
4	FG1544229	GENERIC DEPOT 3, INC	BROWARD	FORT LAUDERDALE	FL	33321	792,400
5	FH0772257	HILLS PHARMACY	HILLSBOROUGH	TAMPA	FL	33615	653,400
6	BJ9752115	JR PHARMACY	ORANGE	ORLANDO	FL	32837	618,600
7	AW8830247	WALGREEN CO.	PASCO	PORT RICHEY	FL	34668	559,700
8	BW1548760	WALGREEN CO.	SEMINOLE	CASSELBERRY	FL	32730	543,500
9	BW4713992	WALGREEN CO.	PASCO	HUDSON	FL	34667	542,300
10	BW5872494	WALGREEN CO.	SAINT LUCIE	FORT PIERCE	FL	34981	517,700
11	BO9931557	OSBORNE PHARM INC	BROWARD	FORT LAUDERDALE	FL	33317	492,000
12	BW3133915	WALGREEN CO.	ORANGE	ORLANDO	FL	32806	470,600
13	AW9808568	WINDSOR PHARMACY	MIDDLESEX	EAST BRUNSWICK	NJ	08816	447,200
14	BK7456052	KABS OF TAMPA	HILLSBOROUGH	TAMPA	FL	33613	405,400
15	BS9255274	SUPERIOR PHARMACY LLC	HILLSBOROUGH	TAMPA	FL	33609	379,300
16	BB6383169	BELEW DRUG	KNOX	KNOXVILLE	TN	37917	362,900
17	FN1282968	NDBP LLC	BROWARD	POMPANO BEACH	FL	33064	359,200
18	AW2058887	WALGREEN CO.	PINELLAS	LARGO	FL	33771	352,700
19	FK1428196	KISKEYA PHARMACY	BROWARD	FORT LAUDERDALE	FL	33312	349,200
20	BH9131436	HYGEIA HOLDINGS, LLC	PINELLAS	LARGO	FL	33771	335,700
21	BW7056547	WALGREEN CO.	PALM BEACH	BOCA RATON	FL	33428	332,800
22	BP6777532	PROSCRIPT PHARMACY SERVICES, INC	BROWARD	FORT LAUDERDALE	FL	33314	322,800
23	AW5430943	WALGREEN CO.	SARASOTA	SARASOTA	FL	34233	319,200
24	BS9699731	SUPERIOR PHARMACY, LLC	HILLSBOROUGH	TAMPA	FL	33615	318,100
25	BR0179730	RUPAL ENTERPRISE INC	SUFFOLK	SELDEN	NY	11784	315,600
26	FJ1672763	JPPD INC	PALM BEACH	BOCA RATON	FL	33431	314,300
27	AS8841428	SCHAEFER DRUGS WELLINGTON	PALM BEACH	WELLINGTON	FL	33414	313,900
28	FF0129709	FUTURE PHARMACY LLC	MIDDLESEX	OLD BRIDGE	NJ	08857	313,800
29	BL3161178	L KRENK	MAUI	KAHULUI	HI	96732	312,600
30	BB9044847	BETTER HEALTH PHARMACY INC	HILLSBOROUGH	SEFFNER	FL	33584	310,300
31	BS9491147	SUPER SAVER PHARMACY	OSCEOLA	KISSIMMEE	FL	34744	300,400
32	BW0882957	WALGREEN CO.	ORANGE	ORLANDO	FL	32812	298,900
33	AW1366877	WALGREEN CO.	LEE	FORT MYERS	FL	33907	295,100

Date Prepared : 04/03/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
34	AW0200939	WALGREEN CO.	BROWARD	HOLLYWOOD	FL	33024	294,100
35	BW6561270	WALGREEN CO.	SAINT LUCIE	PORT SAINT LUCIE	FL	34952	291,000
36	FP1223899	PROGRESSIVE PHARMACY INC.	PALM BEACH	LAKE WORTH	FL	33467	287,400
37	AH2731025	HOLLYWOOD DISCOUNT PHARMACY	BROWARD	HOLLYWOOD	FL	33021	286,300
38	BW7288752	WALGREEN CO.	ORANGE	OCOEE	FL	34761	282,400
39	AW3028304	WALGREEN CO.	BREVARD	PALM BAY	FL	32905	277,700
40	BS9839424	SARASOTA PHARMACY SERVICES	SARASOTA	SARASOTA	FL	34233	277,300
41	FE1512501	EDGE PHARMACY	POLK	LAKELAND	FL	33803	272,900
42	AW3132963	WALGREEN CO.	ORANGE	ORLANDO	FL	32822	262,500
43	BC9698448	CHEMISTS N DRUGGISTS, INC.	PALM BEACH	BOYNTON BEACH	FL	33436	256,500
44	AT0205167	PRESCRIPTION SHOP OF STUART	MARTIN	STUART	FL	34994	254,400
45	AK3221140	KEANSBURG DRUGS	MONMOUTH	KEANSBURG	NJ	07734	251,500
46	FS0617893	SANDLAKE PHARMACY	ORANGE	ORLANDO	FL	32819	251,400
47	FA0523147	A.I.P. HEALTHCARE SERVICES	BROWARD	FORT LAUDERDALE	FL	33309	250,600
48	BW8940923	WALGREEN CO.	PINELLAS	LARGO	FL	33771	249,500
49	BP9741934	PHARMACY XPRESS OF FL, III	BROWARD	FORT LAUDERDALE	FL	33334	245,200
50	FG1524657	GENERIC RX, LLC	BROWARD	DEERFIELD BEACH	FL	33442	245,000

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Date Prepared : 04/03/2012
Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 15mg (NDC 52152-0214-02)
2011

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
1	AW1366877	WALGREEN CO.	LEE	FORT MYERS	FL	33907	411,100
2	FH0853247	HAPPY HARRY'S INC.	SUSSEX	SEAFORD	DE	19973	148,000
3	BE6824317	EXPRESS SCRIPTS	SAINT LOUIS	SAINT LOUIS	MO	63134	131,800
4	BW8487438	WALGREEN CO.	SEMINOLE	OVIEDO	FL	32765	128,300
5	BW4713992	WALGREEN CO.	PASCO	HUDSON	FL	34667	127,800
6	BT0167444	THE MEDICINE SHOPPE	ALLEGHENY	OAKMONT	PA	15139	122,000
7	FW0277283	WALGREEN CO.	CALVERT	PRINCE FREDERICK	MD	20678	121,400
8	BT9937965	THE PILL BOX PHARMACY	SUSSEX	MILFORD	DE	19963	110,600
9	BW5872494	WALGREEN CO.	SAINT LUCIE	FORT PIERCE	FL	34981	109,800
10	BC7126457	CAREMED HEALTH CORPORATIO	LEE	BONITA SPRINGS	FL	34135	109,300
11	FH1151517	HAPPY HARRY'S, INC.	SUSSEX	MILFORD	DE	19963	106,300
12	BN9244726	NORWIN PHARMACY	WESTMORELAND	IRWIN	PA	15642	106,200
13	FP1856446	PHARMA-1	FRANKLIN	COLUMBUS	OH	43207	105,600
14	AB9244497	BERNIE'S PHARMACY	ANCHORAGE	ANCHORAGE	AK	99508	105,600
15	FV2178879	VILLAGE PHARMACY	LIVINGSTON	DENHAM SPRINGS	LA	70726	101,200
16	BW1548760	WALGREEN CO.	SEMINOLE	CASSELBERRY	FL	32730	99,000
17	AW3028304	WALGREEN CO.	BREVARD	PALM BAY	FL	32905	98,900
18	BE9738026	ESTRELLA PHARMACY	MARICOPA	PHOENIX	AZ	85037	96,400
19	AT1701172	CITY PHARMACY INC OF ELKTON	CECIL	ELKTON	MD	21921	94,500
20	BW6561270	WALGREEN CO.	SAINT LUCIE	PORT SAINT LUCIE	FL	34952	93,200
21	AW8830247	WALGREEN CO.	PASCO	PORT RICHEY	FL	34668	92,200
22	AN1556337	NATIONAL FAMILY PHARMACY	SEBASTIAN	FORT SMITH	AR	72901	86,700
23	FW1144574	WALGREEN CO.	RALEIGH	BECKLEY	WV	25801	86,300
24	BW5507415	WALGREEN CO.	SEMINOLE	OVIEDO	FL	32765	83,900
25	FU1700512	UPSTATE PHARMACY CROSS CR	GREENVILLE	GREENVILLE	SC	29605	83,800
26	FW1444695	WALGREEN CO.	ORANGE	ORLANDO	FL	32807	81,800
27	BS8246349	SAFESCRIPT PHARMACY #6	CABELL	HUNTINGTON	WV	25701	81,600
28	BW3819781	WALGREEN ARIZONA DRUG CO.	MARICOPA	GLENDALE	AZ	85308	79,900
29	BF7000526	FOOD CITY PHARMACY #674	KNOX	KNOXVILLE	TN	37919	79,200
30	BH9875026	HAPPY HARRY'S INC.	NEW CASTLE	BEAR	DE	19701	79,100
31	BW5837591	WALGREEN CO.	MILWAUKEE	MILWAUKEE	WI	53222	78,300
32	FJ1305689	JK SERVICES OF SARASOTA LLC	MANATEE	BRADENTON	FL	34202	77,600
33	FH0895815	HAPPY HARRY'S INC.	KENT	DOVER	DE	19904	77,500
34	FW1223659	WALGREEN CO.	RALEIGH	BECKLEY	WV	25801	76,500

Date Prepared : 04/03/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
35	AW6020539	WALGREEN CO.	MANATEE	BRADENTON	FL	34207	76,500
36	FF1280089	FOOD CITY PHARMACY # 616	KNOX	KNOXVILLE	TN	37932	74,400
37	BH9875216	HAPPY HARRY'S INC.	SUSSEX	LAUREL	DE	19956	74,300
38	FW0688272	WALGREEN CO	CLARK	WINCHESTER	KY	40391	74,200
39	BW2101880	WALGREEN CO.	CHARLOTTE	PORT CHARLOTTE	FL	33948	73,900
40	BW7758759	WALGREEN CO.	PINELLAS	SAINT PETERSBURG	FL	33709	73,600
41	AW6043234	WALGREEN CO.	PINELLAS	SAINT PETERSBURG	FL	33712	68,800
42	FW1422512	WALGREEN CO.	MATANUSKA SUSITN	WASILLA	AK	99654	68,600
43	BW3133915	WALGREEN CO.	ORANGE	ORLANDO	FL	32806	68,500
44	AM8423080	MANOR PHARMACY	NEW CASTLE	NEW CASTLE	DE	19720	65,200
45	BW6997906	WALGREEN CO.	PUEBLO	PUEBLO	CO	81001	65,000
46	BH9874341	HAPPY HARRY'S INC.	SUSSEX	GEORGETOWN	DE	19947	64,700
47	AW1768463	WALGREEN CO.	MARTIN	STUART	FL	34997	64,700
48	AW2290699	WALGREEN CO.	SARASOTA	SARASOTA	FL	34233	64,300
49	BT7485166	THE WELLNESS PHARMACY INC	DAVIDSON	ANTIOCH	TN	37013	63,900
50	AW6020541	WALGREEN CO.	MANATEE	BRADENTON	FL	34205	63,600

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Date Prepared : 04/03/2012
Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 30mg (NDC 00228-2879-11
2011

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
1	BF7000526	FOOD CITY PHARMACY #674	KNOX	KNOXVILLE	TN	37919	851,200
2	BW8487438	WALGREEN CO.	SEMINOLE	OVIEDO	FL	32765	817,400
3	BW4713992	WALGREEN CO.	PASCO	HUDSON	FL	34667	718,800
4	AW1366877	WALGREEN CO.	LEE	FORT MYERS	FL	33907	618,500
5	BW5872494	WALGREEN CO.	SAINT LUCIE	FORT PIERCE	FL	34981	439,900
6	BW6561270	WALGREEN CO.	SAINT LUCIE	PORT SAINT LUCIE	FL	34952	429,500
7	FR1435355	ROCKY'S MED SHOPPE, LLC	WASHINGTON	BOGALUSA	LA	70427	418,200
8	BW1249160	WALGREEN CO.	SAINT LUCIE	PORT SAINT LUCIE	FL	34952	404,800
9	FF1280089	FOOD CITY PHARMACY # 616	KNOX	KNOXVILLE	TN	37932	356,800
10	AN1556337	NATIONAL FAMILY PHARMACY	SEBASTIAN	FORT SMITH	AR	72901	334,700
11	BW1548760	WALGREEN CO.	SEMINOLE	CASSELBERRY	FL	32730	308,400
12	AW1307138	WALGREEN CO.	CITRUS	HOMOSASSA	FL	34446	295,300
13	BW9688992	WALGREEN CO.	MARION	OCALA	FL	34482	295,000
14	BW9628631	WALGREEN CO.	PINELLAS	SAINT PETERSBURG	FL	33702	291,200
15	FD0598207	DUANE READE	NEW YORK	NEW YORK	NY	10003	289,800
16	BW1229118	WALGREEN CO.	DUVAL	JACKSONVILLE	FL	32216	285,300
17	BF9649508	FOOD CITY PHARMACY #694	KNOX	KNOXVILLE	TN	37919	259,300
18	FW0457122	WALGREEN CO	CITRUS	HOMOSASSA	FL	34446	247,100
19	AW1768463	WALGREEN CO.	MARTIN	STUART	FL	34997	244,900
20	BW8940923	WALGREEN CO.	PINELLAS	LARGO	FL	33771	228,400
21	AW3028304	WALGREEN CO.	BREVARD	PALM BAY	FL	32905	225,500
22	BW0882957	WALGREEN CO.	ORANGE	ORLANDO	FL	32812	217,400
23	AK3221140	KEANSBURG DRUGS	MONMOUTH	KEANSBURG	NJ	07734	214,700
24	BB6383169	BELEW DRUG	KNOX	KNOXVILLE	TN	37917	210,200
25	AW0201032	WALGREEN CO.	PALM BEACH	WEST PALM BEACH	FL	33404	209,800
26	BW7056547	WALGREEN CO.	PALM BEACH	BOCA RATON	FL	33428	208,000
27	AW2388242	WALGREEN CO.	SAINT LUCIE	FORT PIERCE	FL	34950	206,400
28	FW0064799	WALGREEN CO.	PALM BEACH	WELLINGTON	FL	33414	205,600
29	FH0825313	HUMANA PHARMACY INC DBA RIGHTSO	BUTLER	WEST CHESTER	OH	45069	204,600
30	AW2290699	WALGREEN CO.	SARASOTA	SARASOTA	FL	34233	202,700
31	BJ3675456	J & H STORES INC	BROWARD	FORT LAUDERDALE	FL	33309	201,900
32	FW1444695	WALGREEN CO.	ORANGE	ORLANDO	FL	32807	197,600
33	AW6043234	WALGREEN CO.	PINELLAS	SAINT PETERSBURG	FL	33712	196,500

Date Prepared : 04/03/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
34	BW4808929	WALGREEN CO.	INDIAN RIVER	VERO BEACH	FL	32962	196,500
35	BW5507415	WALGREEN CO.	SEMINOLE	OVIEDO	FL	32765	191,900
36	BW5108178	WALGREEN EASTERN CO., INC.	MIDDLESEX	EAST BRUNSWICK	NJ	08816	191,700
37	BH4285309	HEALTHWISE PHARMACY	HILLSBOROUGH	TAMPA	FL	33614	190,700
38	BE9503687	E. HARTMAN LLC DBA DEAL DRUGS	DAVIDSON	NASHVILLE	TN	37211	188,800
39	AW9808568	WINDSOR PHARMACY	MIDDLESEX	EAST BRUNSWICK	NJ	08816	185,000
40	AW6041153	WALGREEN CO.	PINELLAS	SAINT PETERSBURG	FL	33703	180,700
41	BW7758759	WALGREEN CO.	PINELLAS	SAINT PETERSBURG	FL	33709	178,900
42	FH0853247	HAPPY HARRY'S INC.	SUSSEX	SEAFORD	DE	19973	178,600
43	BW0523488	WALGREEN CO.	PASCO	NEW PORT RICHEY	FL	34653	177,400
44	BW4933114	WALGREEN CO.	PINELLAS	SAINT PETERSBURG	FL	33707	177,400
45	BW2101880	WALGREEN CO.	CHARLOTTE	PORT CHARLOTTE	FL	33948	174,400
46	BA3438505	NEW ALBERTSON'S, INC.	CLARK	LAS VEGAS	NV	89128	173,900
47	AW3050995	WALGREEN CO.	PINELLAS	LARGO	FL	33770	173,000
48	FM1807289	MAYNARDVILLE PHARMACY INC	UNION	MAYNARDVILLE	TN	37807	171,700
49	AH2731025	HOLLYWOOD DISCOUNT PHARMACY	BROWARD	HOLLYWOOD	FL	33021	171,600
50	FP1067164	PERRY DRUG INC.	JOHNSON	LENEXA	KS	66215	166,100

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Date Prepared : 04/03/2012
Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 15mg (NDC 00228-2878-11)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
1	BW5837591	WALGREEN CO.	MILWAUKEE	MILWAUKEE	WI	53222	132,200
2	AB9244497	BERNIE'S PHARMACY	ANCHORAGE	ANCHORAGE	AK	99508	127,600
3	FB2049446	BYPASS PHARMACY, INC	RALEIGH	BECKLEY	WV	25801	105,800
4	FH1151517	HAPPY HARRY'S, INC.	SUSSEX	MILFORD	DE	19963	104,000
5	BF7000526	FOOD CITY PHARMACY #674	KNOX	KNOXVILLE	TN	37919	88,000
6	BT0167444	THE MEDICINE SHOPPE	ALLEGHENY	OAKMONT	PA	15139	84,000
7	FH1454999	HOWARD FAMILY PHARMACY, INC.	FLOYD	EASTERN	KY	41622	82,600
8	BW4713992	WALGREEN CO.	PASCO	HUDSON	FL	34667	81,800
9	BF4478803	FRANCK'S EPS	ALLEGHENY	PITTSBURGH	PA	15202	81,600
10	FA2348616	ARIZONA PHARMACY # 2	MARICOPA	PHOENIX	AZ	85027	79,600
11	AW5430943	WALGREEN CO.	SARASOTA	SARASOTA	FL	34233	76,400
12	BW5093858	WALGREEN EASTERN CO., INC.	PROVIDENCE	WOONSOCKET	RI	02895	75,800
13	BC8361343	CRAIN TOWERS PHARMACY	ANNE ARUNDEL	GLEN BURNIE	MD	21061	75,800
14	BW4050996	WALGREEN CO.	MILWAUKEE	MILWAUKEE	WI	53208	75,600
15	FW1144574	WALGREEN CO.	RALEIGH	BECKLEY	WV	25801	74,000
16	BW7920413	WALGREEN CO.	BALTIMORE	PARKVILLE	MD	21234	73,400
17	FU1700512	UPSTATE PHARMACY CROSS CREEK	GREENVILLE	GREENVILLE	SC	29605	72,800
18	FH0853247	HAPPY HARRY'S INC.	SUSSEX	SEAFORD	DE	19973	72,000
19	BW6997906	WALGREEN CO.	PUEBLO	PUEBLO	CO	81001	70,200
20	FW1223659	WALGREEN CO.	RALEIGH	BECKLEY	WV	25801	70,200
21	FF1280089	FOOD CITY PHARMACY # 616	KNOX	KNOXVILLE	TN	37932	69,600
22	BN7185386	NORTHSIDE PHARMACY LLC	LAFAYETTE	LAFAYETTE	LA	70501	69,600
23	FW1422512	WALGREEN CO.	MATANUSKA SUSITNA	WASILLA	AK	99654	67,000
24	BH9874341	HAPPY HARRY'S INC.	SUSSEX	GEORGETOWN	DE	19947	65,200

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 15mg (NDC 00228-2878-11)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
25	BW3819781	WALGREEN ARIZONA DRUG CO.	MARICOPA	GLENDALE	AZ	85308	64,400
26	BW8910879	WALGREENS MAIL SERVICE, INC.	ORANGE	ORLANDO	FL	32819	64,000
27	BT7485166	THE WELLNESS PHARMACY INC	DAVIDSON	ANTIOCH	TN	37013	63,400
28	FJ1305689	JK SERVICES OF SARASOTA LLC	MANATEE	BRADENTON	FL	34202	63,000
29	BW6678734	WALGREEN CO.	BALTIMORE CITY	BALTIMORE	MD	21224	63,000
30	BW2101880	WALGREEN CO.	CHARLOTTE	PORT CHARLOTTE	FL	33948	63,000
31	FM1704825	MEDARBOR PHARMACY	MONTGOMERY	BALA CYNWYD	PA	19004	62,400
32	BW7143908	WALGREEN CO.	HILLSBOROUGH	TAMPA	FL	33603	61,800
33	BX9625560	XPRESS CARE PHARMACY	MARICOPA	AVONDALE	AZ	85392	58,600
34	BL9260415	LAKE PHARMACY	LAKE	CLEARLAKE	CA	95422	58,200
35	BW9404358	WALGREEN EASTERN CO., INC.	BUCKS	LEVITTOWN	PA	19054	58,000
36	BW3057393	WALGREEN HASTINGS CO.	SANDOVAL	RIO RANCHO	NM	87124	58,000
37	FR2333780	RT 70 PHARMACY, INC	CAMDEN	CHERRY HILL	NJ	08034	56,400
38	BW6057790	WALGREEN CO.	PUEBLO	PUEBLO	CO	81005	56,200
39	BW5119498	WALGREEN CO.	MILWAUKEE	MILWAUKEE	WI	53208	56,000
40	BS7479959	SUSITNA PROFESSIONAL PHARMACY	MATANUSKA SUSITNA	WASILLA	AK	99654	56,000
41	BW5108178	WALGREEN EASTERN CO., INC.	MIDDLESEX	EAST BRUNSWICK	NJ	08816	54,600
42	BM8708692	MEDICAP PHARMACY	CRAVEN	NEW BERN	NC	28560	53,600
43	AW5120237	WALGREEN ARIZONA DRUG CO.	MARICOPA	PHOENIX	AZ	85051	53,400
44	BW3834555	WALGREEN CO.	MANITOWOC	MANITOWOC	WI	54220	53,200
45	FW0812532	WALGREEN CO	CHARLES	LA PLATA	MD	20646	52,600
46	BH9875040	HAPPY HARRY'S INC.	NEW CASTLE	WILMINGTON	DE	19806	52,600
47	BH9875026	HAPPY HARRY'S INC.	NEW CASTLE	BEAR	DE	19701	52,600
48	FH0895815	HAPPY HARRY'S INC.	KENT	DOVER	DE	19904	52,000

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 15mg (NDC 00228-2878-11)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
49	**AW0201210**	**WALGREEN CO.**	MANATEE	**BRADENTON**	FL	34205	52,000
50	**AW6020541**	**WALGREEN CO.**	MANATEE	**BRADENTON**	FL	34205	52,000

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 15mg (NDC 52152-0214-02)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
1	FQ1872844	QUICK CARE PHARMACY INC	SAN BERNARDINO	RANCHO CUCAMONG	CA	91730	3,600
2	AA8612790	CIGNA HEALTH PLAN OF ARIZONA	MARICOPA	SUN CITY	AZ	85351	2,400
3	BF3545704	FRUTH PHARMACY #16	PIKE	WAVERLY	OH	45690	2,400
4	FD0982846	DELCO DRUGS & SPECIALTY PHARMACY IN	RICHMOND	STATEN ISLAND	NY	10312	1,000
5	BB9732389	BASHAS UNITED DRUG #160	PIMA	TUCSON	AZ	85704	1,000
6	BF1124609	FRUTH PHARMACY OF HURRICANE	PUTNAM	HURRICANE	WV	25526	900
7	FM0386082	MORRILTON FOOD & DRUG BIG STAR	CONWAY	MORRILTON	AR	72110	600
8	FT0748333	TOTAL PHARMACY AND COMPOUNDING S	HARRIS	HOUSTON	TX	77006	500
9	AK5643095	KLINGENSMITH'S DRUG STORE	ARMSTRONG	FORD CITY	PA	16226	500
10	BR3876084	REEDSBURG MEDIC ARTS PHAR	SAUK	REEDSBURG	WI	53959	300
11	AW4125452	BUFFALO DRUGS INC	BERRIEN	NEW BUFFALO	MI	49117	200
12	BE8487589	EDMONDSON DRUG CO INC	CULLMAN	HANCEVILLE	AL	35077	100
13	FT0710649	TAINO STAR PHARMACY INC	NEW YORK	NEW YORK	NY	10035	100

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 30mg (NDC 52152-0215-02)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
1	BO9283184	OLD TOWN PHARMACY INC	RICHMOND	STATEN ISLAND	NY	10305	26000
2	BM4633269	MW & W GLOBAL ENTERPRISES INC	KINGS	BROOKLYN	NY	11222	17600
3	BB4896784	BARRINGTON-WILSHIRE PHARMACY	LOS ANGELES	LOS ANGELES	CA	90025	12000
4	FS2338918	SAV MART PHARMACY II	WAYNE	DETROIT	MI	48207	9700
5	AR5920079	ROSSMORE PHARMACY INC	ESSEX	BELLEVILLE	NJ	07109	8300
6	BS9114000	SAINT MARY AND JESSIE, LLC	MIDDLESEX	PERTH AMBOY	NJ	08861	7900
7	AP5437199	PARAMOUNT DRUG	BURLINGTON	RIVERSIDE	NJ	08075	7200
8	BM9698551	MEDMART PHARMACY	FAYETTE	CONNELLSVILLE	PA	15425	7200
9	BG4568715	BRIDGE & PRATT FAMILY PHARMACY	PHILADELPHIA	PHILADELPHIA	PA	19124	6100
10	AM9597800	MOUNDSVILLE PHARMACY	MARSHALL	MOUNDSVILLE	WV	26041	5600
11	FS1638266	SCRIPT LIFE PHARMACY	FRESNO	CLOVIS	CA	93612	5400
12	BD0100317	DEAL ENTERPRISE	VENTURA	SIMI VALLEY	CA	93065	4800
13	BM0180086	MEDICINE SHOPPE	FRESNO	FRESNO	CA	93727	4500
14	BR6655712	RIVERSIDE PHARMACY	ETOWAH	GADSDEN	AL	35901	4100
15	BS9442966	SUPER RX PHARMACY #151	SAN DIEGO	OCEANSIDE	CA	92054	3600
16	FF1382542	FAMILY PHARMACY	NYE	PAHRUMP	NV	89048	3000
17	BF4837071	FOLLANSBEE PHARMACY	BROOKE	FOLLANSBEE	WV	26037	3000
18	BQ0878629	QUICK CHEK PHARMACY DEPT	OCEAN	BEACHWOOD	NJ	08722	3000
19	BS9128516	SULLIVAN PHARMACY INC	SULLIVAN	LIBERTY	NY	12754	2400
20	FH1614519	HARPER WOODS PHARMACY LLC	WAYNE	HARPER WOODS	MI	48225	2400
21	BF3545704	FRUTH PHARMACY #16	PIKE	WAVERLY	OH	45690	2400
22	FQ1872844	QUICK CARE PHARMACY INC	SAN BERNARDINO	RANCHO CUCAMONG	CA	91730	2400
23	AP1653117	P & G PHARMACY INC	NASSAU	FARMINGDALE	NY	11735	2000
24	FM2413780	MAST PHARMACY & SURGICAL	BURLINGTON	BORDENTOWN	NJ	08505	2000

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 30mg (NDC 52152-0215-02)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
25	AQ2494297	QUICK CHEK PHCY DEPT	HUDSON	BAYONNE	NJ	07002	2000
26	BM1457642	MISSION PHARMACY	LOS ANGELES	LONG BEACH	CA	90813	2000
27	AM2905935	M B DRUGS INC	KINGS	BROOKLYN	NY	11215	1800
28	BF7447774	FARMACIA SAN ANTONIO	CAMDEN	CAMDEN	NJ	08105	1800
29	FC0792704	CHURCH SQUARE PHARMACY	CUYAHOGA	CLEVELAND	OH	44103	1700
30	BB9732389	BASHAS UNITED DRUG #160	PIMA	TUCSON	AZ	85704	1600
31	FA2650807	AGHAPY PHARMACY INC	RIVERSIDE	SAN JACINTO	CA	92583	1500
32	FT0748333	TOTAL PHARMACY AND COMPOUNDING SERVICES	HARRIS	HOUSTON	TX	77006	1500
33	FS2058611	SANKOFA PHARMACY INC	PHILADELPHIA	PHILADELPHIA	PA	19111	1500
34	FM0386082	MORRILTON FOOD & DRUG BIG STAR	CONWAY	MORRILTON	AR	72110	1400
35	BA4725315	AMAN PHARMACY	SUFFOLK	SHOREHAM	NY	11786	1200
36	FC2126957	CAMPUS PHARMACY	ESSEX	NEWARK	NJ	07103	1200
37	BO8436669	OKIES PHARMACY	GRAINGER	BLAINE	TN	37709	1200
38	FC1748788	CLARK LOWCOST PHARMACY	CUYAHOGA	CLEVELAND	OH	44109	1100
39	BR3653842	RIDGWAY PHARMACY	MONTGOMERY	DAYTON	OH	45403	1000
40	BW9060702	WILKES FAMILY PHARMACY	WILKES	WILKESBORO	NC	28697	1000
41	FG1277044	GAULEY RIVER PHARMACY	NICHOLAS	CRAIGSVILLE	WV	26205	1000
42	AI9065423	FRANWIN PHARMACY	NASSAU	MINEOLA	NY	11501	1000
43	BP6460632	PLATINUM CARE PHARMACY INC	WAYNE	DETROIT	MI	48206	1000
44	BF1124609	FRUTH PHARMACY OF HURRICANE	PUTNAM	HURRICANE	WV	25526	800
45	BF0323775	FRENCHTOWN PHARMACY	HUNTERDON	FRENCHTOWN	NJ	08825	800
46	AM0561010	MACLEOD PRESCRIPTION PHARMACY	NIAGARA	NIAGARA FALLS	NY	14304	800
47	BA3799511	CVS ALBANY, L.L.C.	NASSAU	HICKSVILLE	NY	11801	600
48	BG9929071	GETMAN-APOTHECARY SHOPPE	TULSA	TULSA	OK	74104	600

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 30mg (NDC 52152-0215-02)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
49	**AL2338754**	**HARROLD'S PHARMACY**	LUZERNE	**WILKES BARRE**	PA	18702	600
50	**FP0152277**	**PEOPLE PHARMACY LLC**	WAYNE	**DETROIT**	MI	48235	600

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 30mg (NDC 00228-2879-11)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
1	BF7000526	FOOD CITY PHARMACY #674	KNOX	KNOXVILLE	TN	37919	628,100
2	BA3438505	NEW ALBERTSON'S, INC.	CLARK	LAS VEGAS	NV	89128	409,200
3	FF1280089	FOOD CITY PHARMACY # 616	KNOX	KNOXVILLE	TN	37932	279,200
4	FD0598207	DUANE READE	NEW YORK	NEW YORK	NY	10003	265,200
5	BF9649508	FOOD CITY PHARMACY #694	KNOX	KNOXVILLE	TN	37919	227,400
6	AW9808568	WINDSOR PHARMACY	MIDDLESEX	EAST BRUNSWICK	NJ	08816	193,800
7	BW2101880	WALGREEN CO.	CHARLOTTE	PORT CHARLOTTE	FL	33948	165,600
8	BW4963977	WALGREEN CO.	CLARK	NORTH LAS VEGAS	NV	89030	156,100
9	BW5108178	WALGREEN EASTERN CO., INC.	MIDDLESEX	EAST BRUNSWICK	NJ	08816	154,600
10	BW6630380	WAL-MART PHARMACY 10-2627	HILLSBOROUGH	TAMPA	FL	33612	154,300
11	FR1435355	ROCKY'S MED SHOPPE, LLC	WASHINGTON	BOGALUSA	LA	70427	151,600
12	AK3221140	KEANSBURG DRUGS	MONMOUTH	KEANSBURG	NJ	07734	149,100
13	BW6917972	WALGREEN CO.	CLARK	NORTH LAS VEGAS	NV	89032	143,500
14	BH9875040	HAPPY HARRY'S INC.	NEW CASTLE	WILMINGTON	DE	19806	143,400
15	BB6383169	BELEW DRUG	KNOX	KNOXVILLE	TN	37917	138,700
16	BW4713992	WALGREEN CO.	PASCO	HUDSON	FL	34667	137,700
17	FH1306984	HOPKINS PHARMACY	PHILADELPHIA	PHILADELPHIA	PA	19128	136,800
18	AW5732119	WALGREEN ARIZONA DRUG CO.	PIMA	TUCSON	AZ	85712	136,600
19	BW8421707	WALGREEN CO.	CLARK	LAS VEGAS	NV	89107	134,800
20	FH0825313	HUMANA PHARMACY INC DBA RIGHTSOURCE	BUTLER	WEST CHESTER	OH	45069	132,900
21	BH4285309	HEALTHWISE PHARMACY	HILLSBOROUGH	TAMPA	FL	33614	132,900
22	BW4986622	WALGREEN CO.	CLARK	LAS VEGAS	NV	89108	132,800
23	BW4319338	WALGREEN CO.	BLOUNT	ALCOA	TN	37701	132,300
24	BW5737791	WALGREEN CO.	CLARK	LAS VEGAS	NV	89121	131,000

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 30mg (NDC 00228-2879-11)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
25	BW0882957	WALGREEN CO.	ORANGE	ORLANDO	FL	32812	129,600
26	BS7719795	SHAYONA PHARMACY	MIDDLESEX	PERTH AMBOY	NJ	08861	128,600
27	BW6842656	WALGREEN EASTERN CO., INC.	SUFFOLK	SELDEN	NY	11784	120,100
28	BD1649978	DISNEY PHARMACY SEVICES	KNOX	POWELL	TN	37849	119,700
29	FW1672422	WALGREEN EASTERN CO., INC.	RICHMOND	STATEN ISLAND	NY	10305	116,500
30	BW6997906	WALGREEN CO.	PUEBLO	PUEBLO	CO	81001	115,100
31	BW8855655	WALGREEN EASTERN CO., INC.	RICHMOND	STATEN ISLAND	NY	10312	114,700
32	AW5430943	WALGREEN CO.	SARASOTA	SARASOTA	FL	34233	112,800
33	BW5837591	WALGREEN CO.	MILWAUKEE	MILWAUKEE	WI	53222	112,100
34	BT6419053	THE HOMETOWN PHARMACY	LAWRENCE	NEW CASTLE	PA	16101	111,000
35	BW7249623	WALGREEN CO.	CLARK	LAS VEGAS	NV	89106	110,800
36	BP9744524	PRESCRIPTION SOLUTIONS BY OPTUMRX	SAN DIEGO	CARLSBAD	CA	92010	110,800
37	BE9503687	E. HARTMAN LLC DBA DEAL DRUGS	DAVIDSON	NASHVILLE	TN	37211	110,600
38	AW1124306	WALGREEN CO.	DONA ANA	LAS CRUCES	NM	88001	110,400
39	FM1083500	MEDPOINT PHARMACY, INC.	MILWAUKEE	MILWAUKEE	WI	53209	109,400
40	BW4616299	WALGREEN EASTERN CO., INC.	UNION	ELIZABETH	NJ	07208	107,700
41	FB2049446	BYPASS PHARMACY, INC	RALEIGH	BECKLEY	WV	25801	107,500
42	BW1548760	WALGREEN CO.	SEMINOLE	CASSELBERRY	FL	32730	104,700
43	BW7577490	WALGREEN CO.	ORANGE	ORLANDO	FL	32806	104,600
44	FC0863274	CKC INVESTMENT INC	ORANGE	FULLERTON	CA	92835	103,100
45	FW1223659	WALGREEN CO.	RALEIGH	BECKLEY	WV	25801	102,800
46	FR2333780	RT 70 PHARMACY, INC	CAMDEN	CHERRY HILL	NJ	08034	102,600
47	BW5483970	WALGREEN CO.	CLARK	LAS VEGAS	NV	89104	102,600
48	FW1840289	WALGREEN EASTERN CO., INC.	RICHMOND	STATEN ISLAND	NY	10305	102,200

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

Top 50 Pharmacies
Sales of Oxycodone 30mg (NDC 00228-2879-11)
January 1, 2012 to June 30, 2012

Rank	Buyer's DEA Number	Buyer's Name	Buyer's County	Buyer's City	Buyer's State	Buyer's Zip	Total
49	AH2731025	HOLLYWOOD DISCOUNT PHARMACY	BROWARD	HOLLYWOOD	FL	33021	101,800
50	BW1229118	WALGREEN CO.	DUVAL	JACKSONVILLE	FL	32216	100,500

Date Prepared: 06/30/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Source: ARCOS

UPS Supply Chain Sales
to Distributors

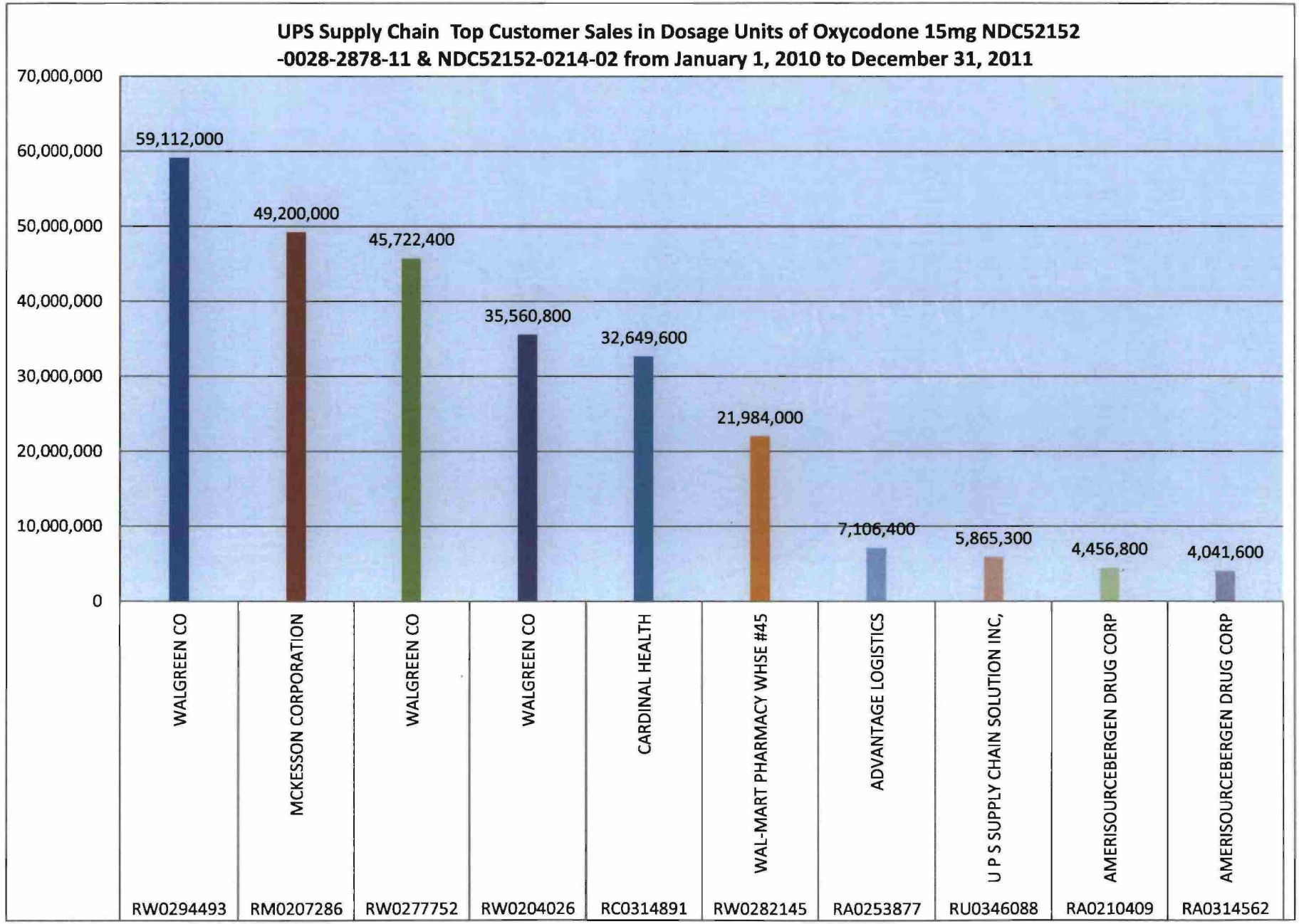
The following charts and graphs have been compiled from ARCOS reports your firm has previously submitted to DEA. The data was reviewed and the purchases of a few of your customers will be addressed during our discussion.

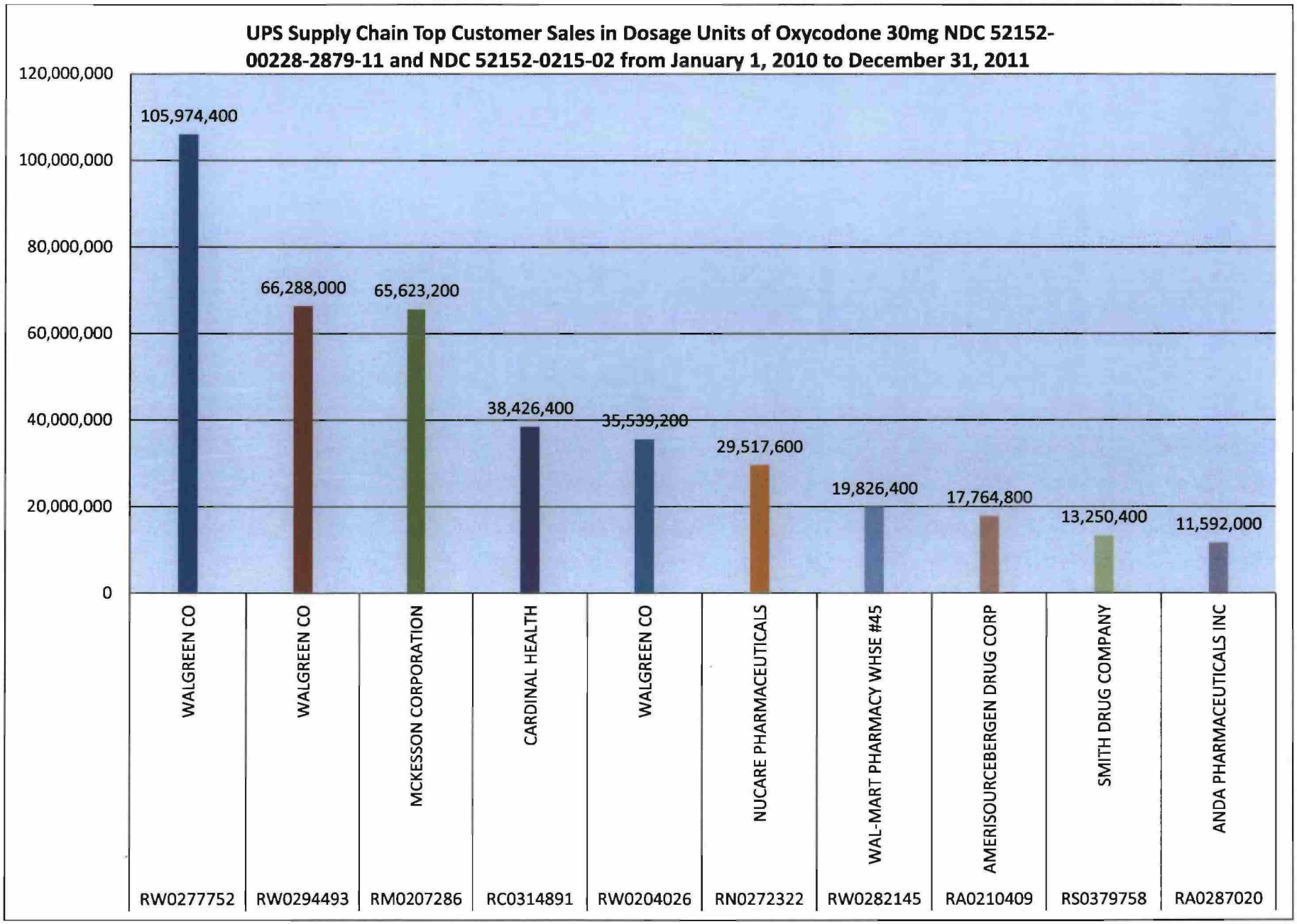
The mentioning of specific customers is NOT to be implied that the sale of controlled substances to these customers is illicit or that they may be involved in illicit activities.

It also should NOT be inferred that based upon the documentation provided to you that your company should terminate or restrict business with any customer discussed for the purposes of this presentation.

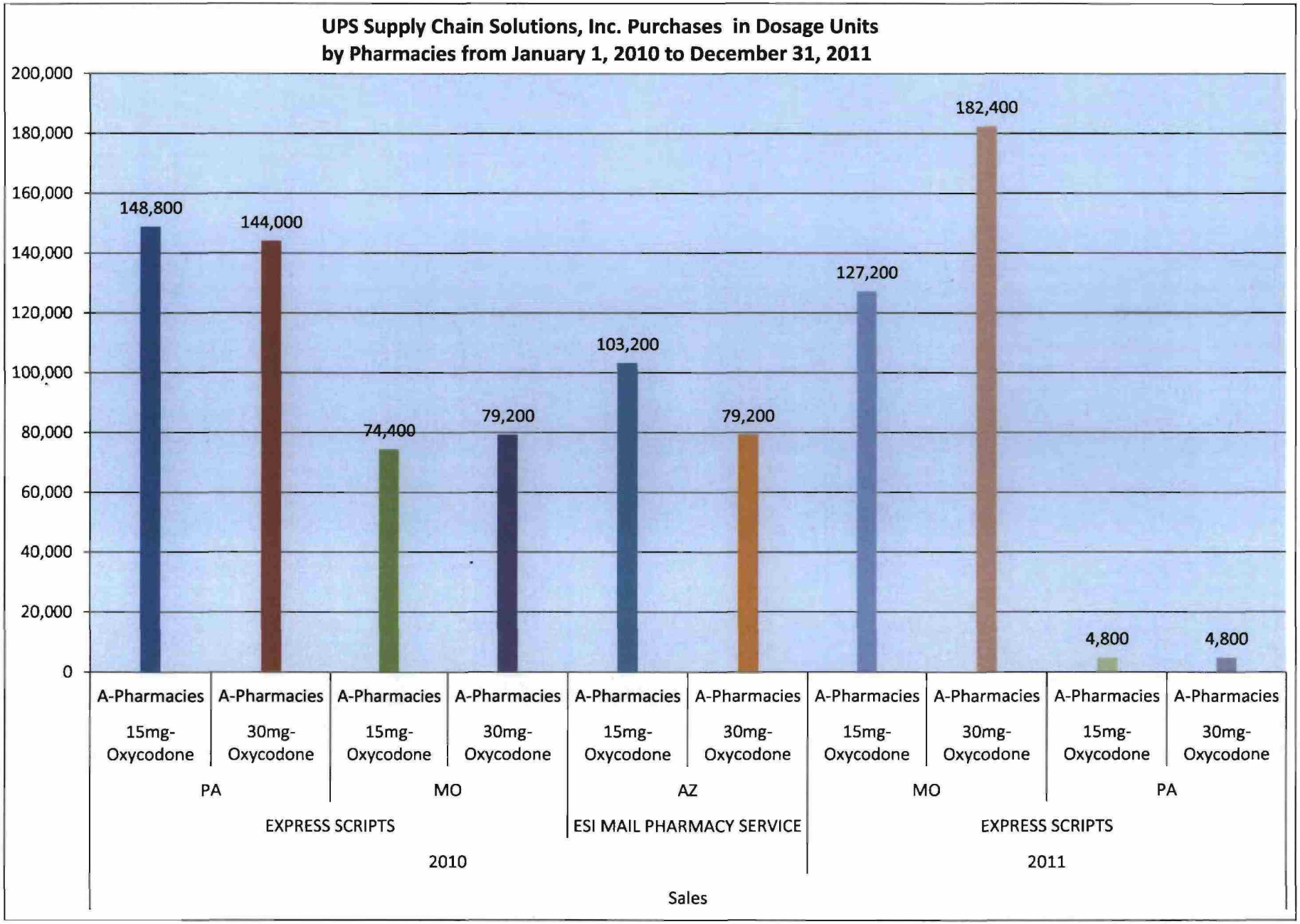
It is incumbent upon you to know your customers, fully review all orders for controlled substances and to exercise due diligence procedures prior to deciding whether or not to terminate or restrict sales to any customer.

September 12, 2012

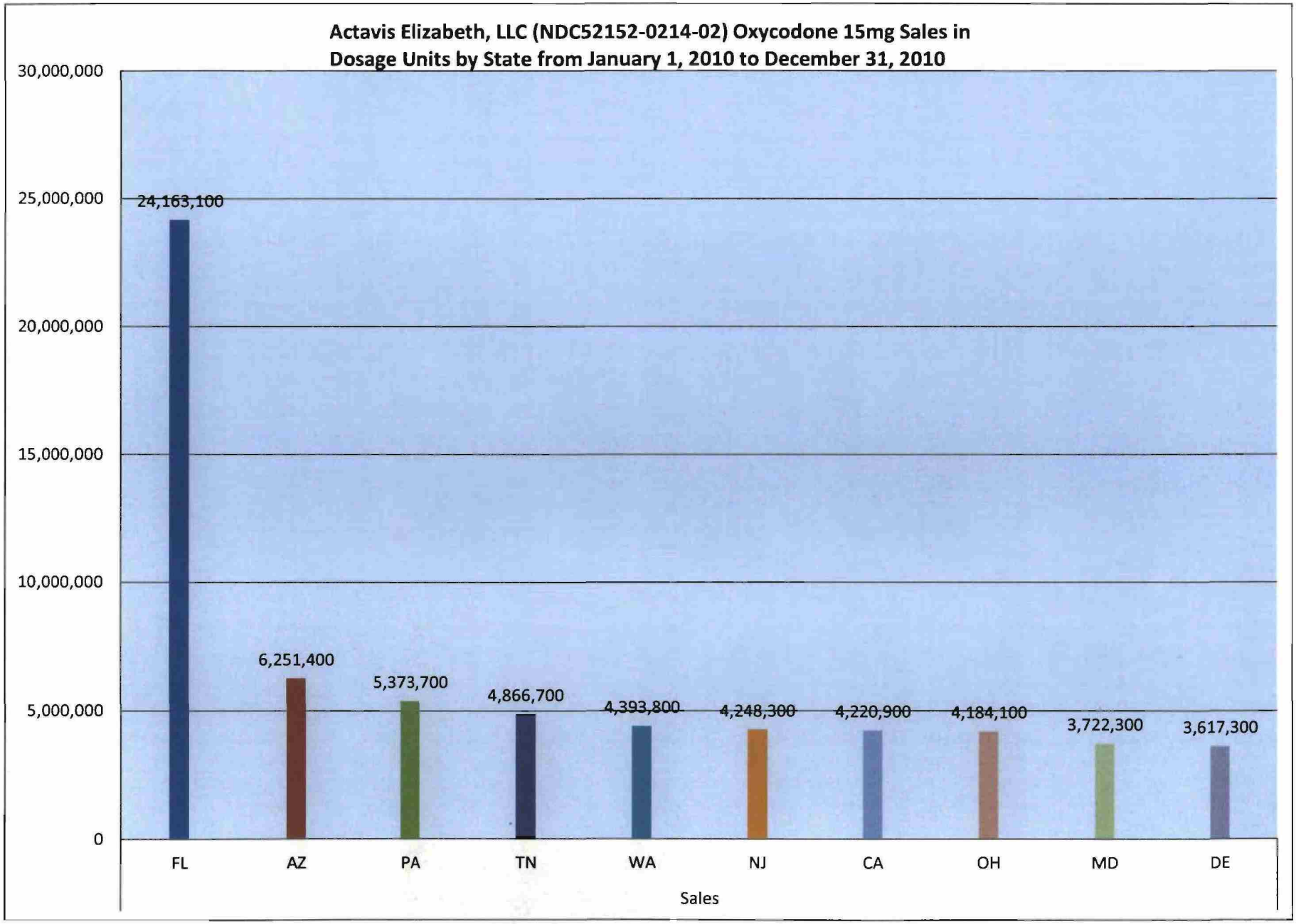


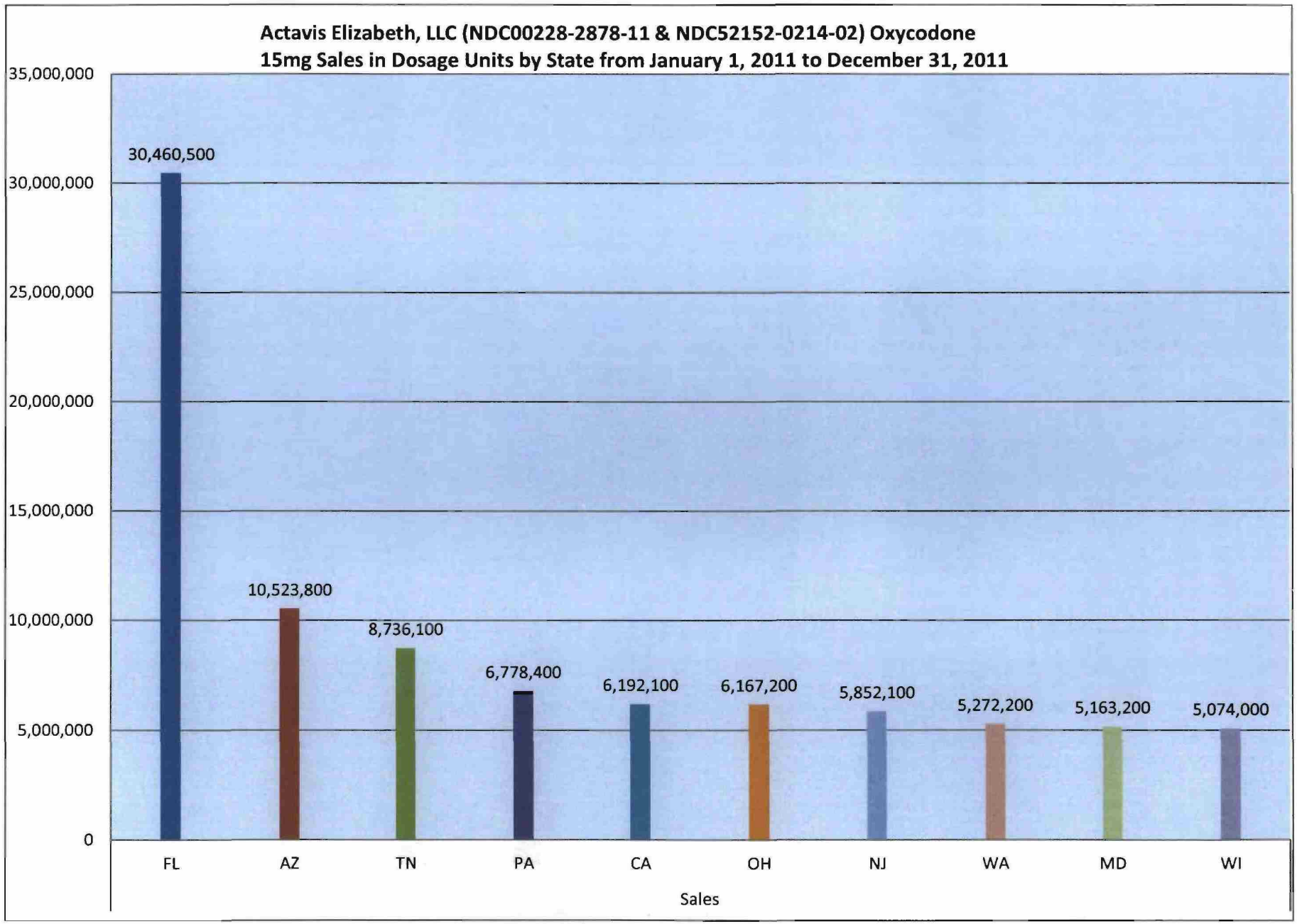


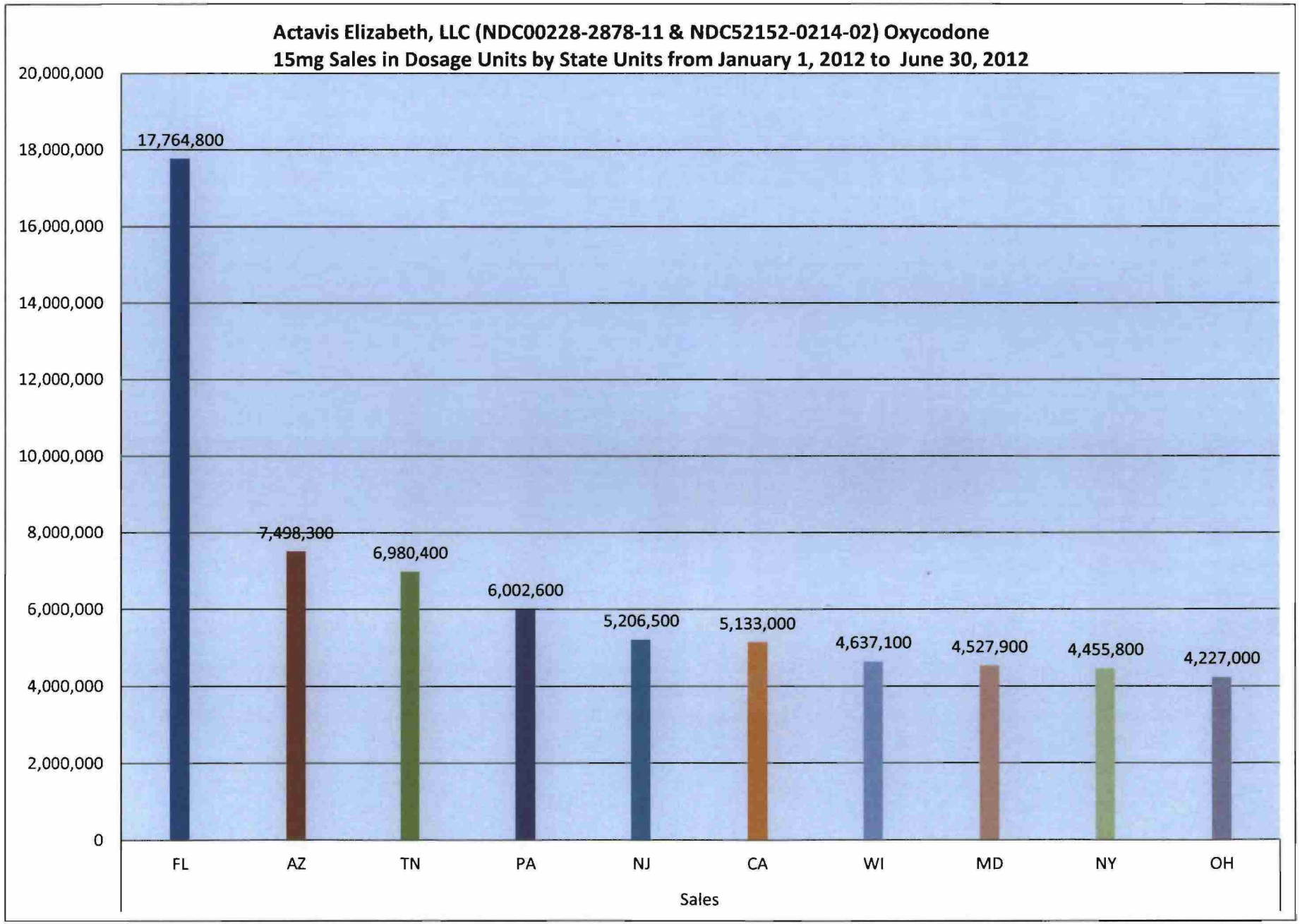
UPS Supply Chain
Sales to Pharmacies



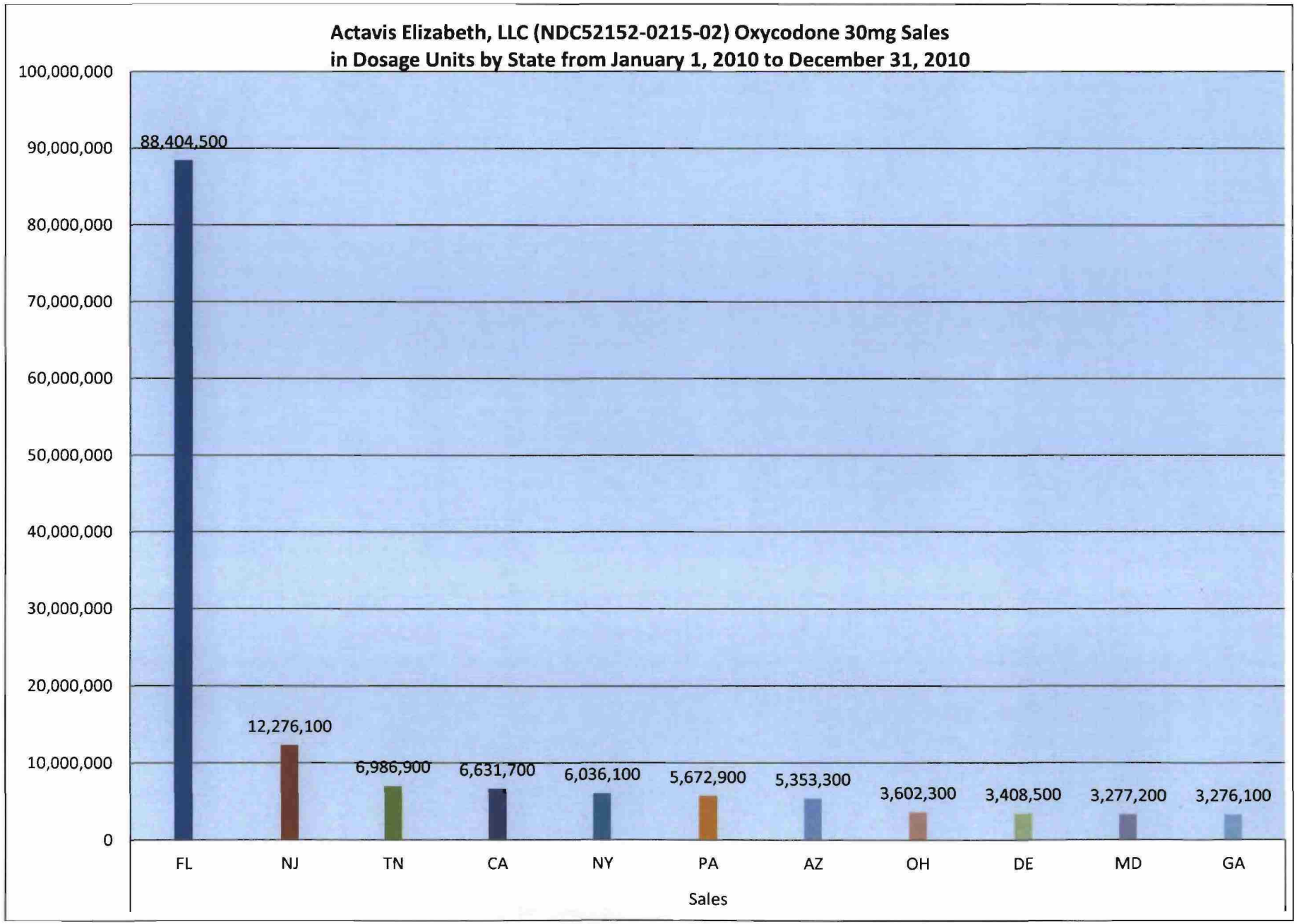
2010-2012 Oxycodone
15mg by State

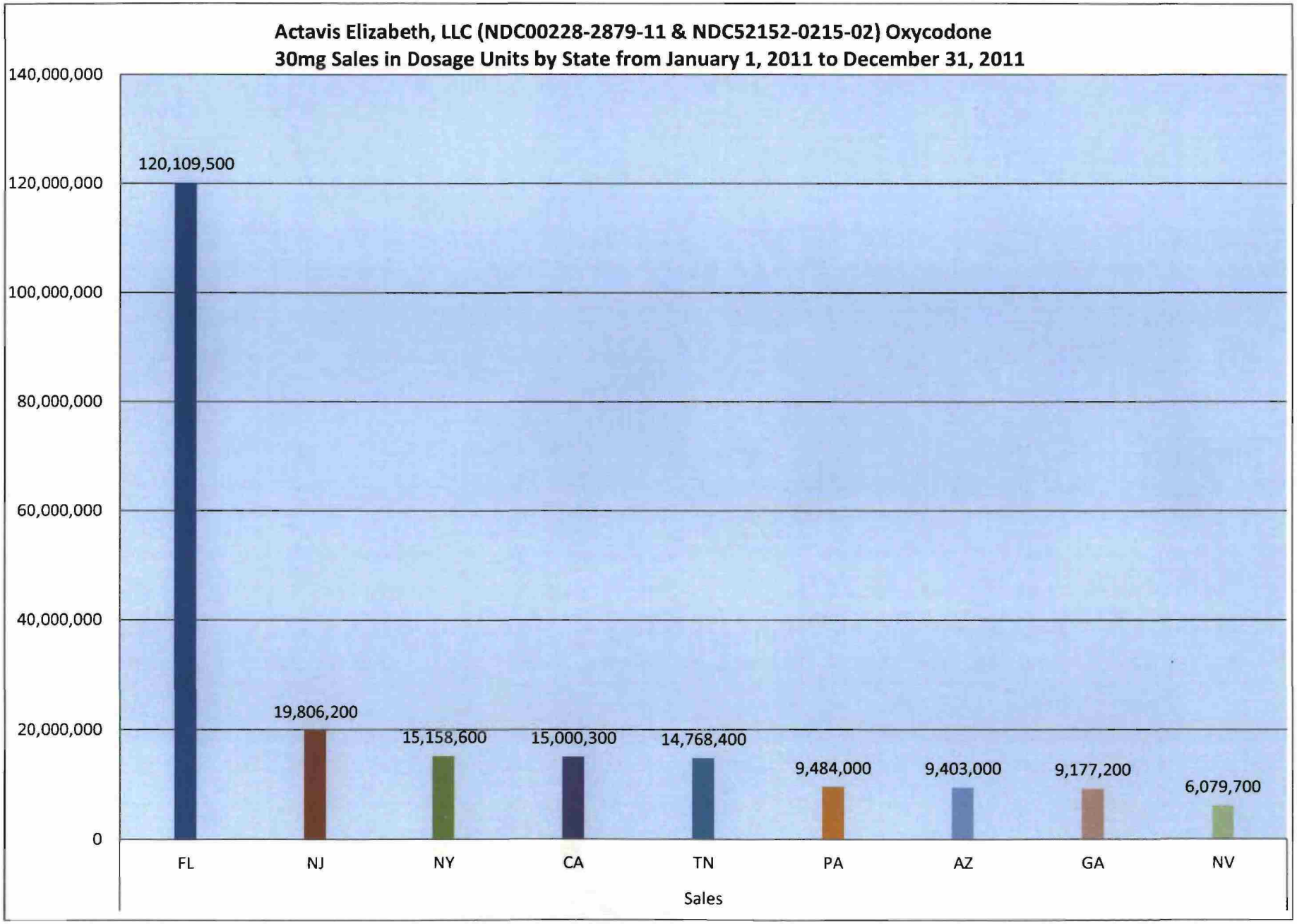


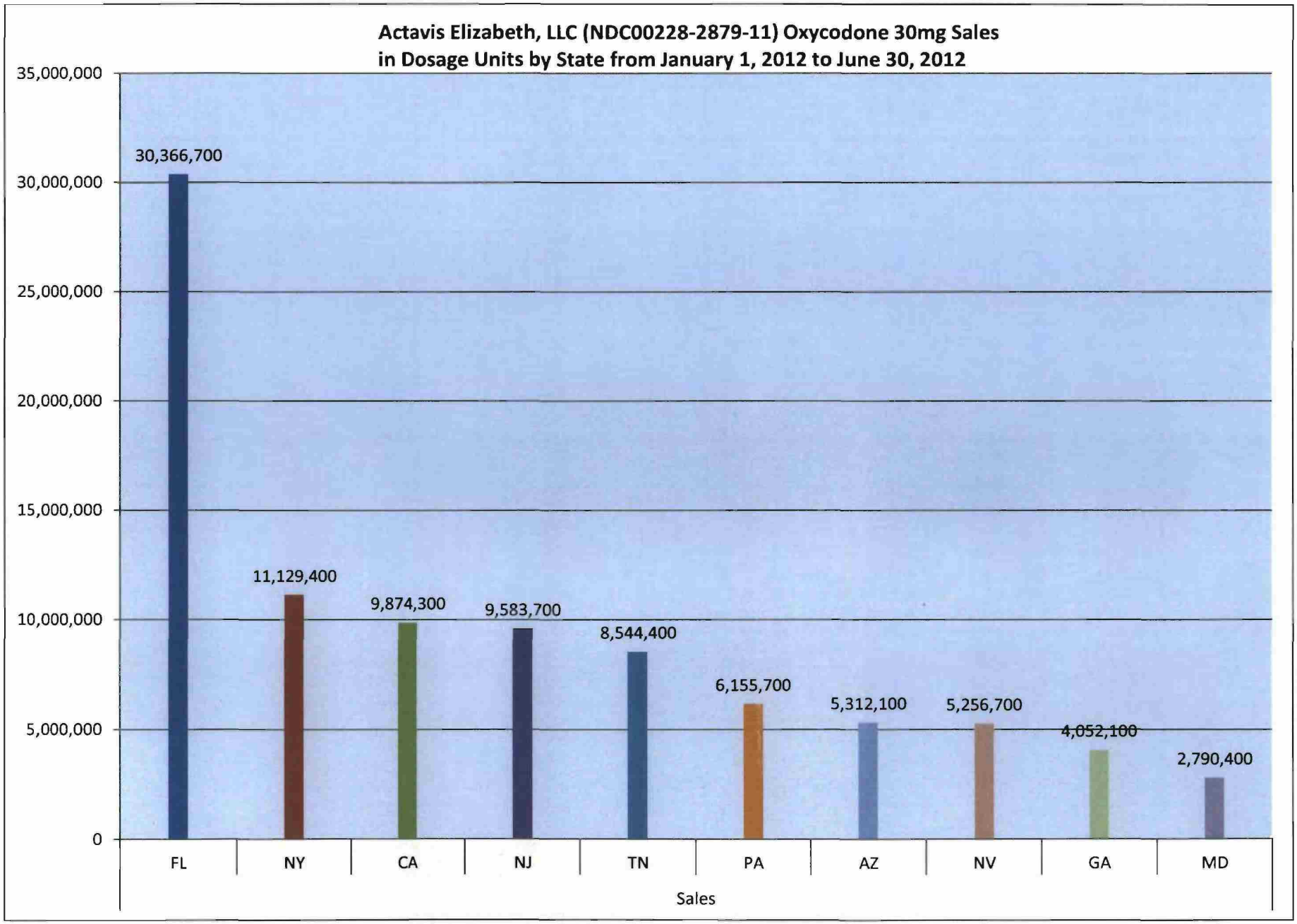




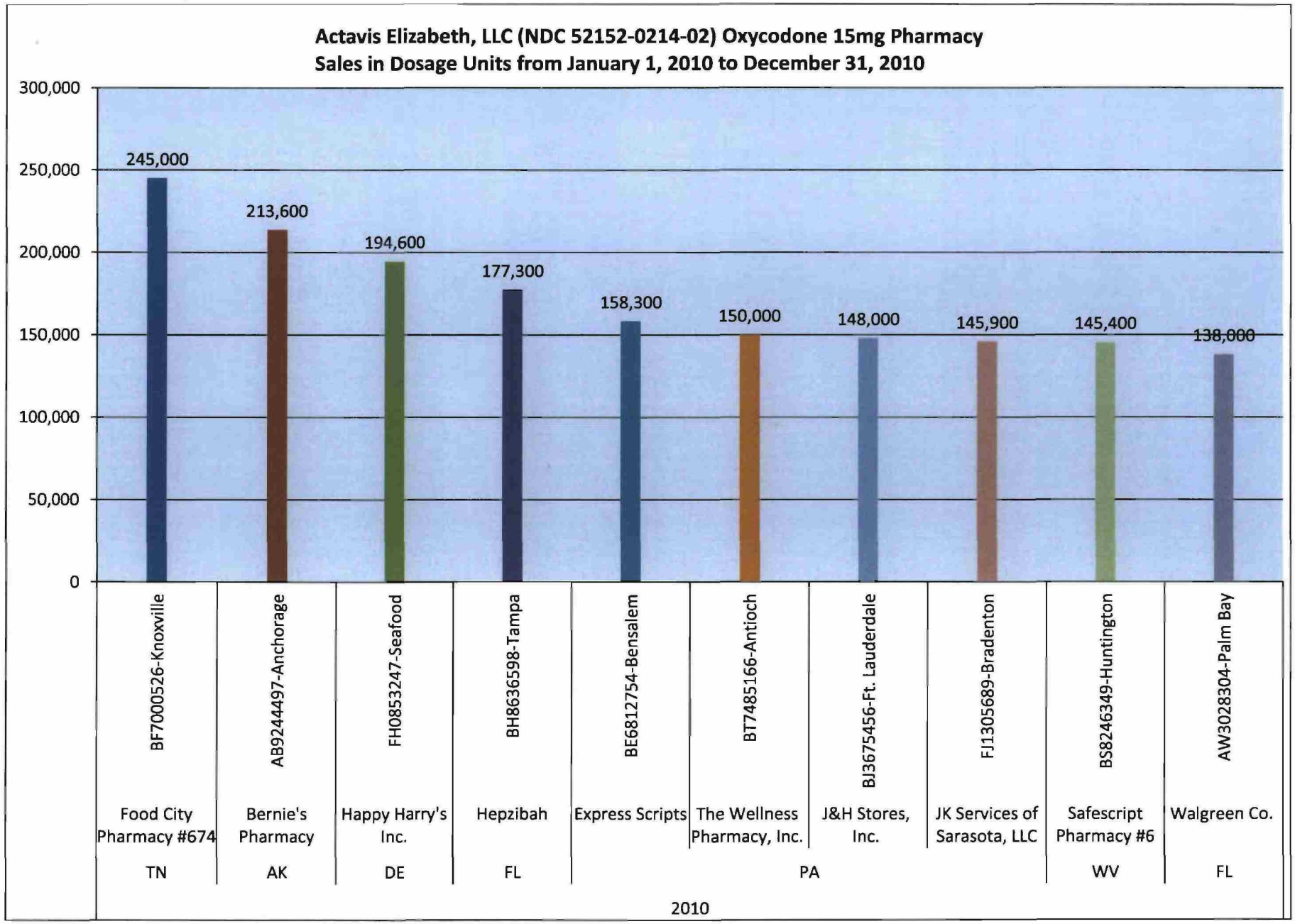
2010-2012 Oxycodone
30mg by State

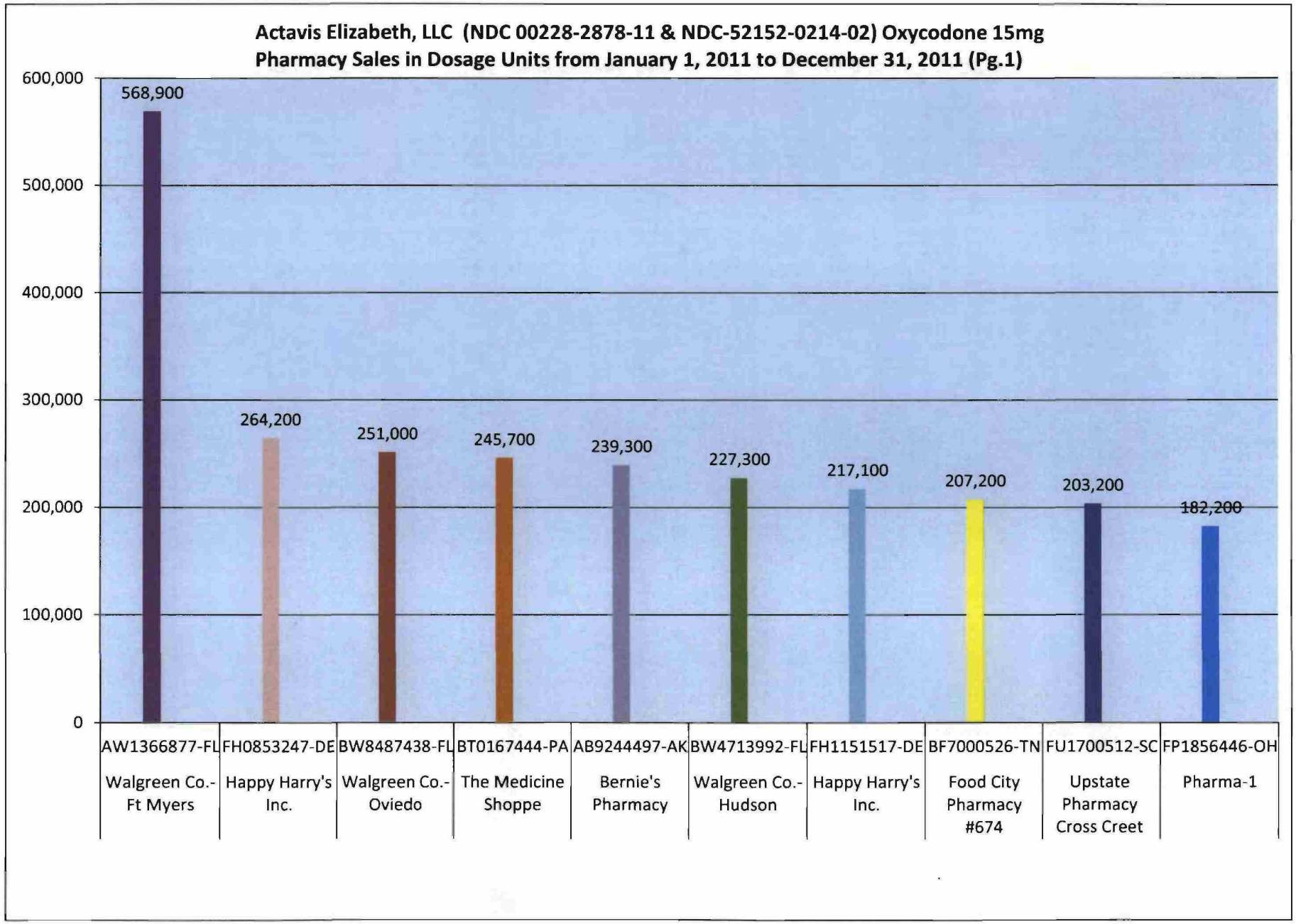


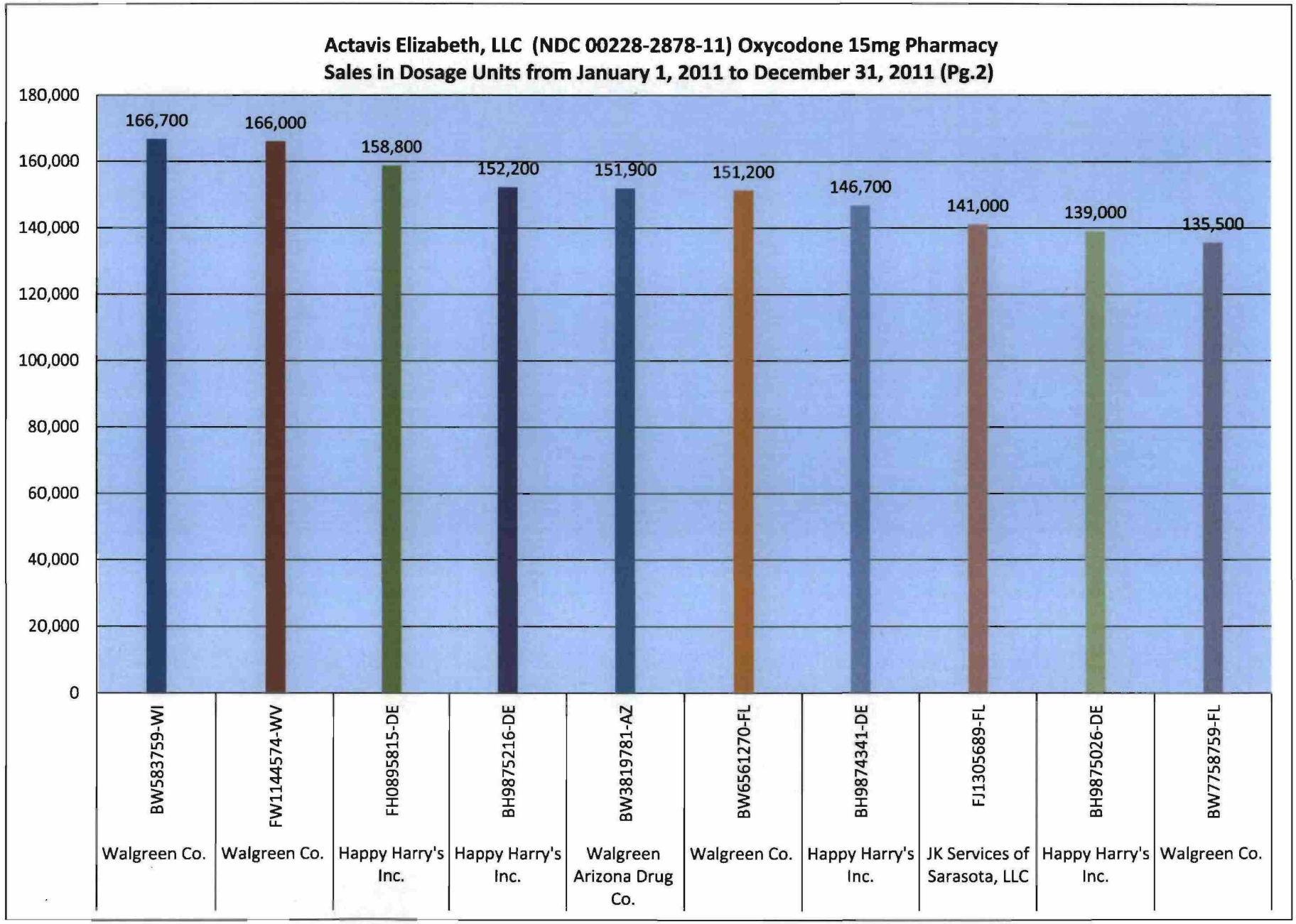


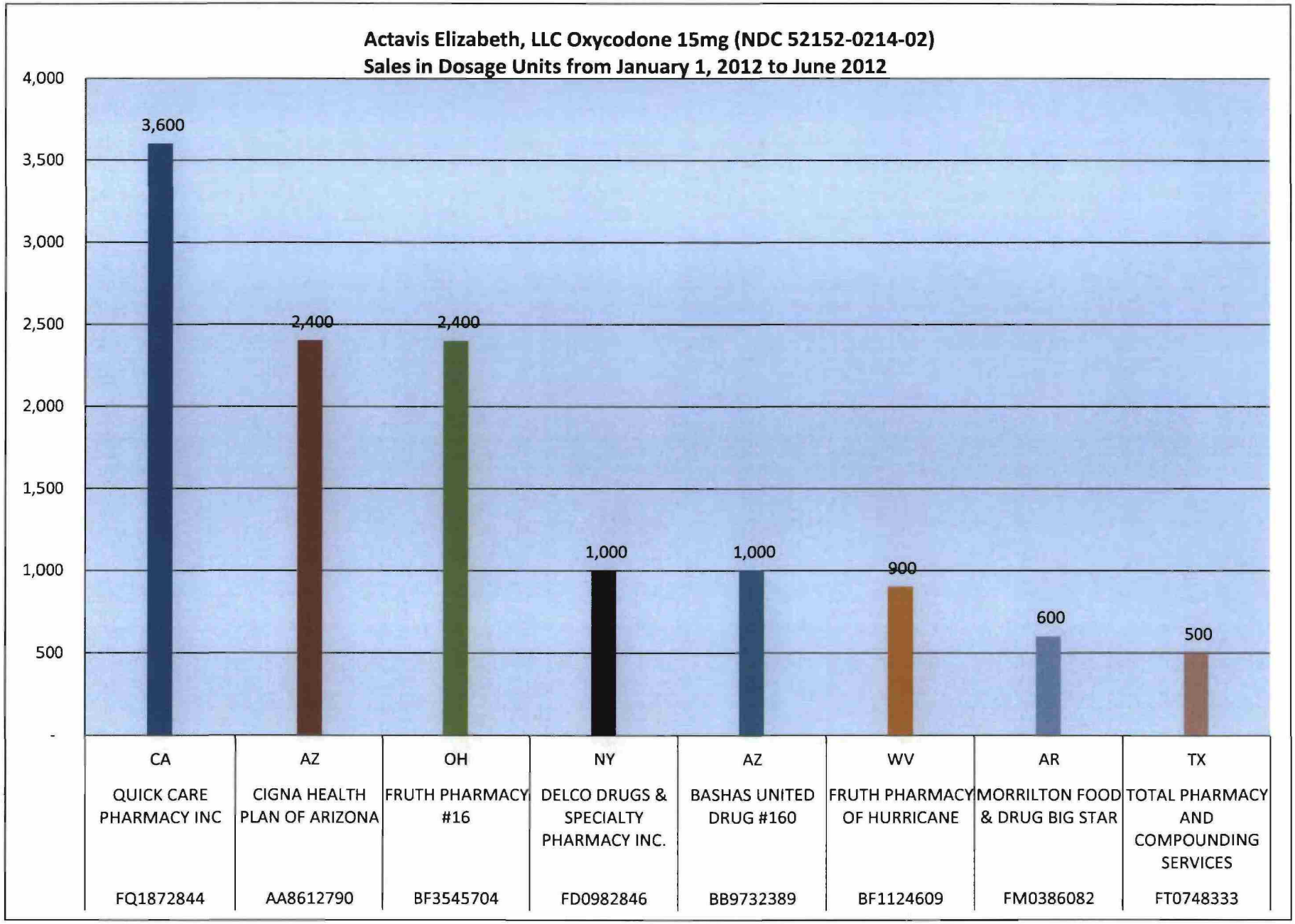


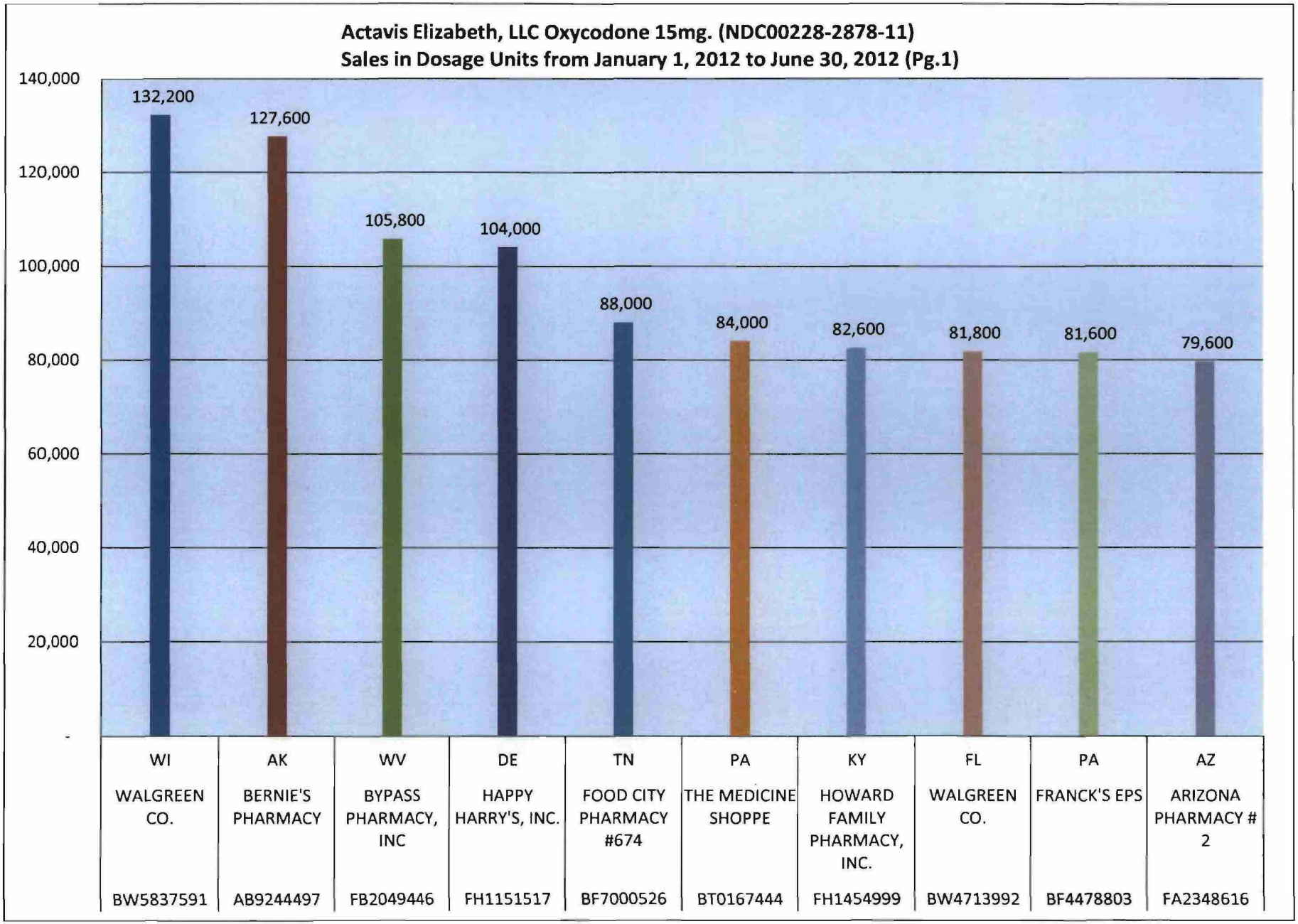
Oxycodone 15mg
Sales to Pharmacies
2010-2012

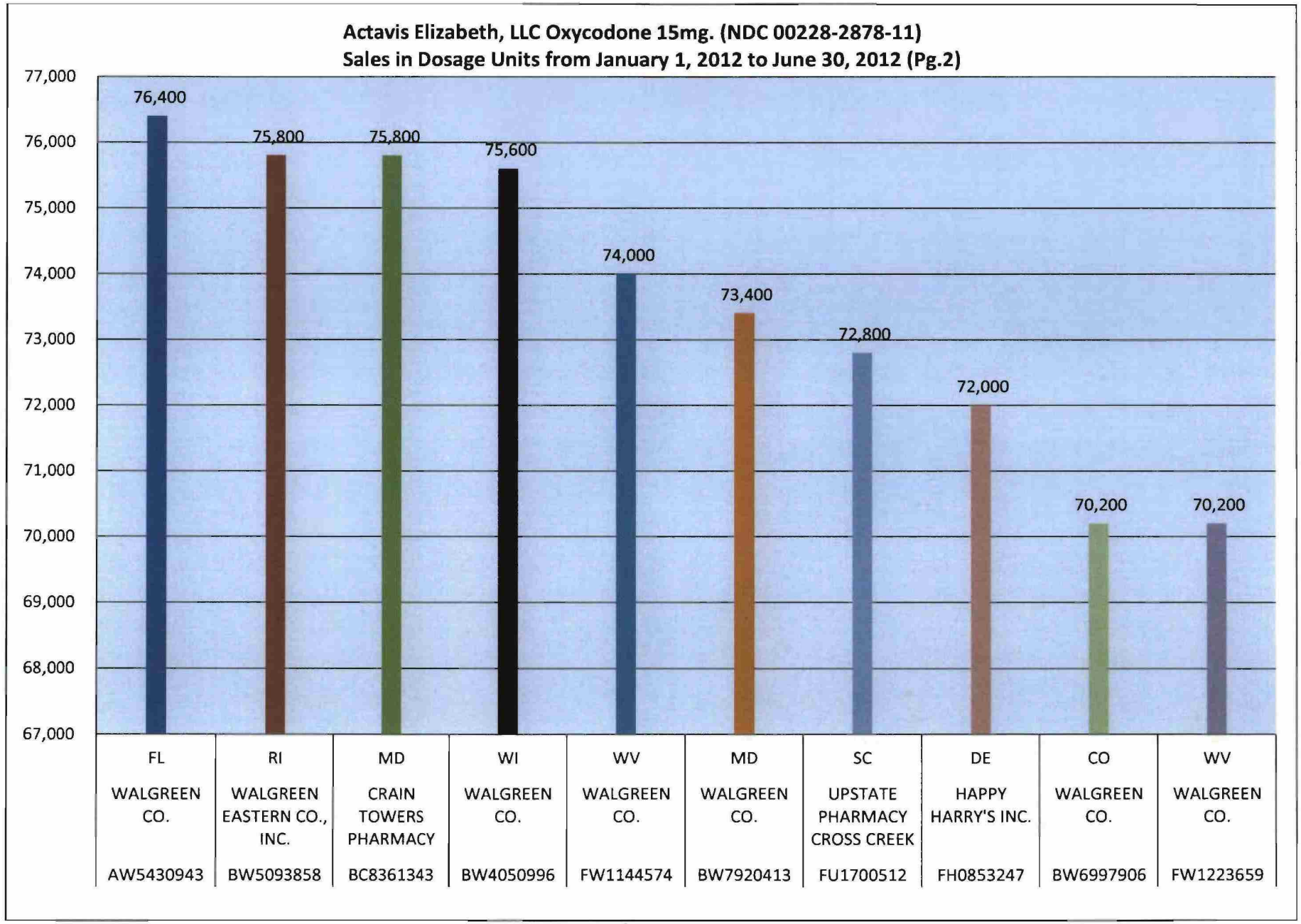




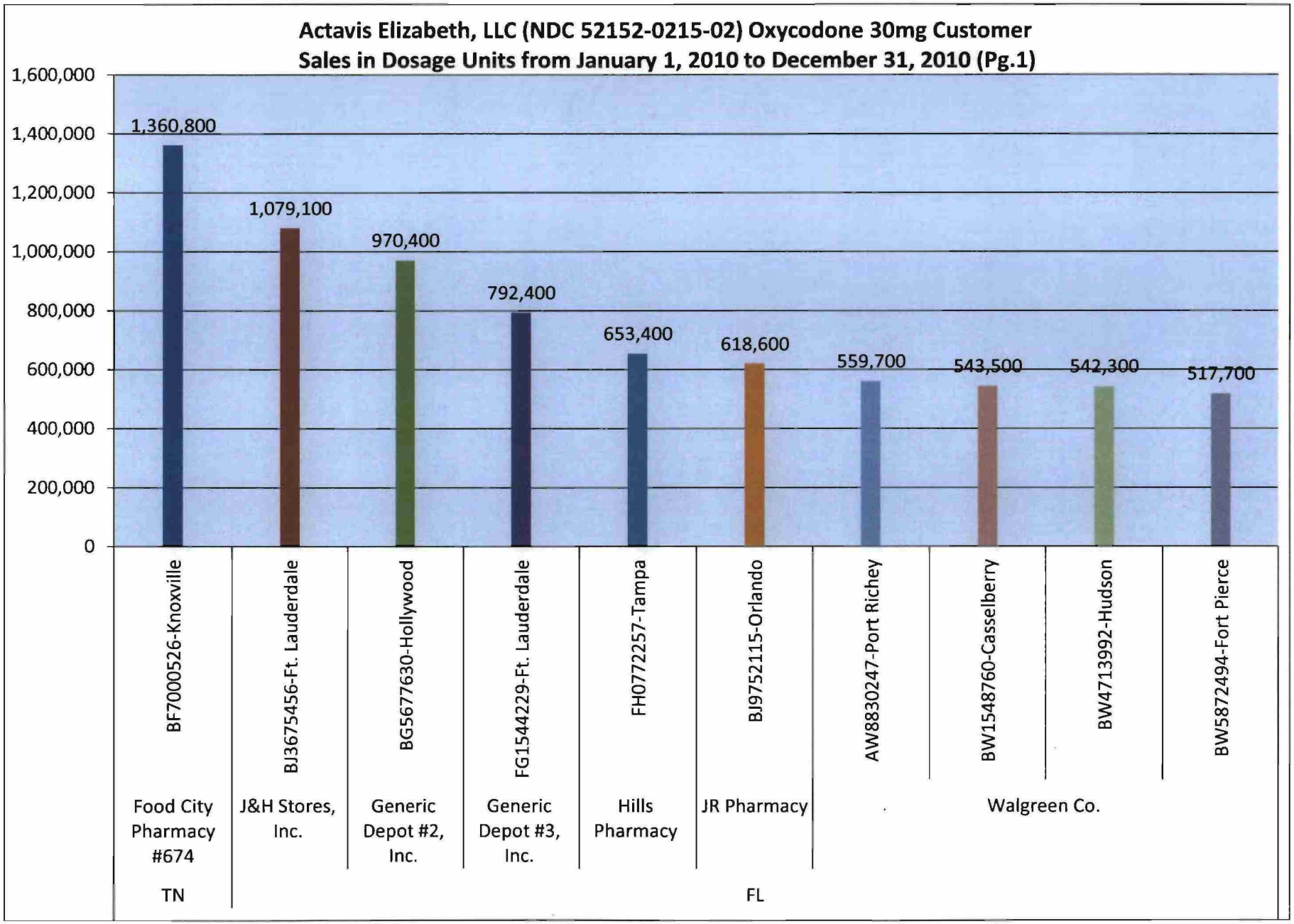


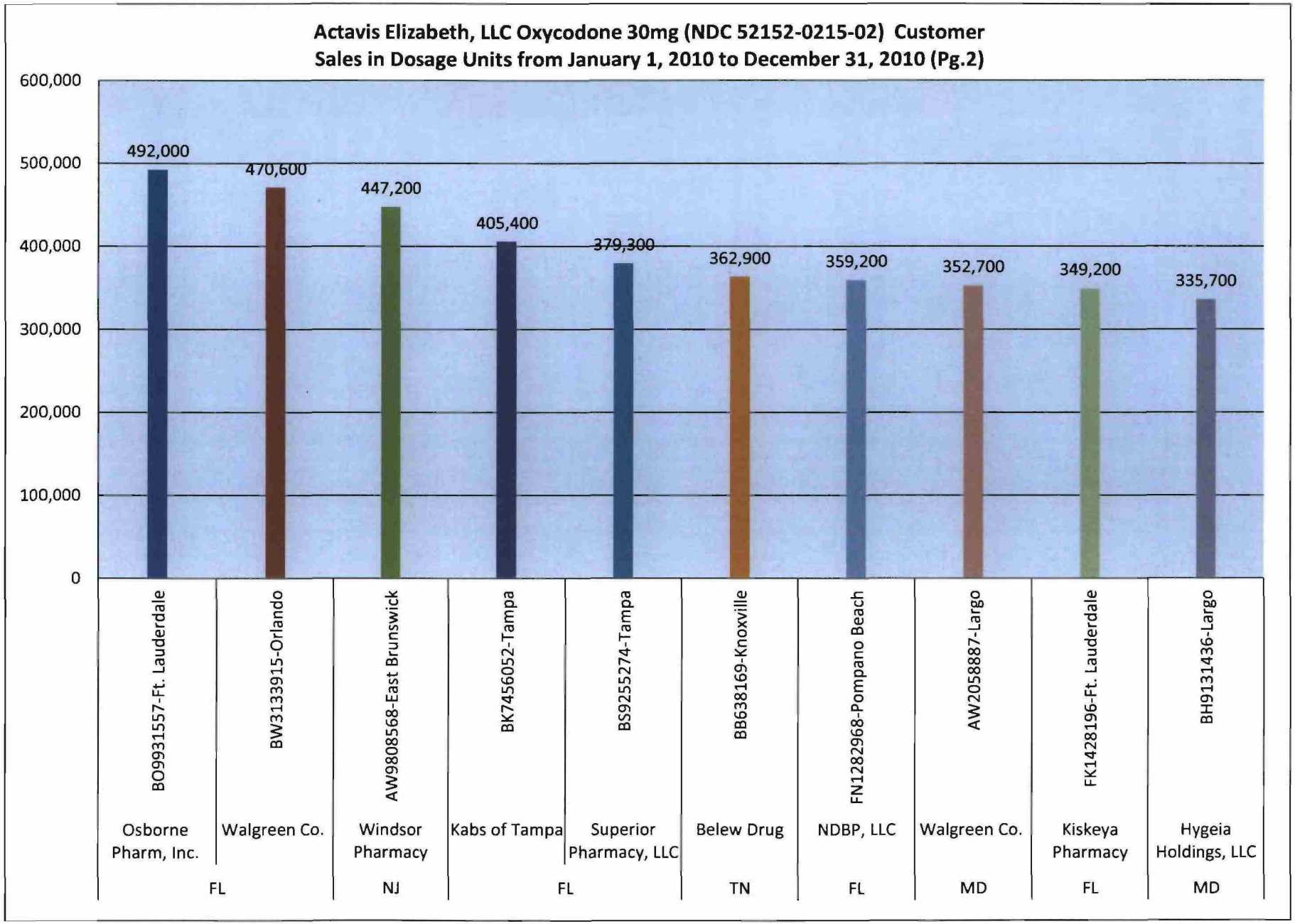


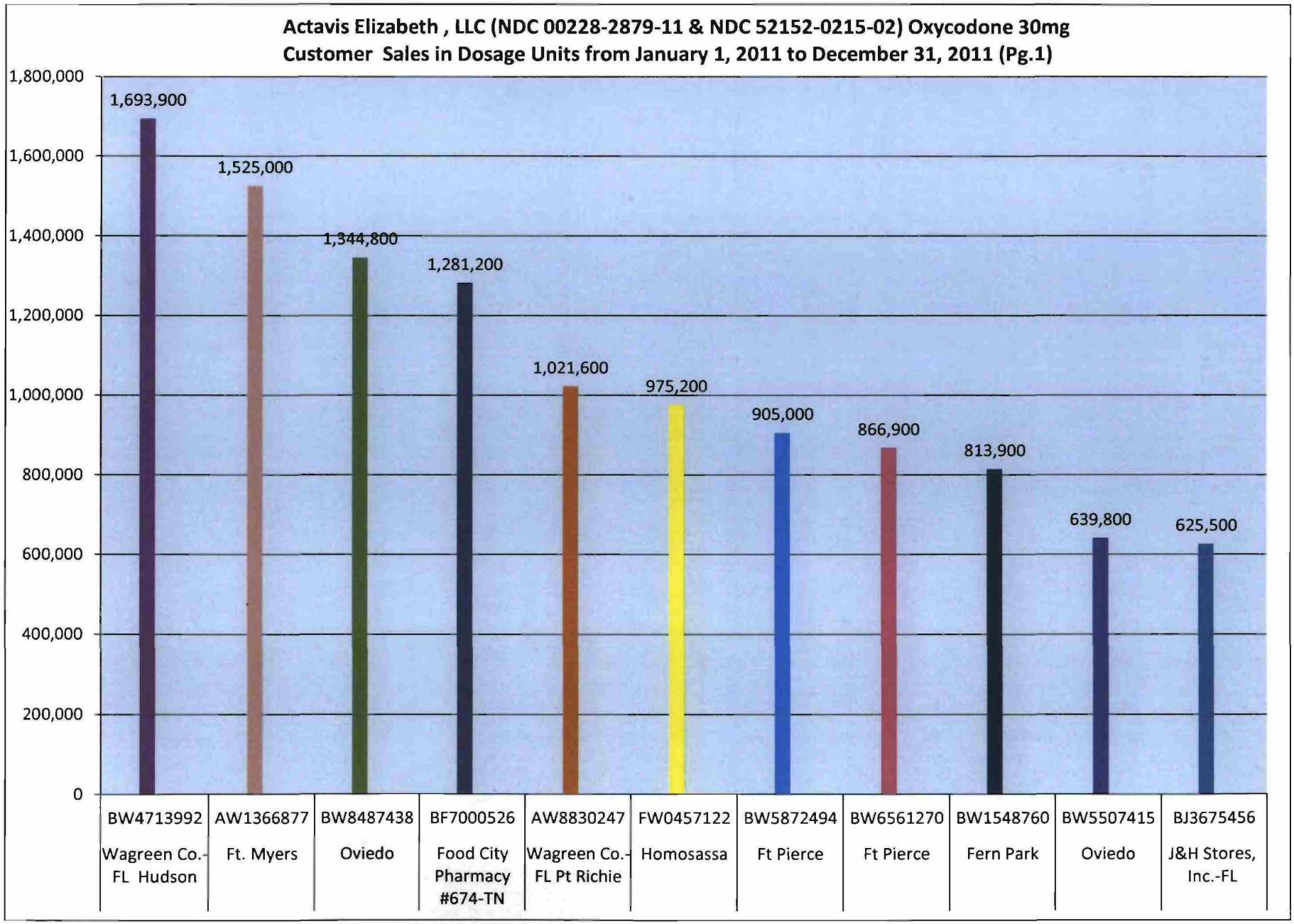


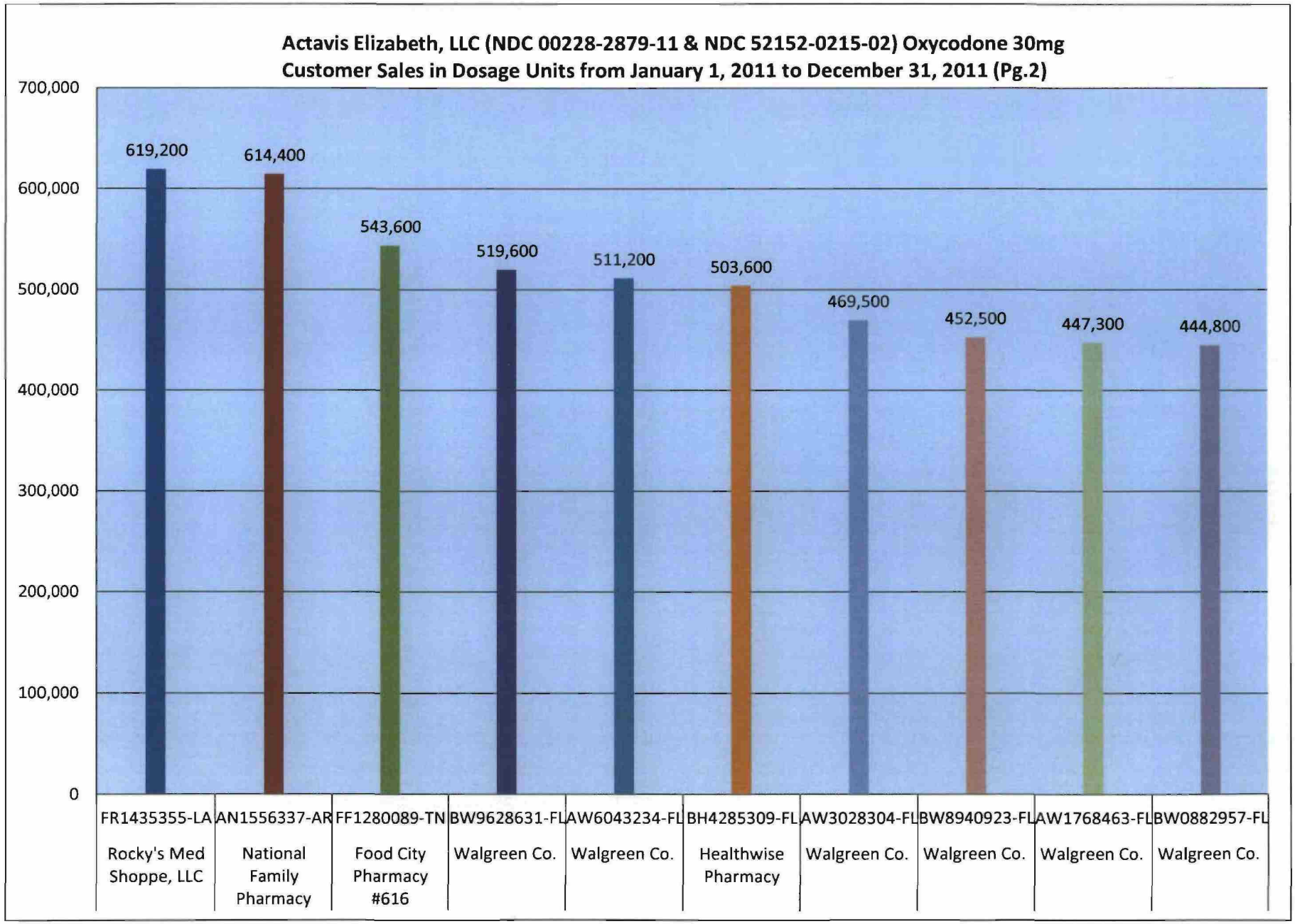


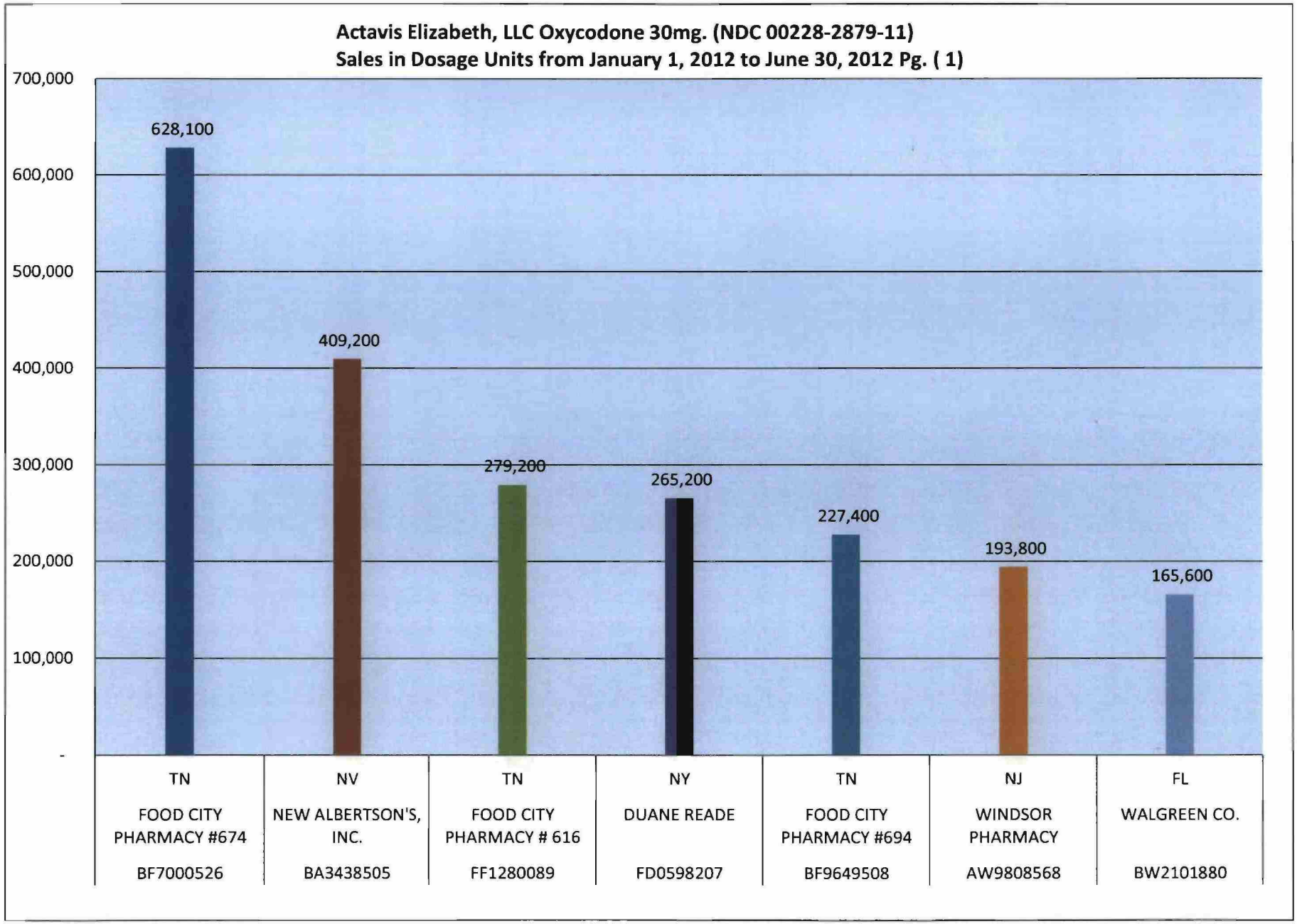
Oxycodone 30mg Sales to Pharmacies 2010-2012

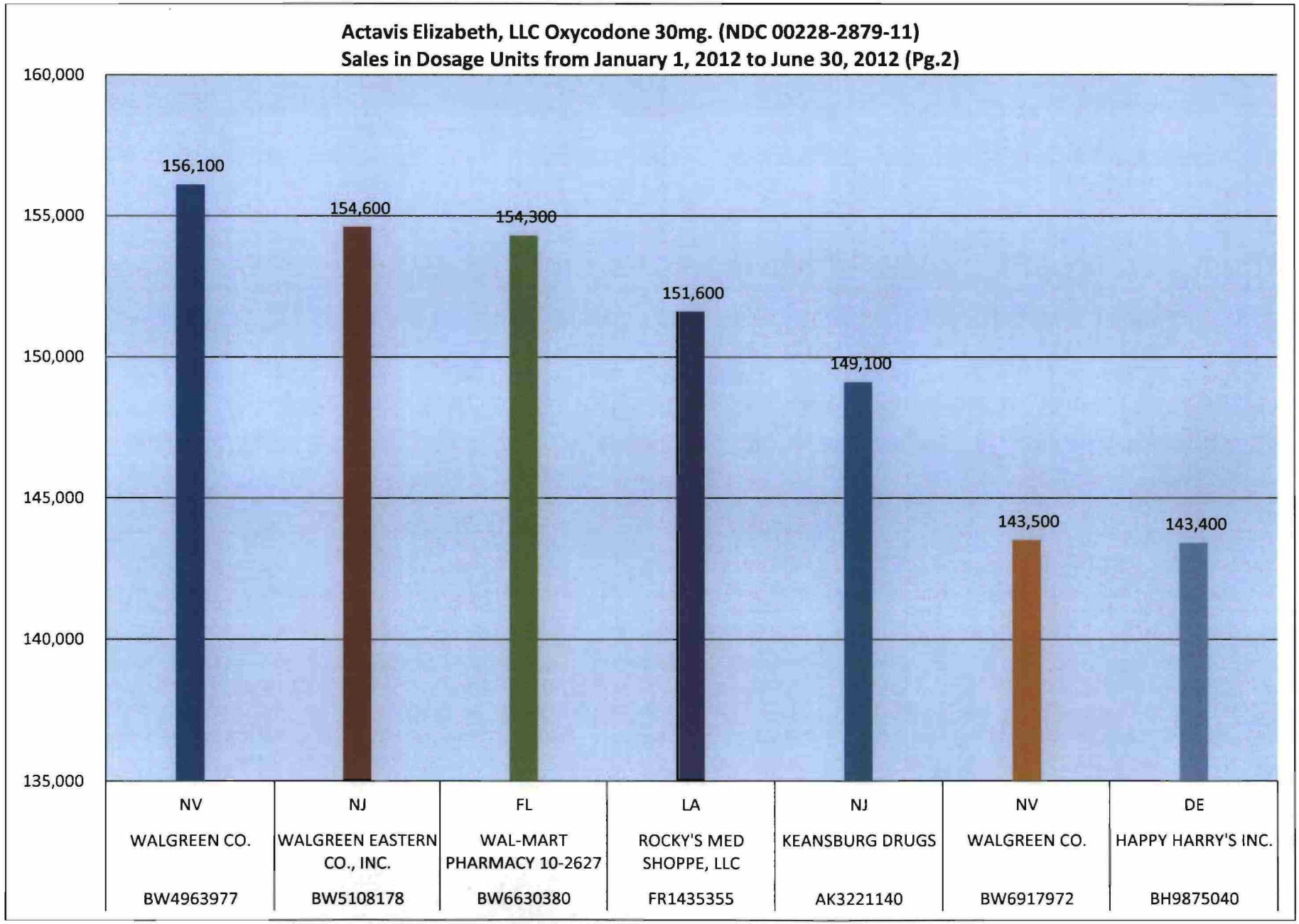


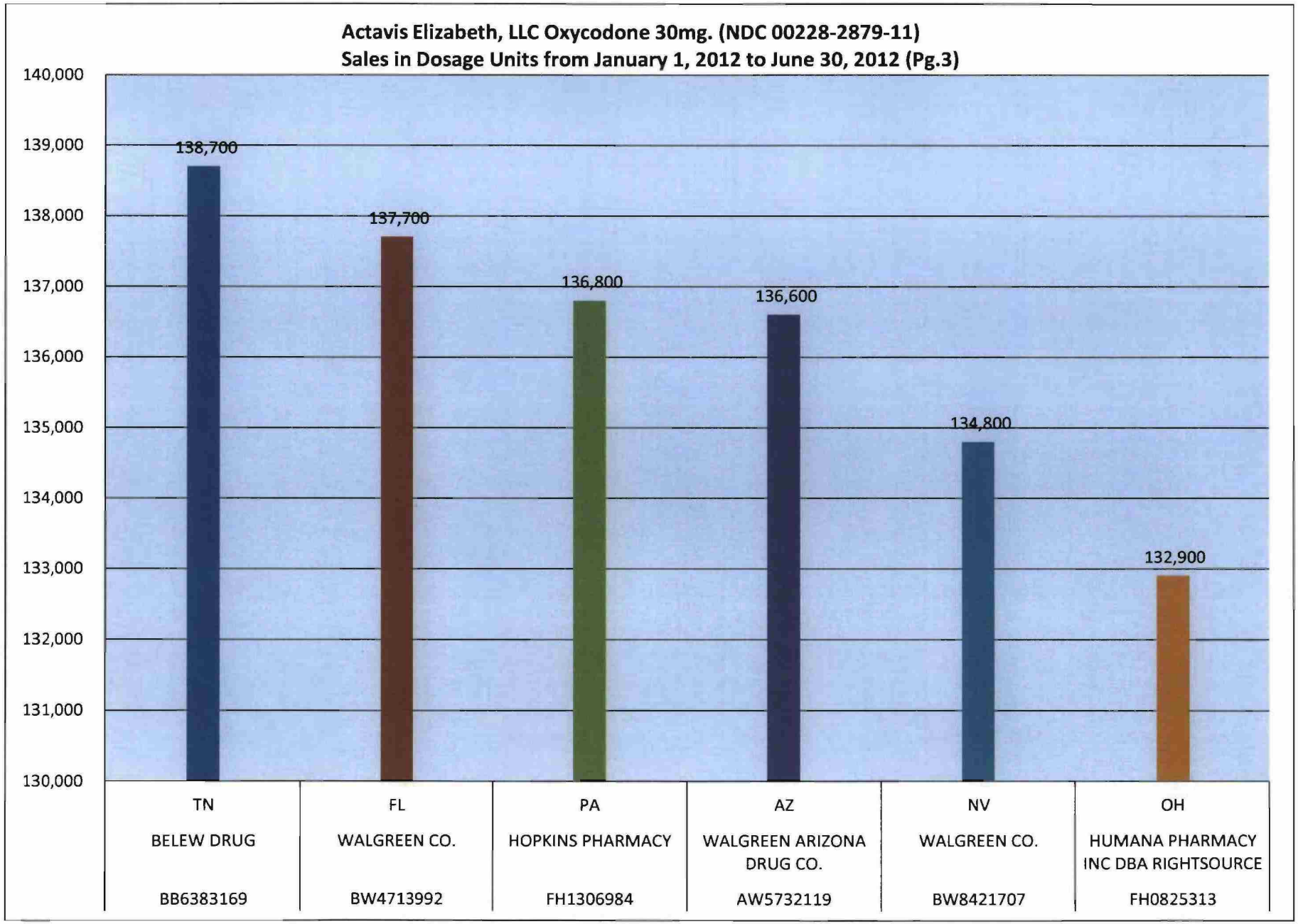


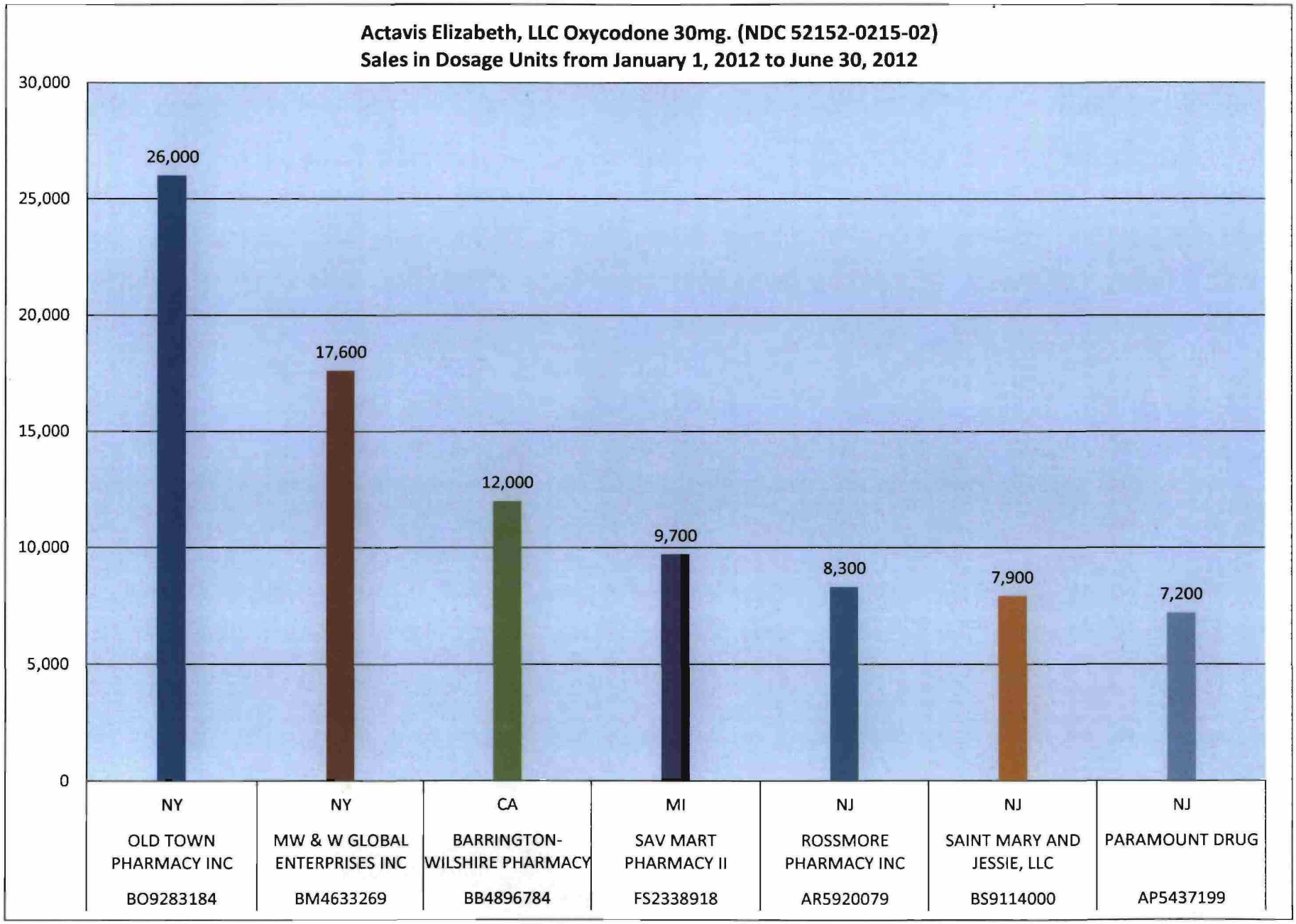




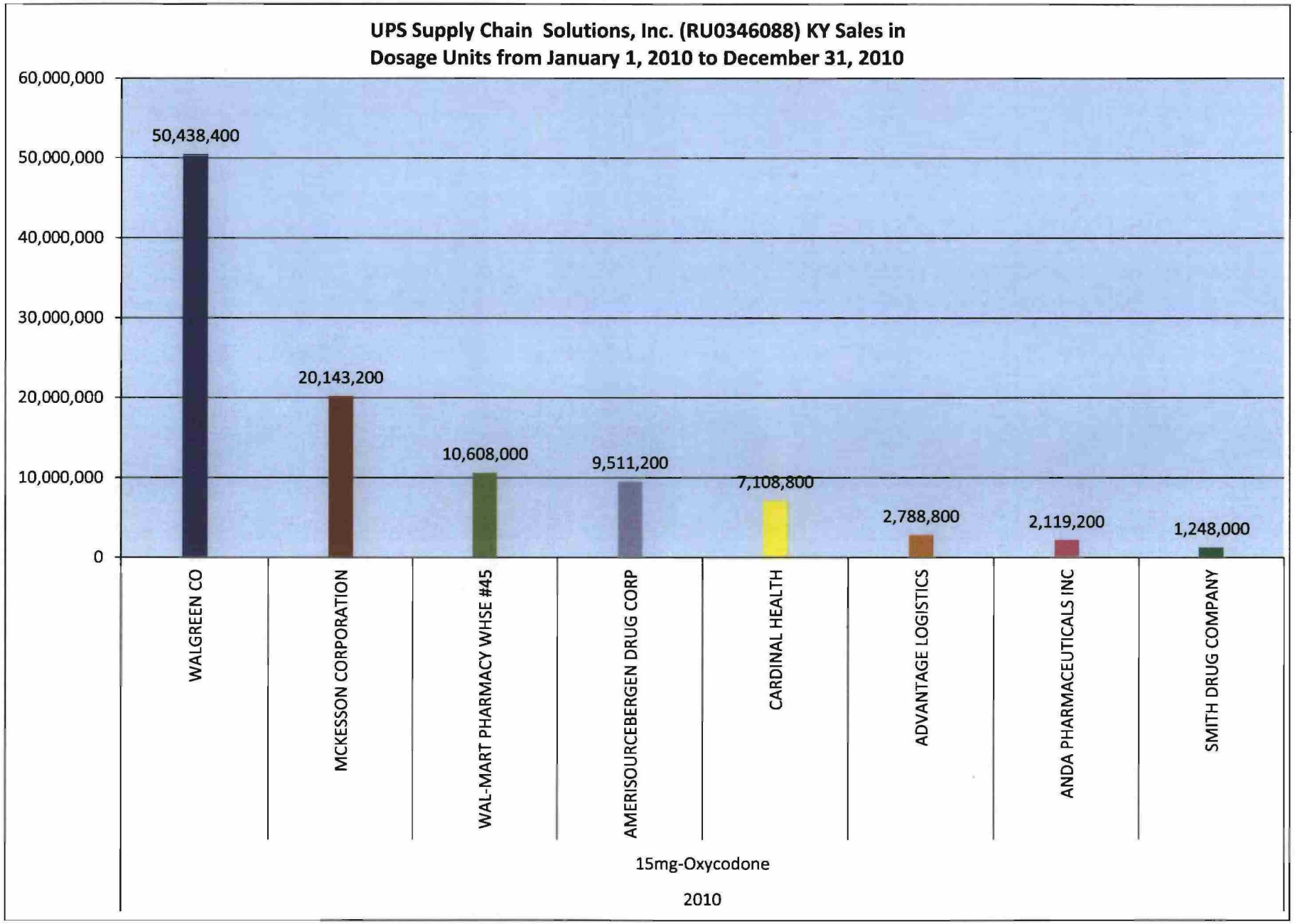


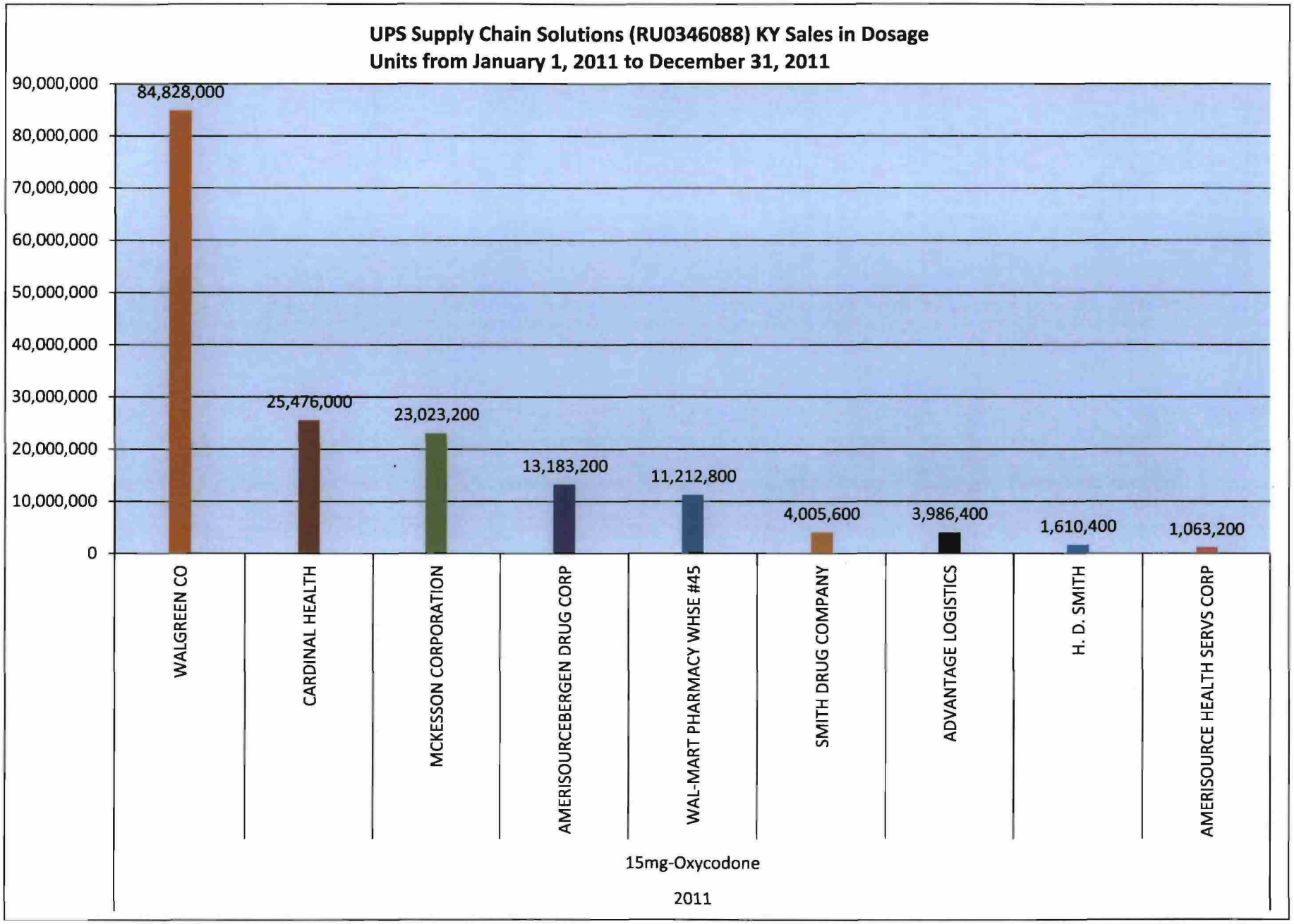


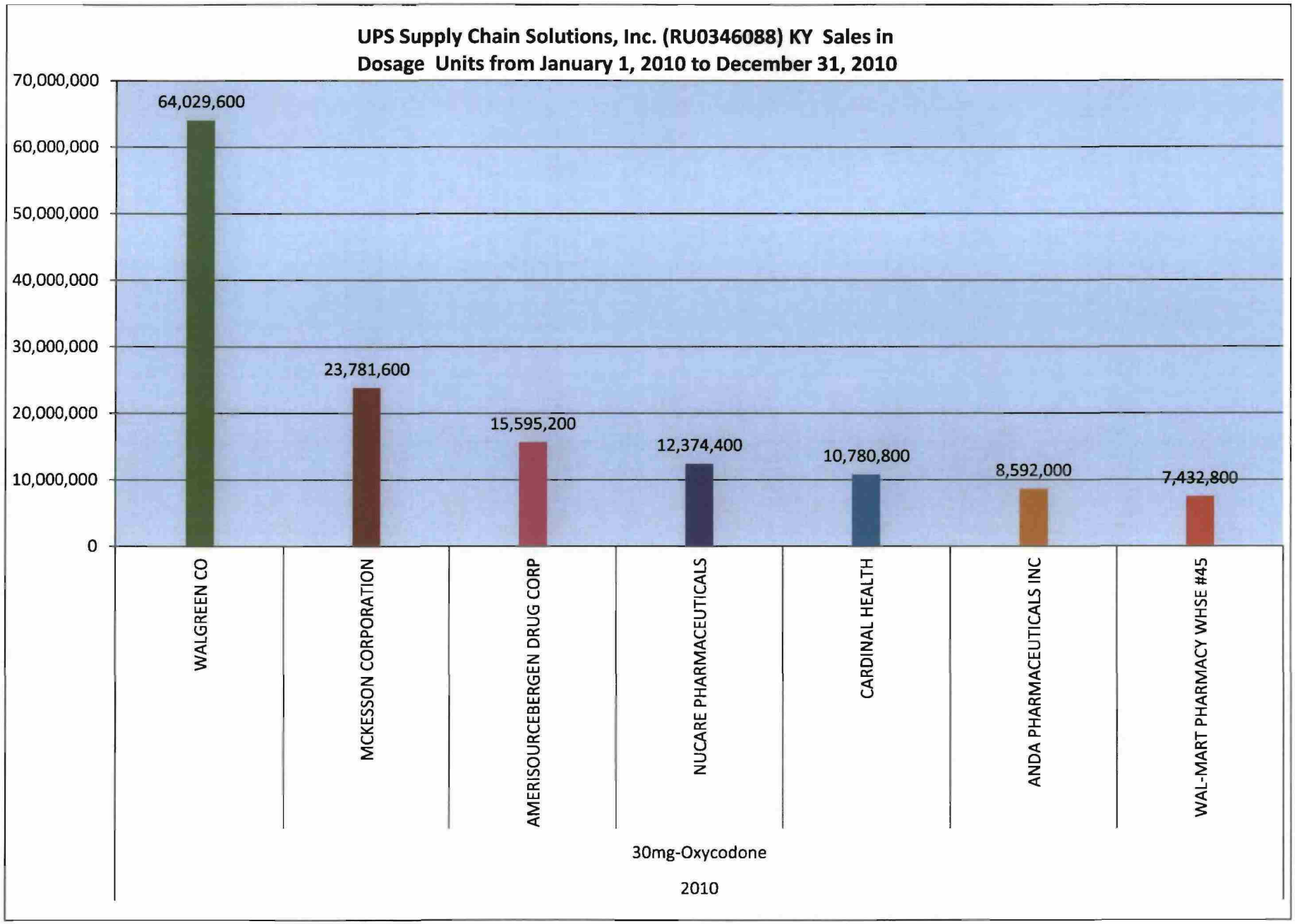


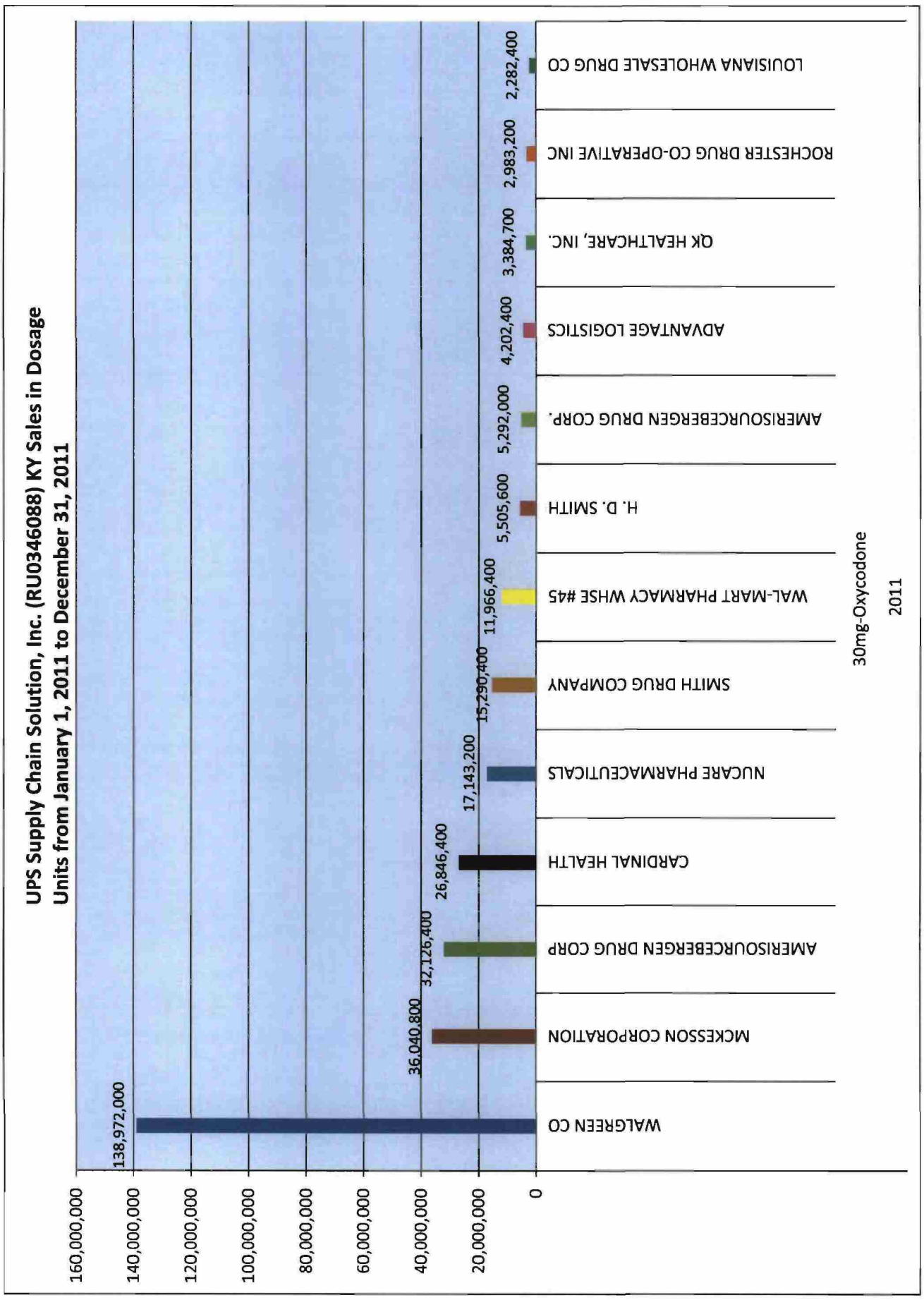


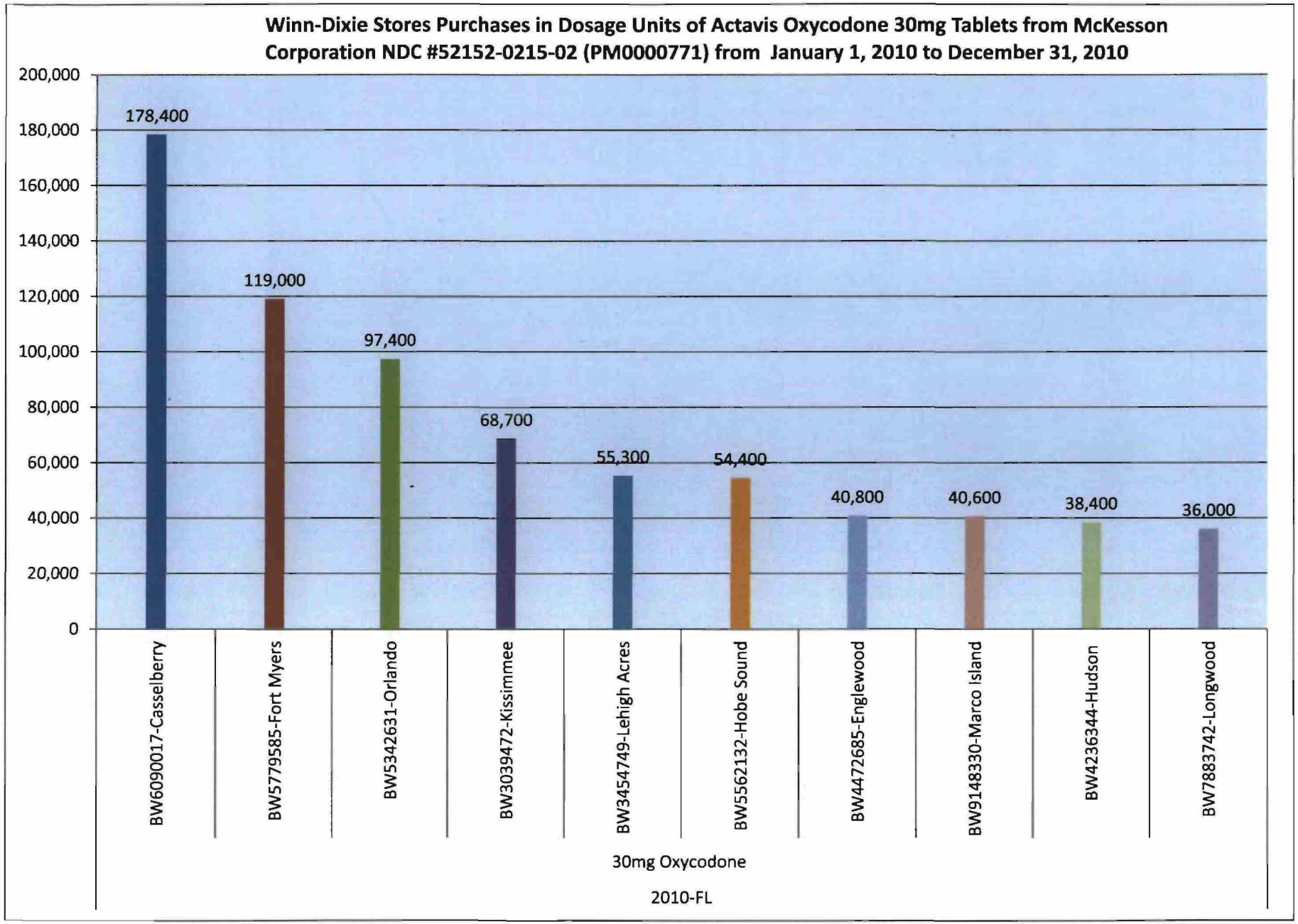
UPS Supply Chain
Solutions, Inc. (KY)



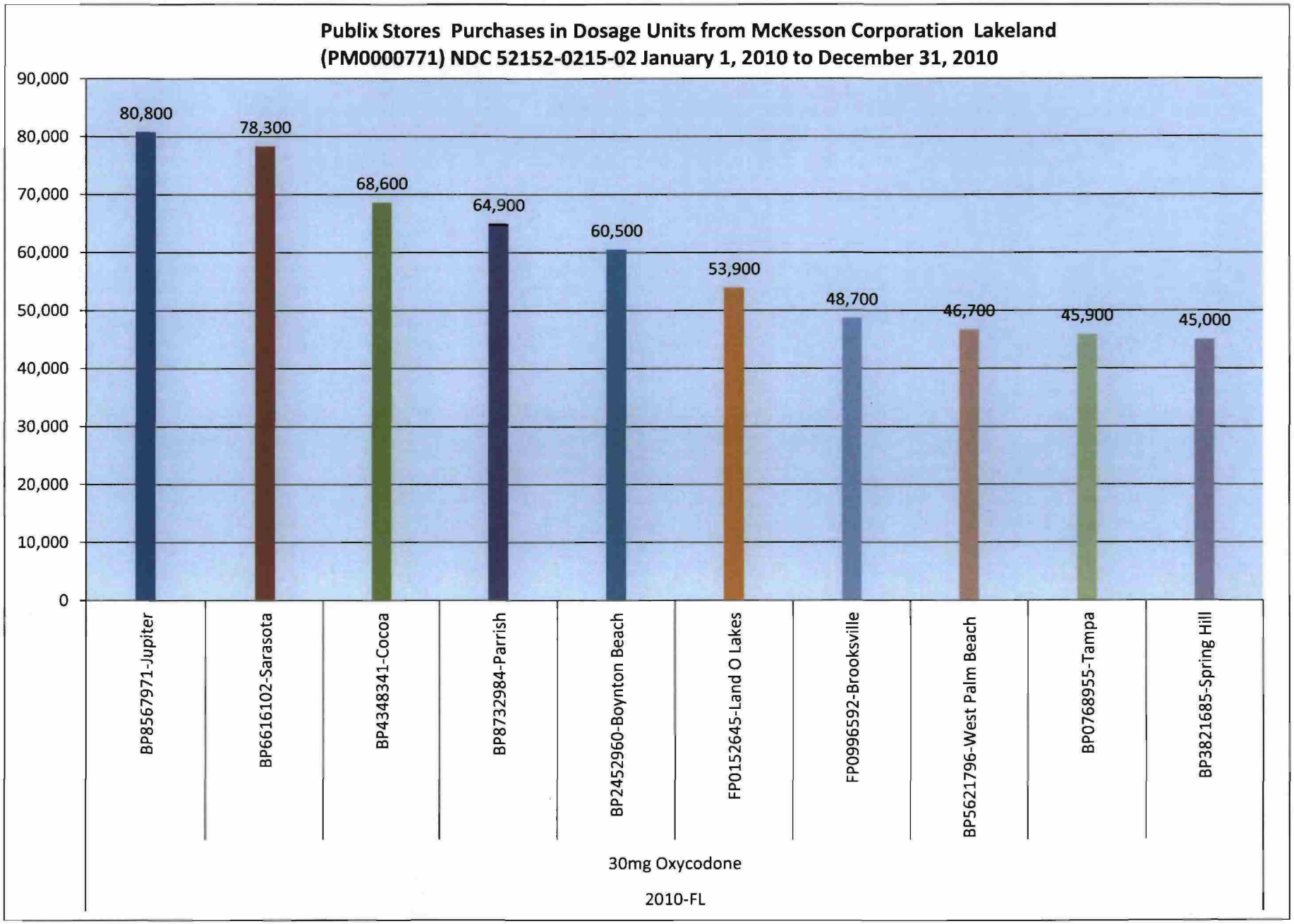


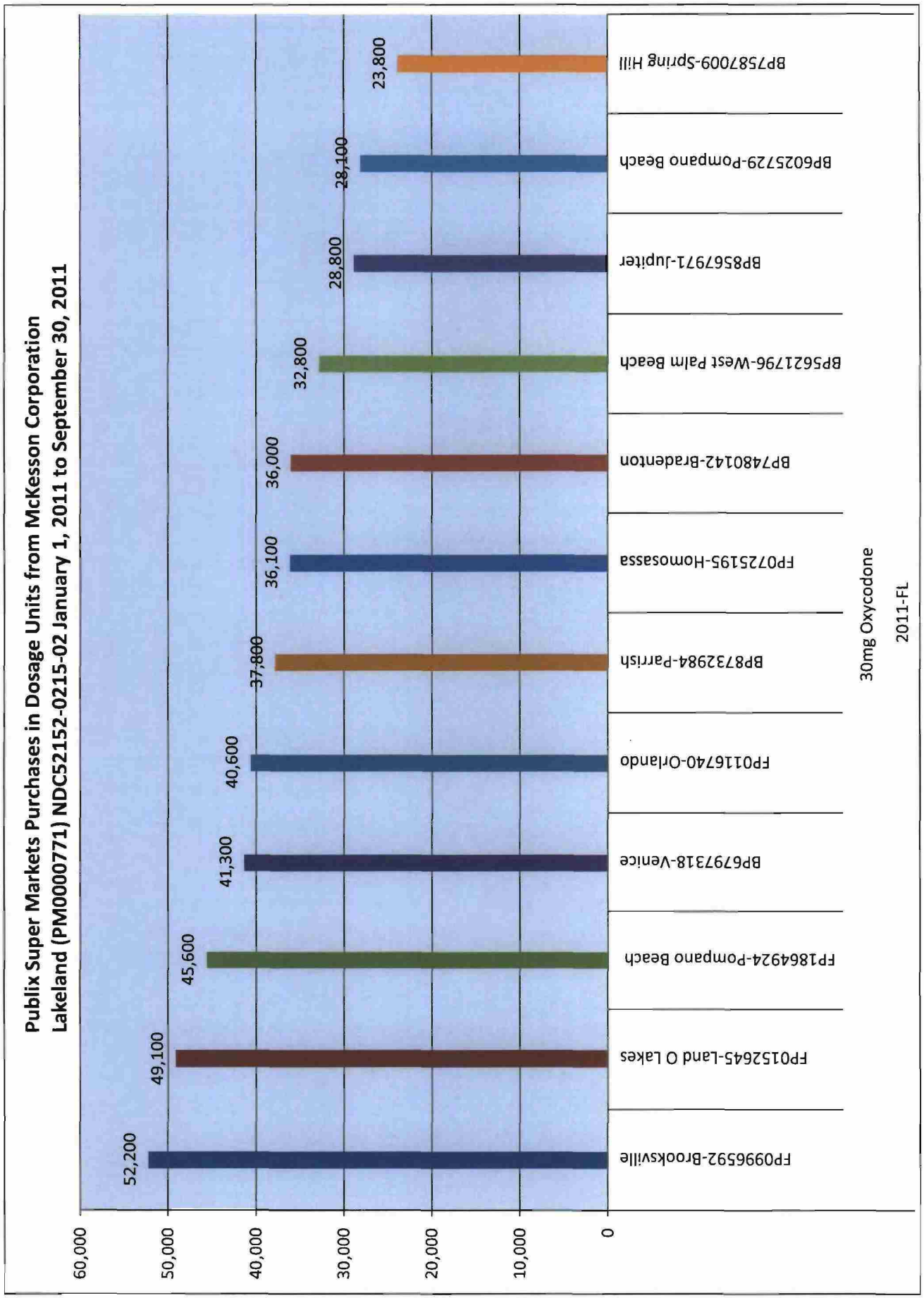



UPS Supply Chain Solution, Inc. (RU0346088) KY Sales in Dosage
Units from January 1, 2011 to December 31, 2011
160,000,000
140,000,000
120,000,000
100,000,000
80,000,000
60,000,000
40,000,000
20,000,000
0
138,972,000
36,040,800
32,126,400
26,846,400
17,143,200
15,290,400
11,966,400
5,505,600
5,292,000
4,202,400
3,384,700
2,983,200
2,282,400
WALGREEN CO
MCKESSON CORPORATION
AMERISOURCEBERGEN DRUG CORP
CARDINAL HEALTH
NUCARE PHARMACEUTICALS
SMITH DRUG COMPANY
WAL-MART PHARMACY WHSE #45
H. D. SMITH
AMERISOURCEBERGEN DRUG CORP.
ADVANTAGE LOGISTICS
QK HEALTHCARE, INC.
ROCHESTER DRUG CO-OPERATIVE INC
LOUISIANA WHOLESALE DRUG CO
30mg-Oxycodone
2011

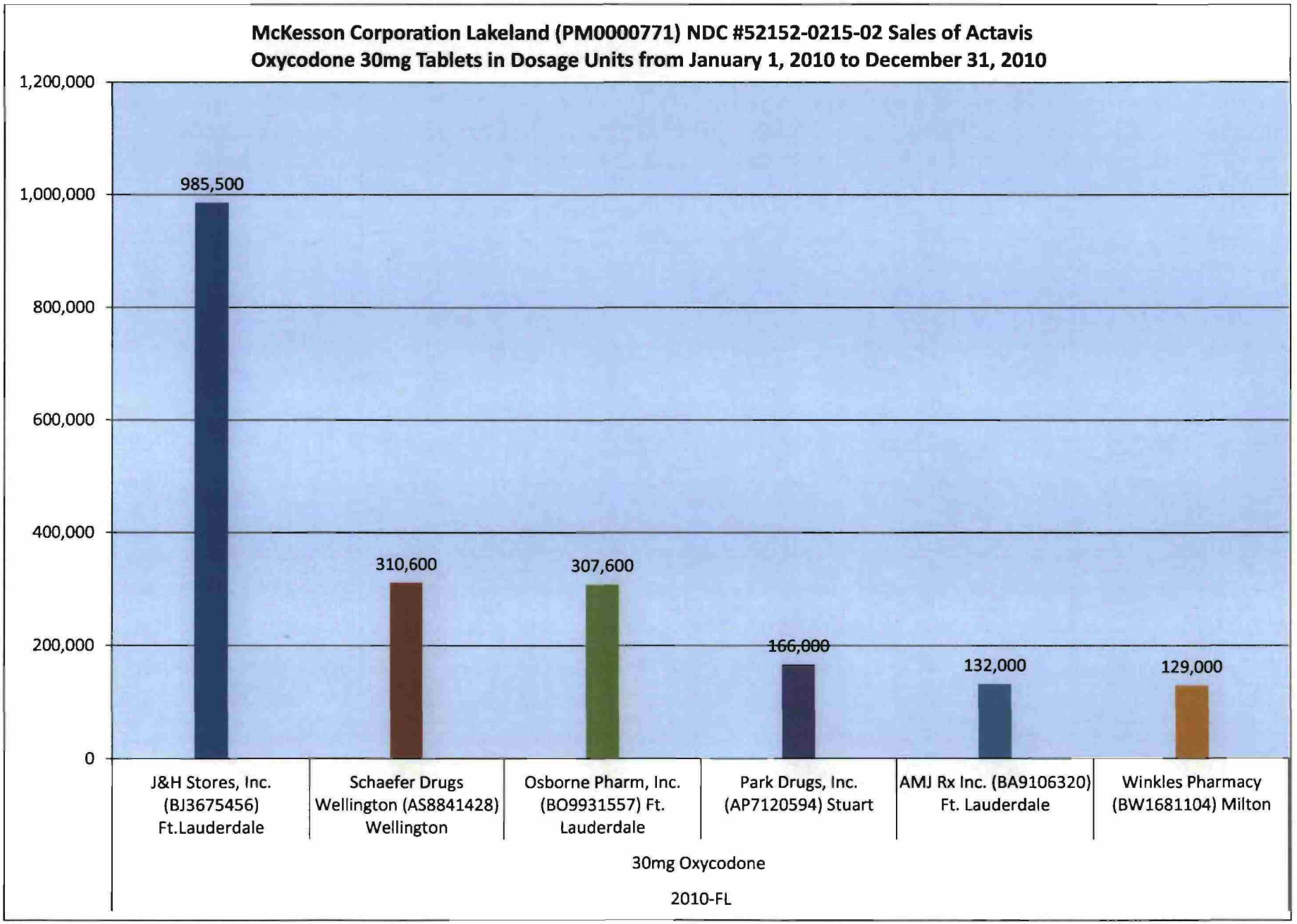


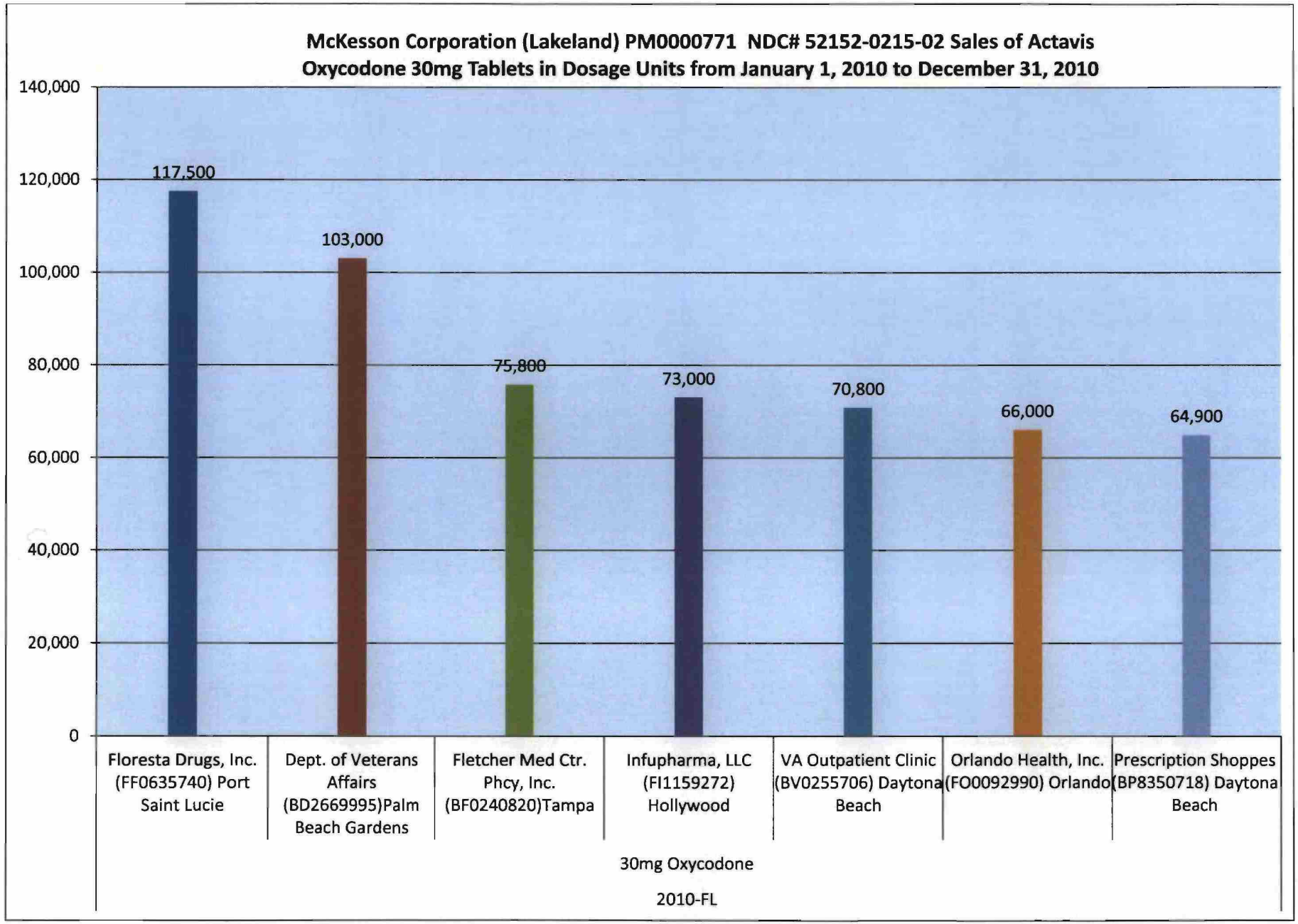
Publix Stores

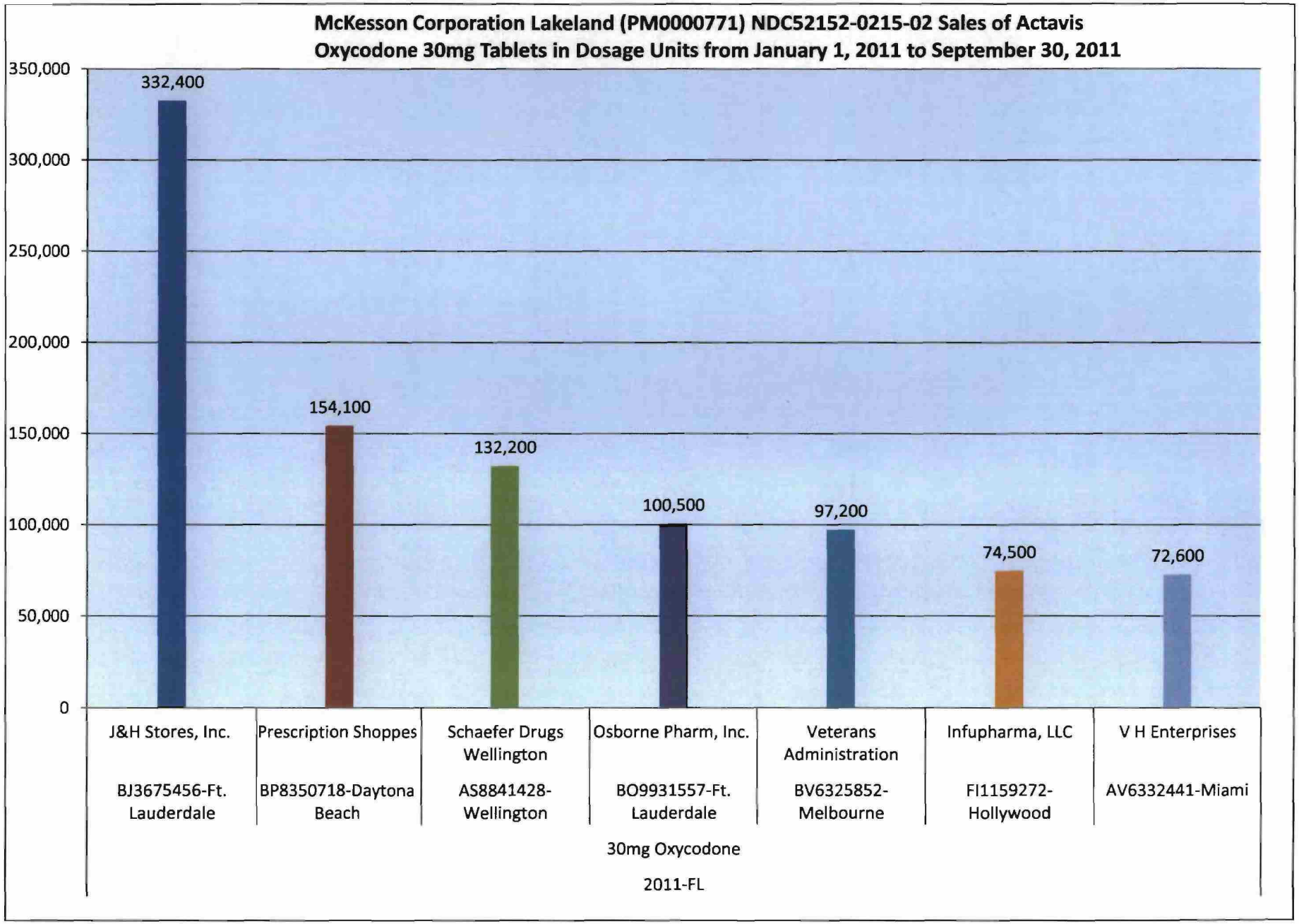



Publix Super Markets Purchases in Dosage Units from McKesson Corporation
Lakeland (PM0000771) NDC52152-0215-02 January 1, 2011 to September 30, 2011
60,000
50,000
40,000
30,000
20,000
10,000
0
52,200
49,100
45,600
41,300
40,600
37,800
36,100
36,000
32,800
28,800
28,100
23,800
FP0996592-Brooksville
FP0152645-Land O Lakes
FP1864924-Pompano Beach
BP6797318-Venice
FP0116740-Orlando
BP8732984-Parrish
FP0725195-Homosassa
BP7480142-Bradenton
BP5621796-West Palm Beach
BP8567971-Jupiter
BP6025729-Pompano Beach
BP7587009-Spring Hill
30mg Oxycodone
2011-FL

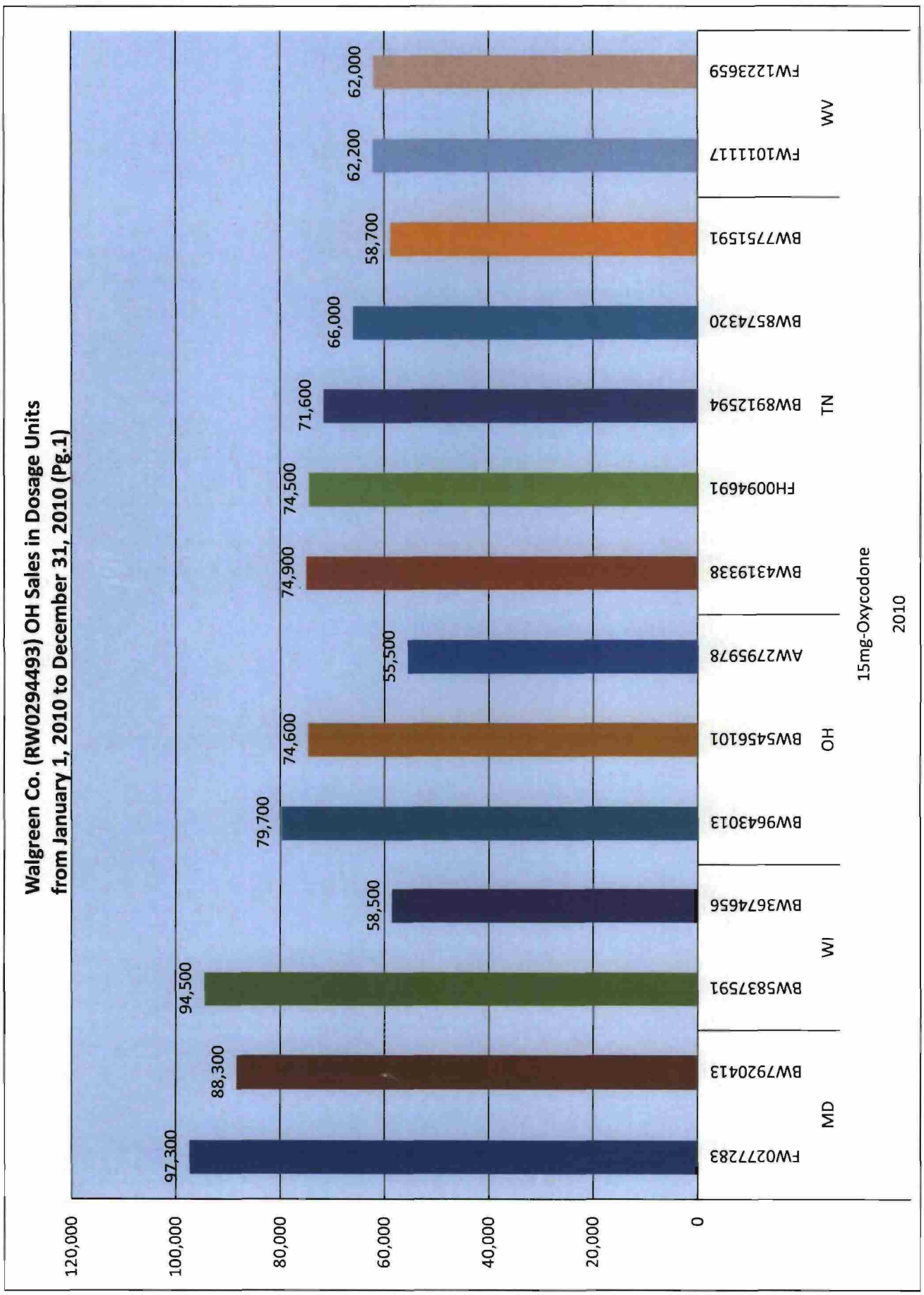
McKesson Corporation
(Lakeland)

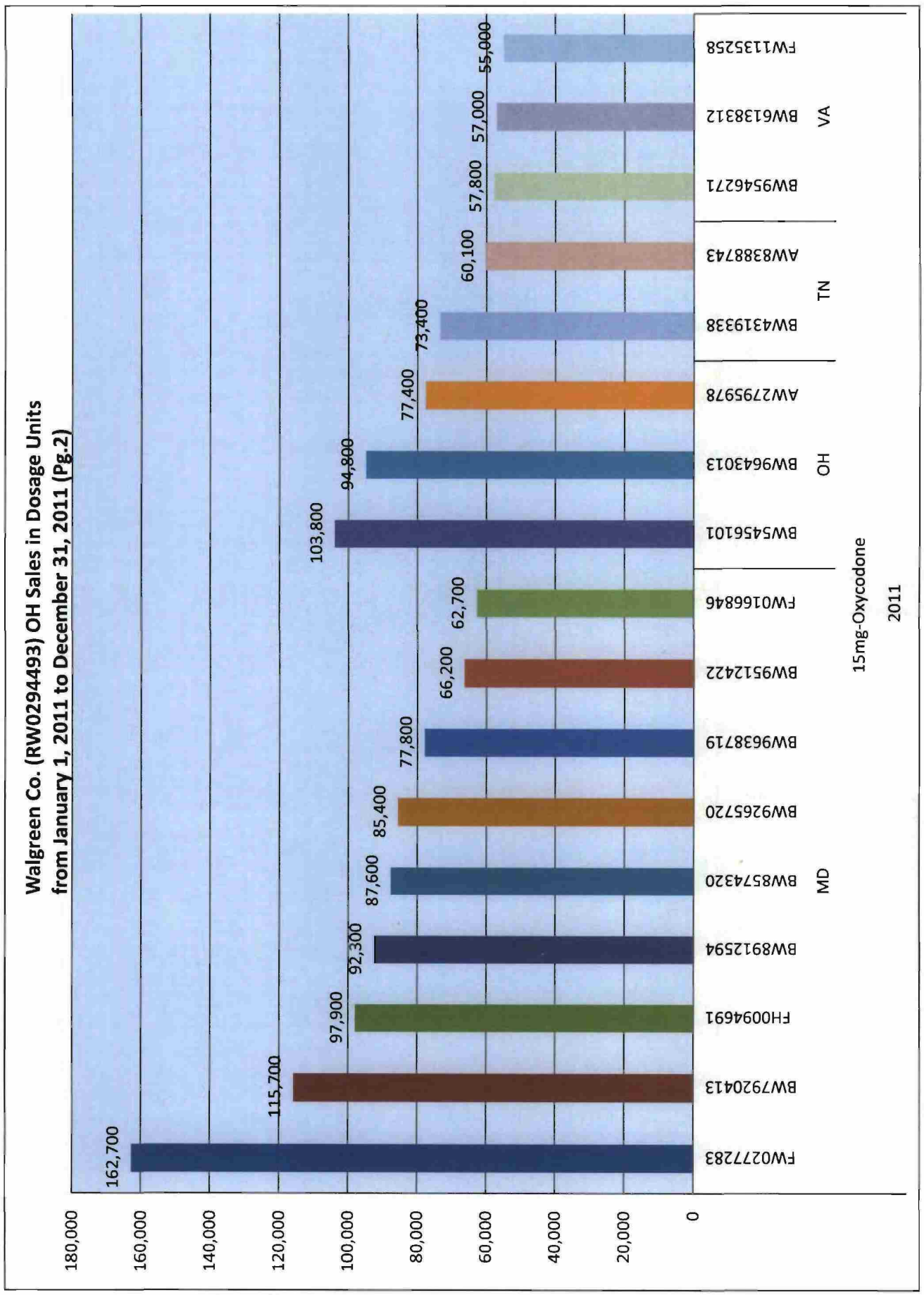


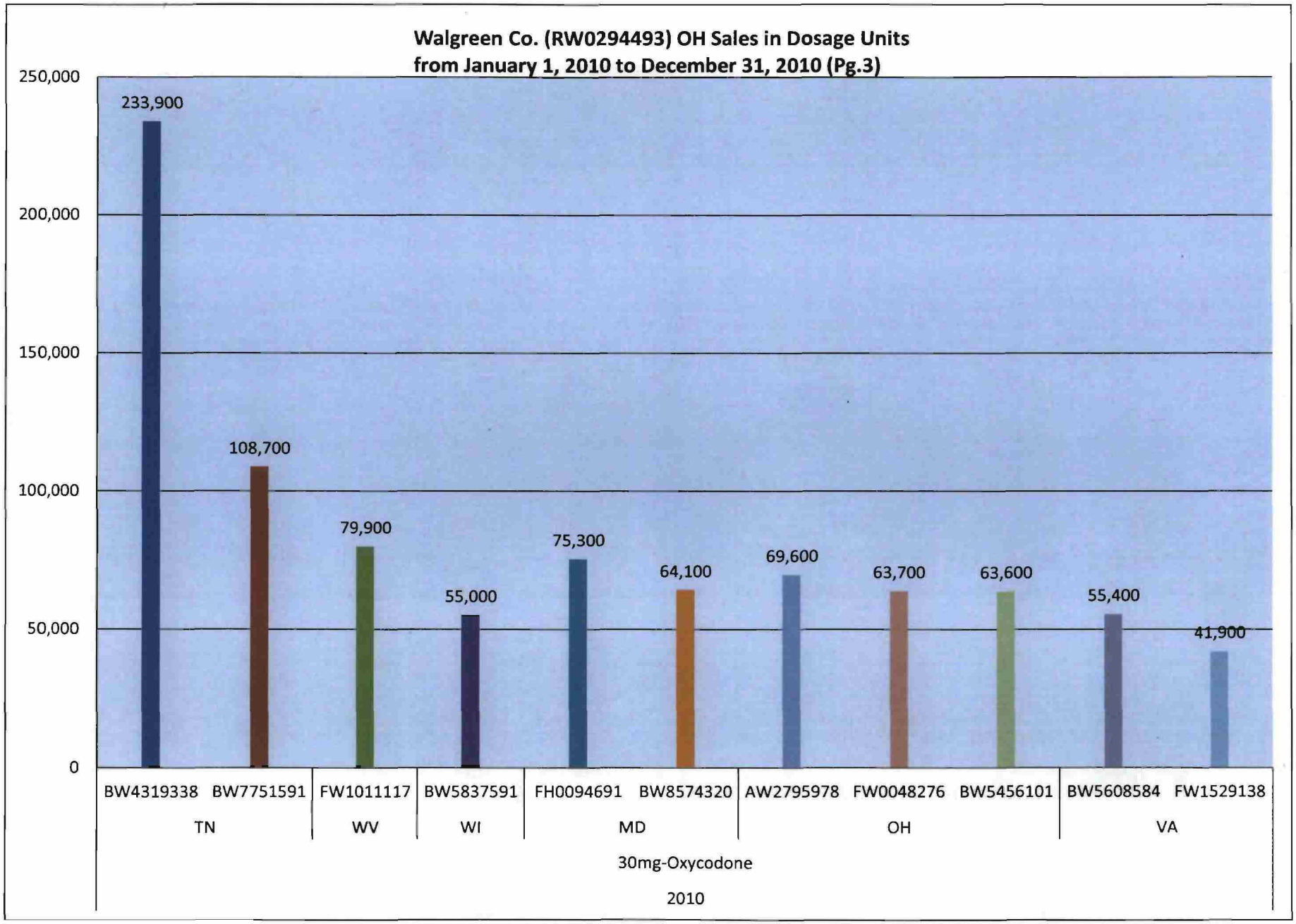


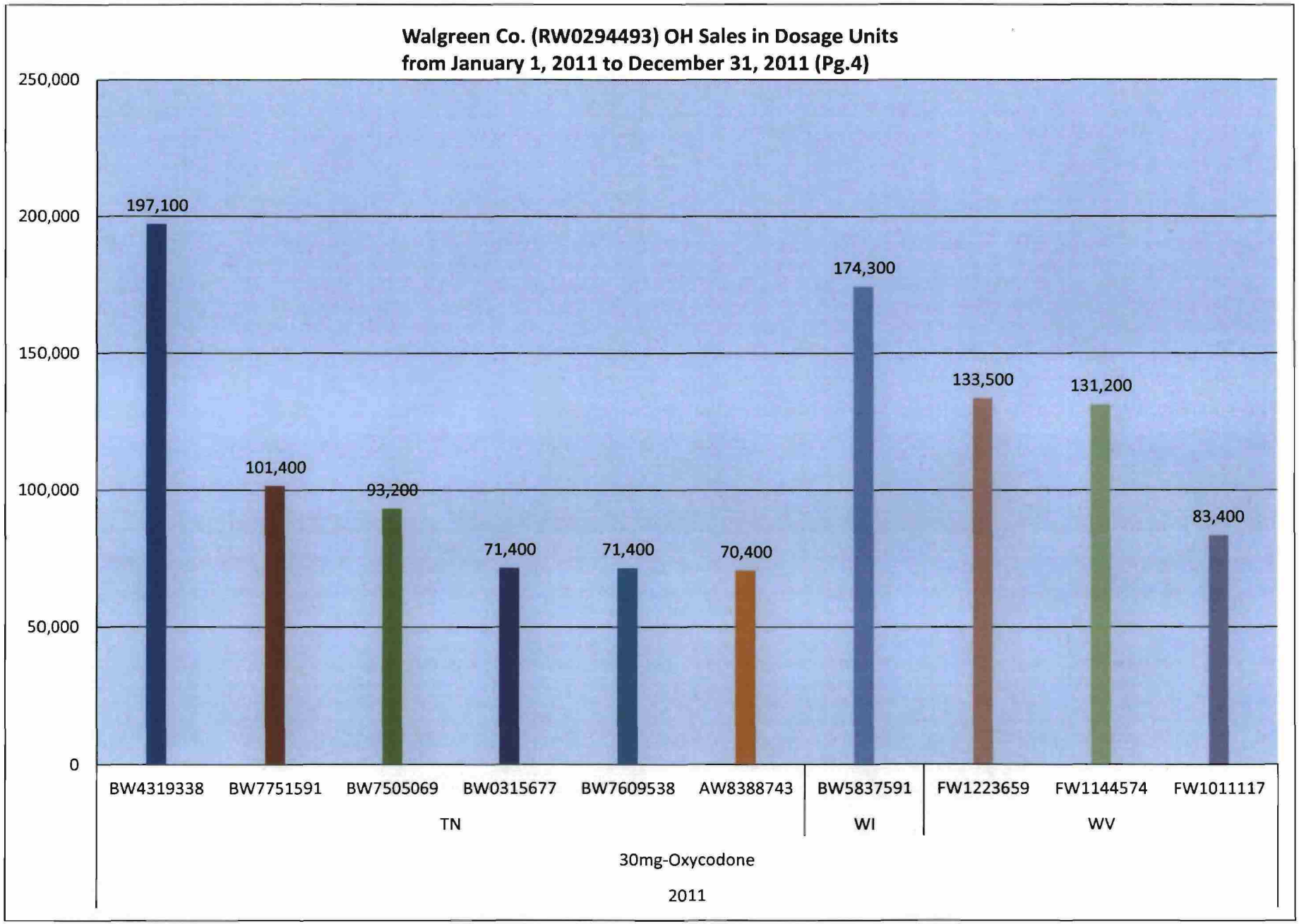


Walgreen Co. (OH)

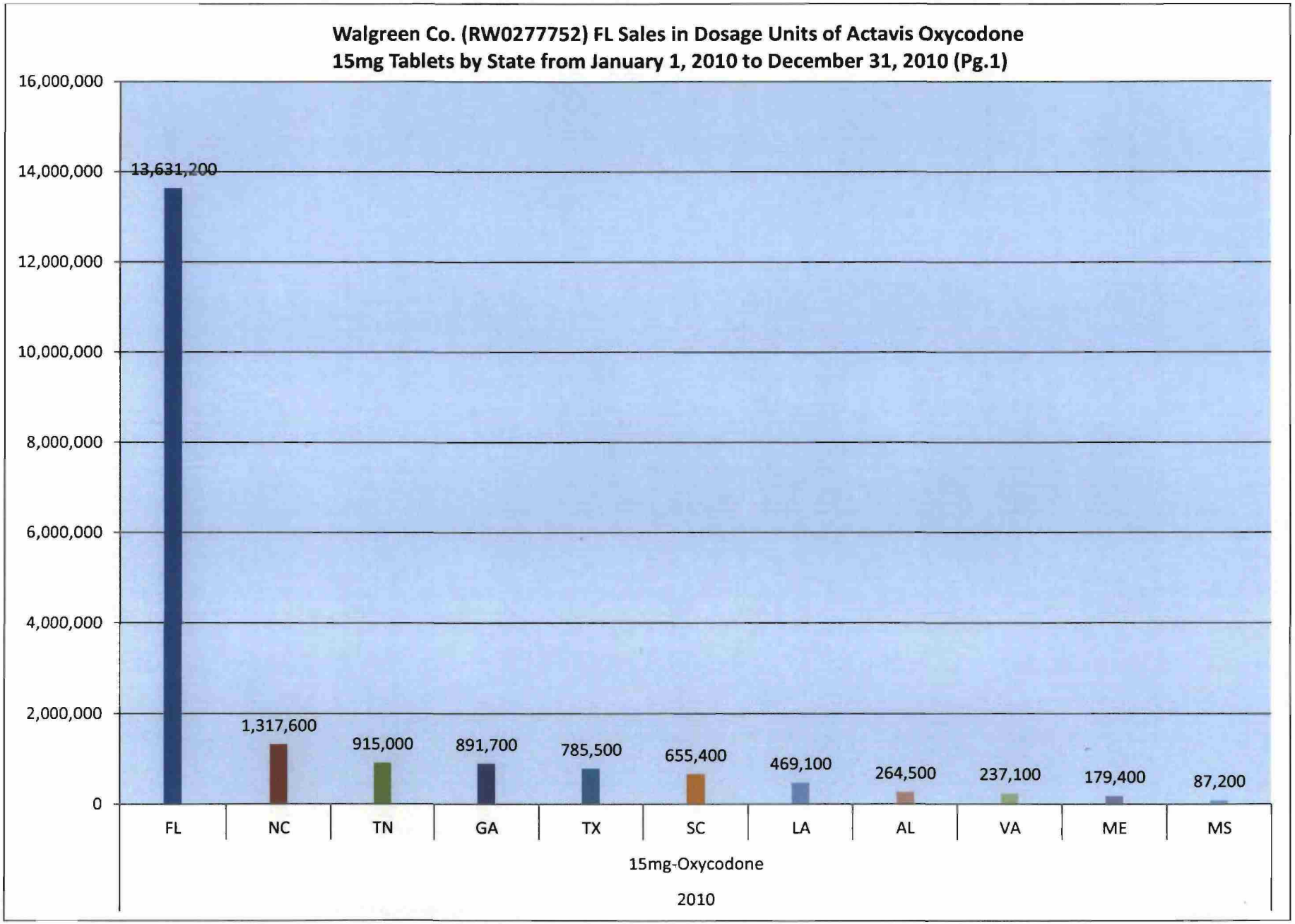

Walgreen Co. (RW0294493) OH Sales in Dosage Units
from January 1, 2010 to December 31, 2010 (Pg.1)
15mg-Oxycodone
2010
120,000
100,000
80,000
60,000
40,000
20,000
0
MD
FW0277283
97,300
BW7920413
88,300
WI
BW5837591
94,500
BW3674656
58,500
OH
BW9643013
79,700
BW5456101
74,600
AW2795978
55,500
TN
BW4319338
74,900
FH0094691
74,500
BW8912594
71,600
BW8574320
66,000
BW7751591
58,700
WV
FW1011117
62,200
FW1223659
62,000

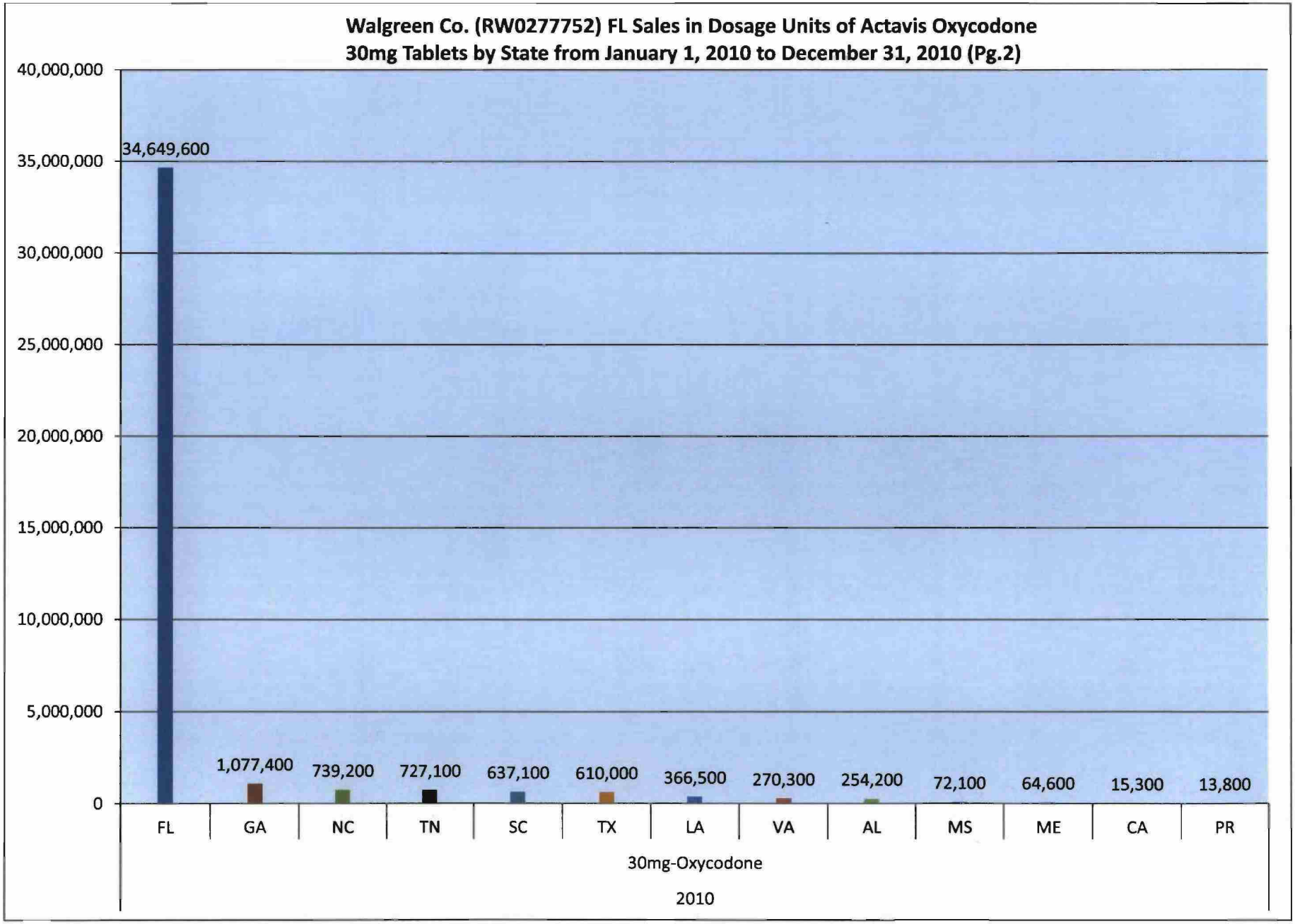

Walgreen Co. (RW0294493) OH Sales in Dosage Units
from January 1, 2011 to December 31, 2011 (Pg.2)
15mg-Oxycodone
2011
MD
OH
TN
VA
FW0277283
BW7920413
FH0094691
BW8912594
BW8574320
BW9265720
BW9638719
BW9512422
FW0166846
BW5456101
BW9643013
AW2795978
BW4319338
AW8388743
BW9546271
BW6138312
FW1135258
162,700
115,700
97,900
92,300
87,600
85,400
77,800
66,200
62,700
103,800
94,800
77,400
73,400
60,100
57,800
57,000
55,000
180,000
160,000
140,000
120,000
100,000
80,000
60,000
40,000
20,000
0

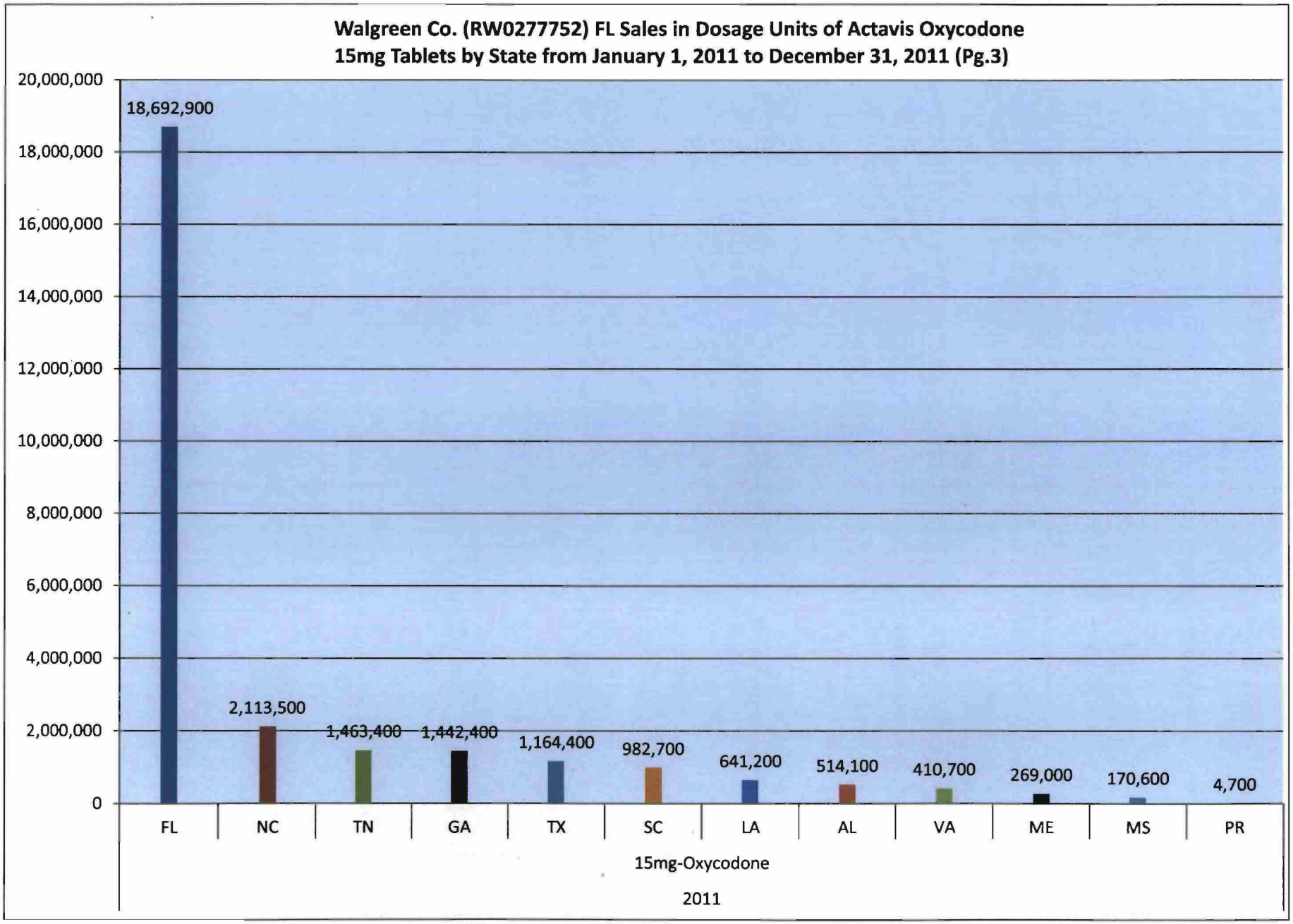


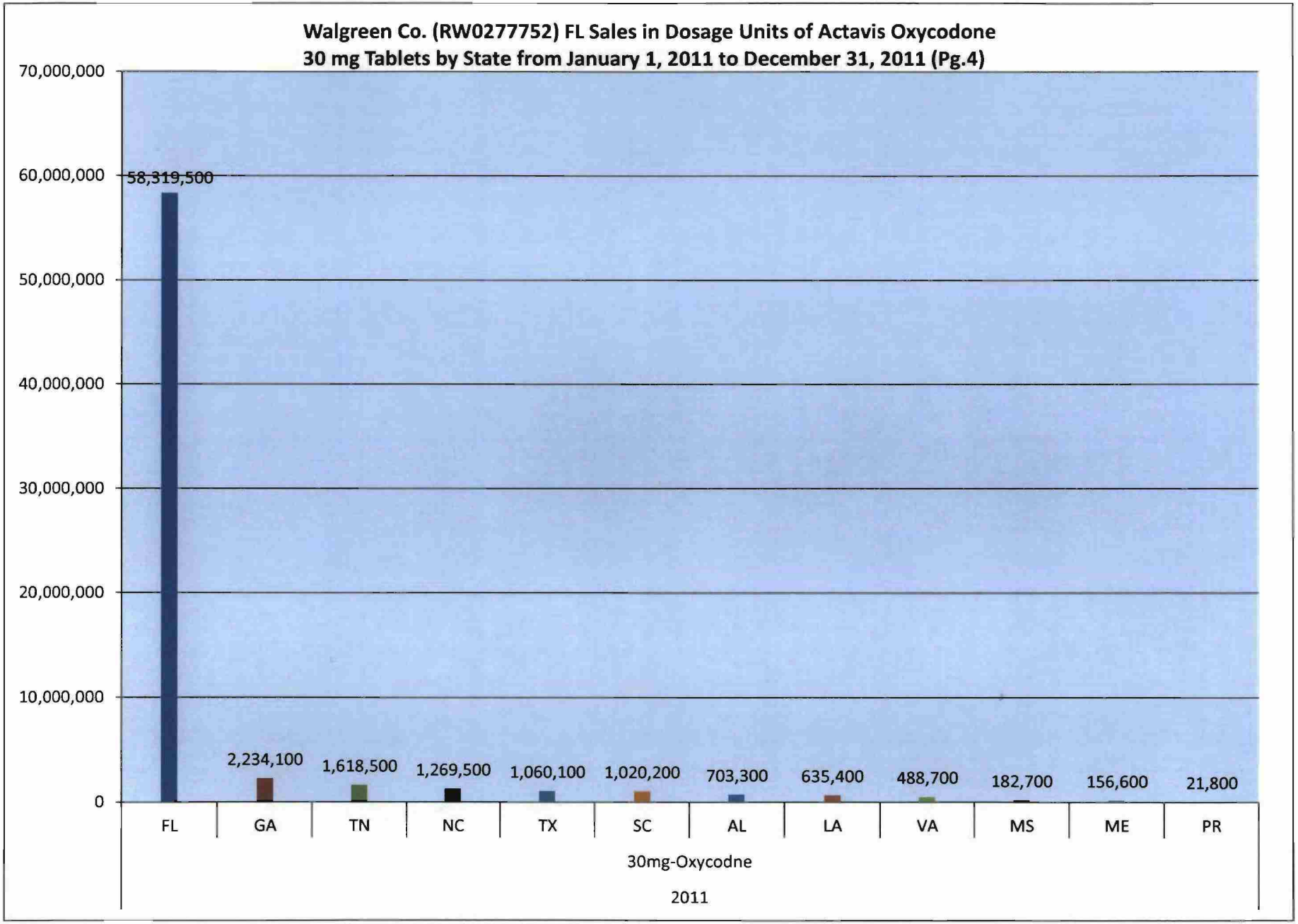


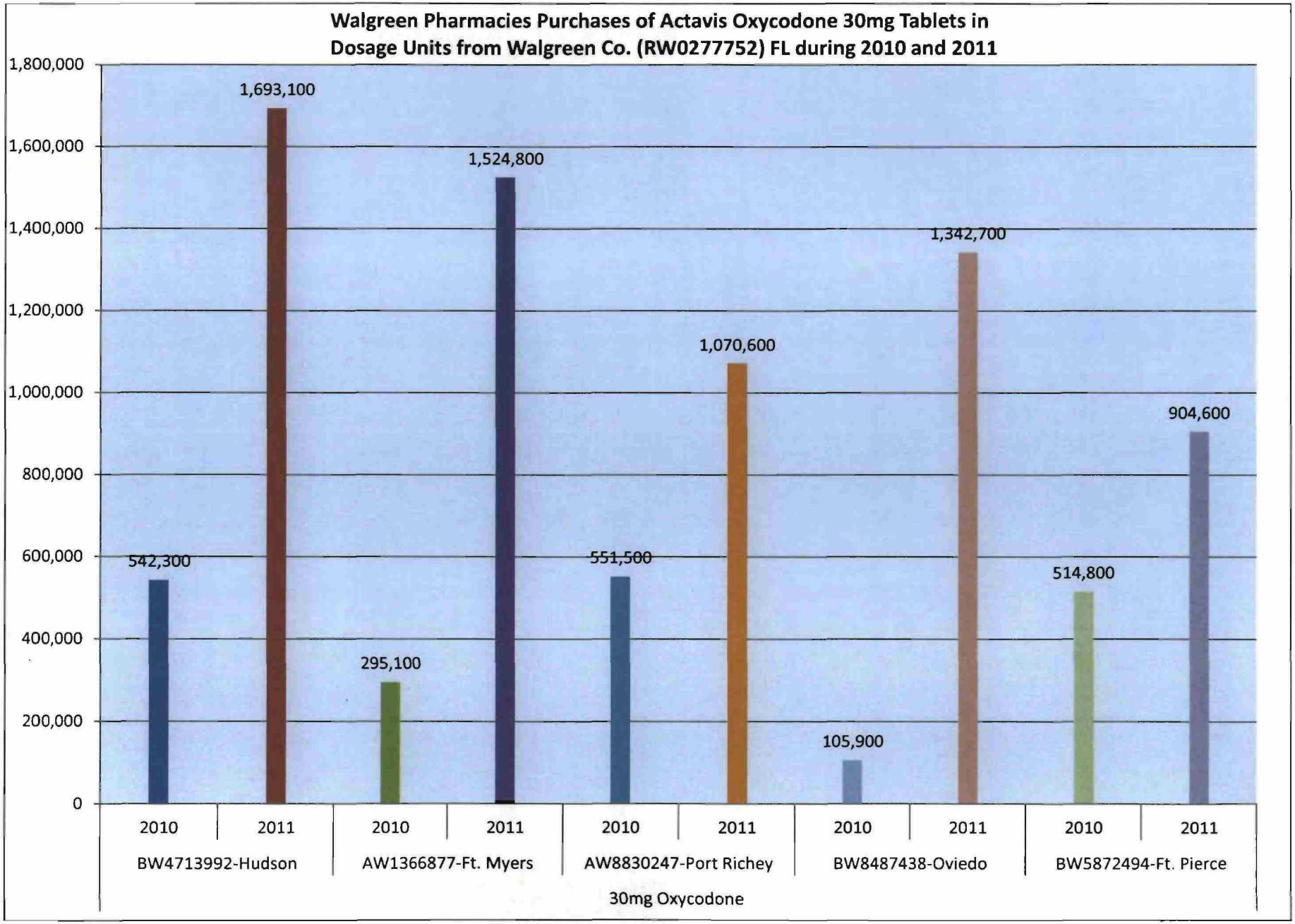
Walgreen Co. (FL)

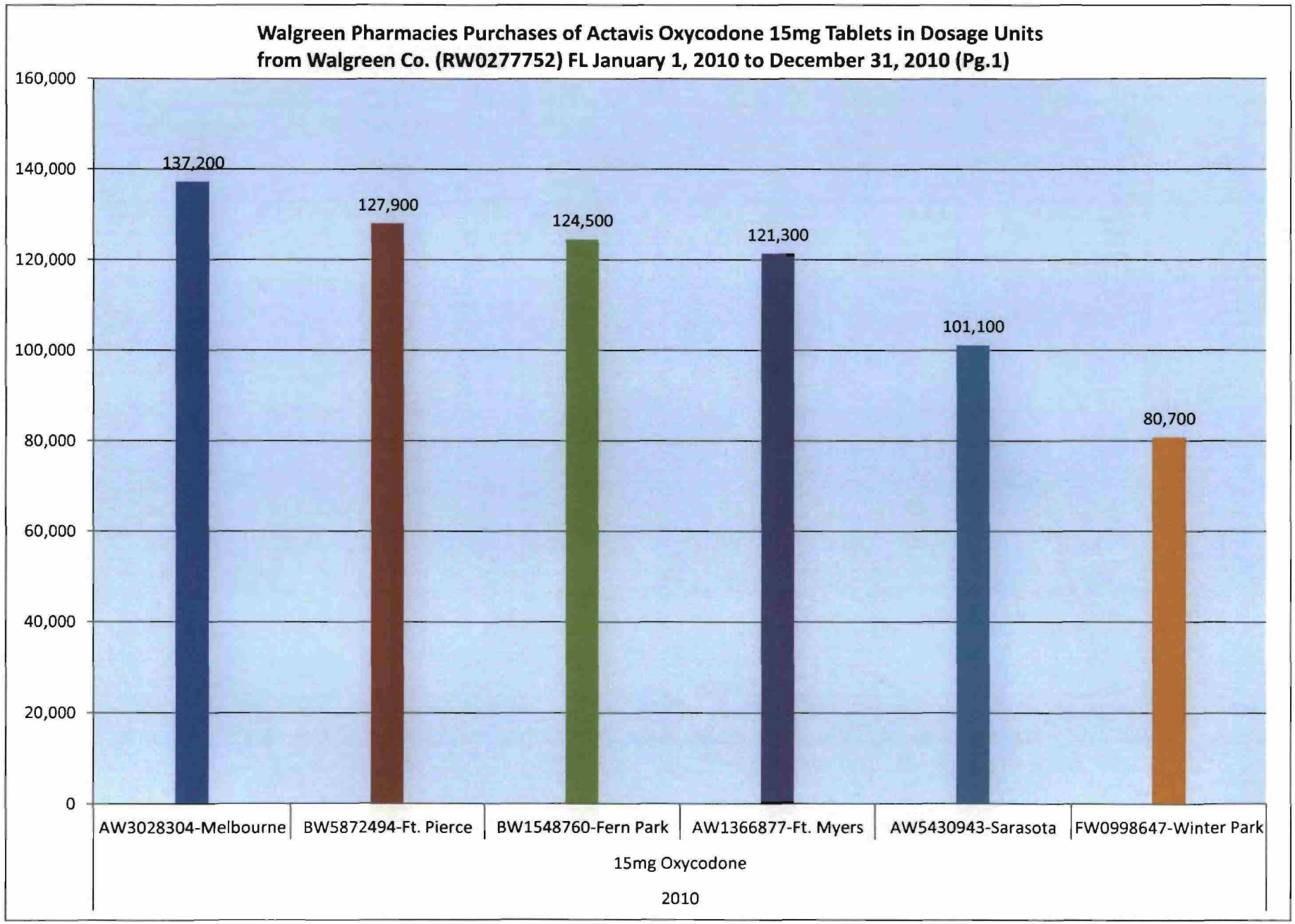


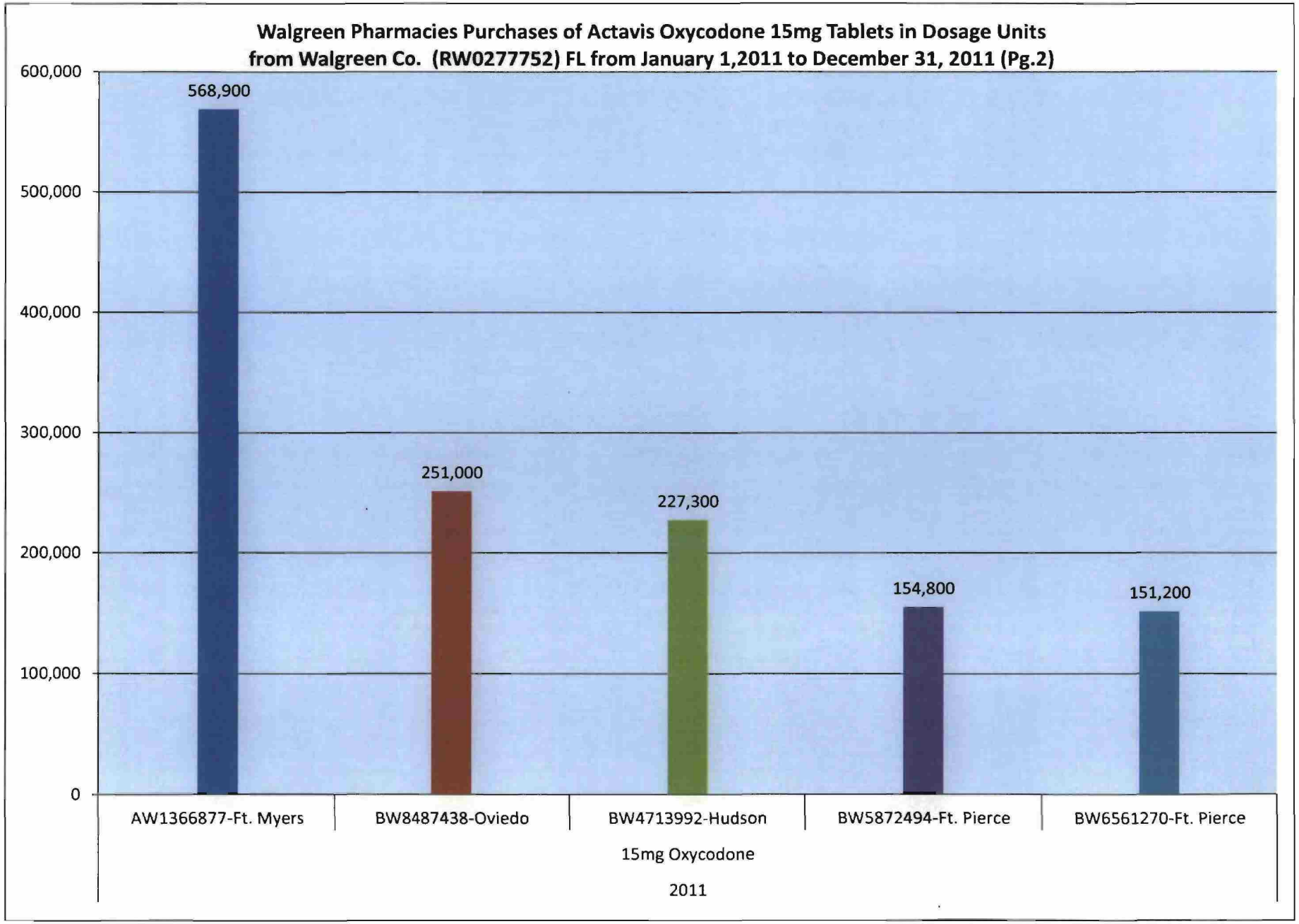




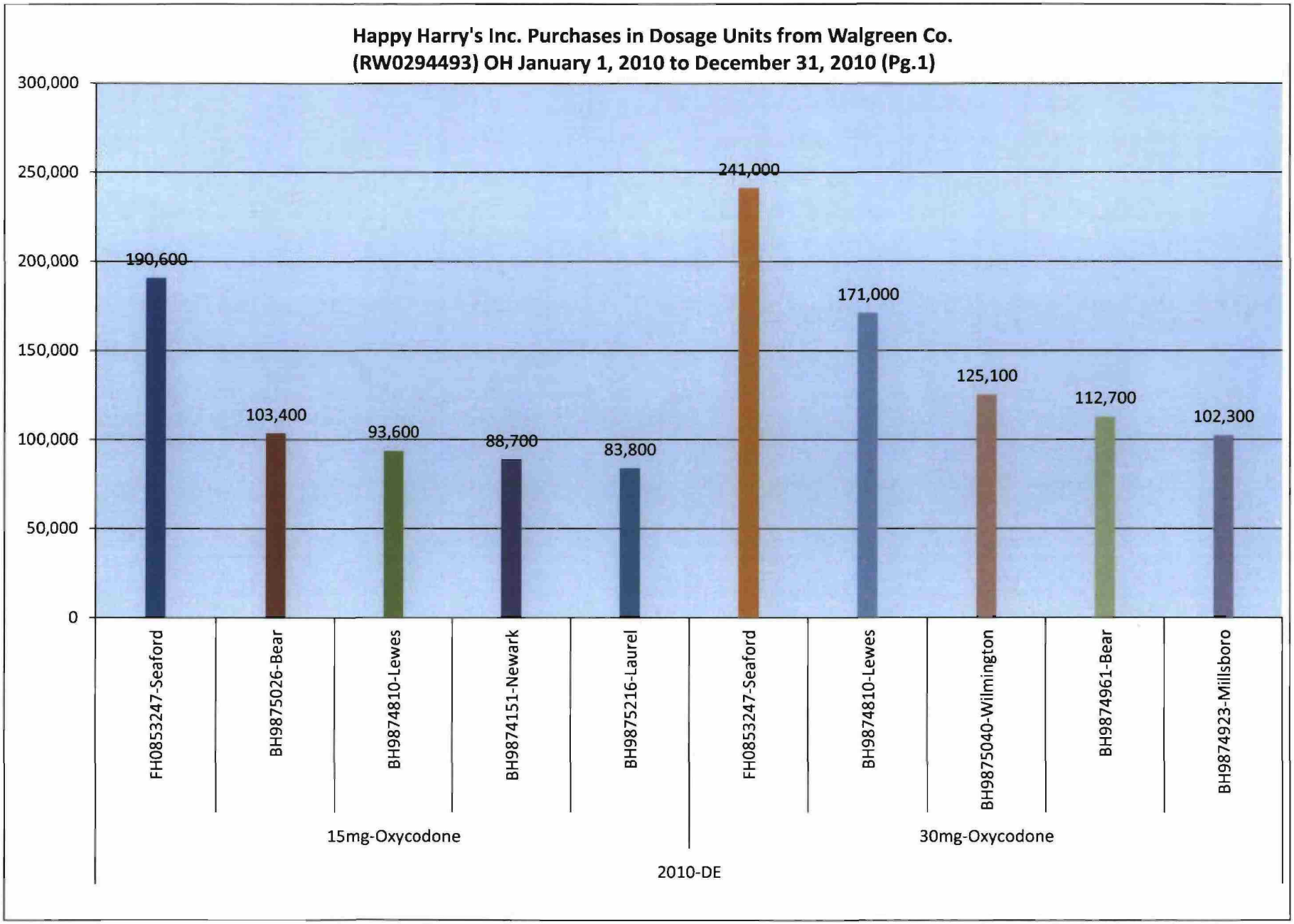


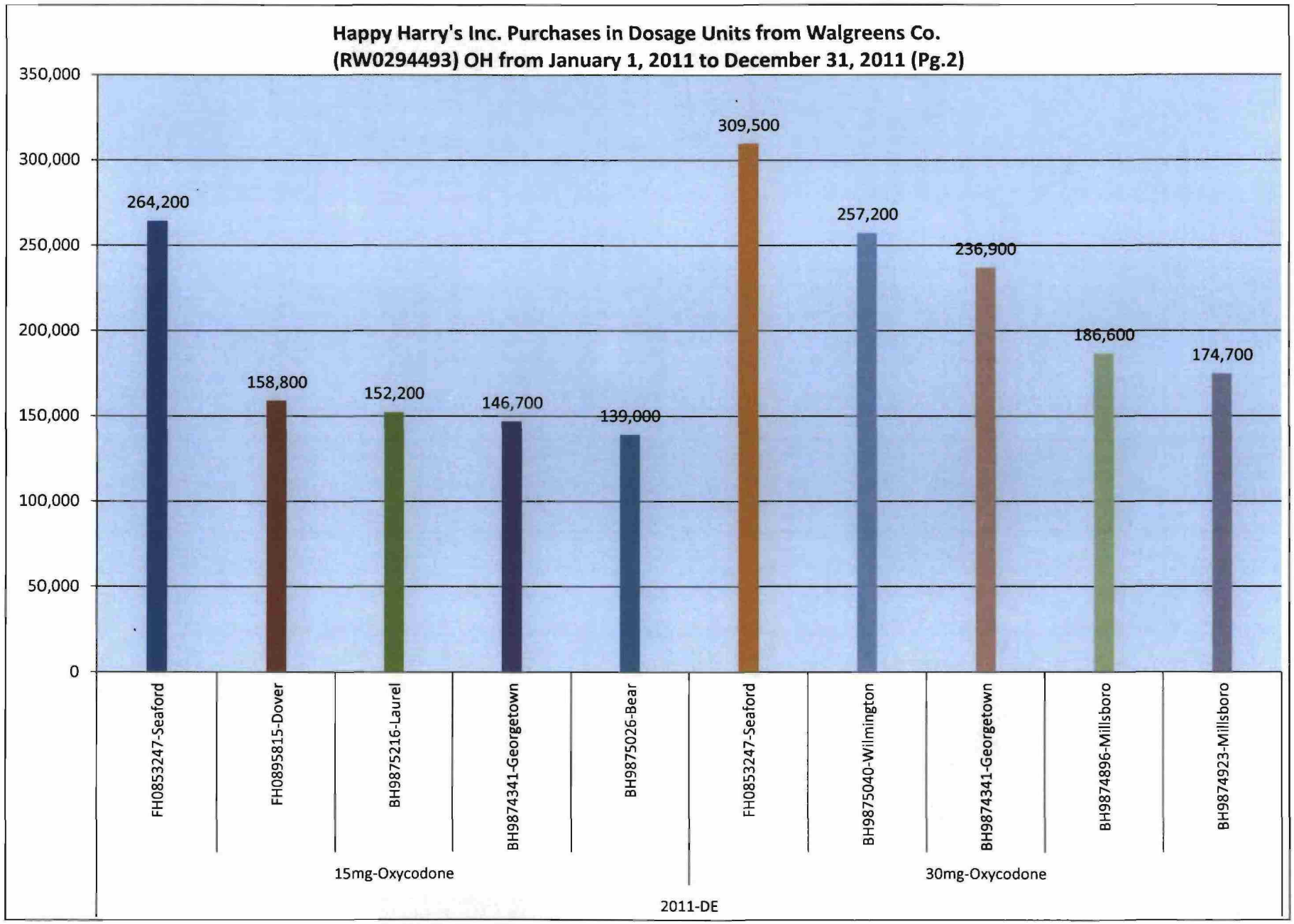






Happy Harry's, Inc.





Decision Questions

Suggested Questions a Distributor should ask prior to shipping controlled substances.

This list of questions is not intended to be all inclusive nor should it be interpreted that every situation or registrant activity is covered. This questionnaire is provided to assist the distributor to formulate a better understanding of who their customers are and whether or not they should sell to them controlled substances. It is incumbent upon you, the distributors, to ensure that sales to your customers are for legitimate purposes. It is further incumbent upon you to identify illicit or suspicious activities which may result in the diversion of controlled substances.

The use of this questionnaire should not be construed in any manner to be a mechanism or means that you have fully met the criteria and actions required by 21 USC 823 or other state and federal laws that are applicable.

Possible questions for a pharmacy:

- Does the pharmacy fill prescriptions via the Internet? If so, is the pharmacy registered with the DEA under the Ryan Haight Act?
- Is this a mail order pharmacy (fills prescriptions for insurance, etc.)?
  Note: A pharmacist may claim to be mail order pharmacy but may actually be operating as an Internet pharmacy. Do not accept the response to this question at face value.
- Is the pharmacy licensed in all states for which it mails or fills prescriptions?
- Does the pharmacy report to all states that have prescription monitoring programs in which their customers reside and to whom they dispense?
- Does the pharmacy provide services for any specialty customers such as Long Term Health Care, Hospice Centers, Assisted Care Living Facilities, etc.?
- Does the pharmacy have staff or a private firm that solicits practitioners to get more business?
- What is the pharmacy's ratio of controlled vs. non-controlled orders?
- Does the pharmacy order a full variety of controlled substances and are they fairly evenly dispersed? If not, why the disparity?
- What are the hours of operation of the pharmacy?
- Does the pharmacy offer a full assortment of sundries to its customers (e.g., aspirin, snacks, cosmetics, etc.)?
- Does the pharmacy have security guards on the premises? If so, why?
- What methods of payment does the pharmacy accept (cash, insurance, Medicaid, and in what ratios)?
- Who is the pharmacy's primary supplier?
- Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?
- If this is a new account, why does the pharmacy want you to be their supplier?

- If you are not the only supplier, what controlled substances will the pharmacy be ordering from you, in what quantities, in what time frame, and will they be ordering these same products from other suppliers?
- What ratio will you be supplying compared to other suppliers?
- Does the pharmacy fill prescriptions for out of state customers? If so, for how many out of state customers does the pharmacy fill (ratio or approximate number)?
- If the pharmacy fills prescriptions for Pain Management or other specialty practitioners (diet, oncology, etc.), is the pharmacist comfortable with the prescribing practices of the practitioner?
- Has the pharmacist questioned or been uncomfortable with, the prescribing practices of any practitioner?
- Has the pharmacy ever refused to fill prescriptions for a practitioner? If so, why and who?
- Are there particular practitioners who constitute most of the prescriptions it fills? Who are these practitioners (Name and DEA registration number)?
- Does the pharmacy have any exclusive contracts, agreements, arrangements, etc., with any particular practitioner, business group, investors, etc.? If so, explain those arrangements and/or obtain copies of those agreements.
- Is the pharmacist comfortable enough with the prescribing practices of any or all practitioners for which they fill, to stake their professional livelihood on it?
- Does the pharmacy supply, order for, or sell to any practitioners or other pharmacies?
- How does the pharmacy sell/transfer controlled substances to other pharmacies or practitioners? Via a prescription, sales invoice, or DEA Form-222? (Transfer by prescriptions is not authorized).

Possible questions for a practitioner:

- What is the practitioner's specialty, if any (family practice, oncology, geriatrics, pain management, etc.)?
- Do the controlled substances being ordered correspond to his specialty or the treatment he provides?
- What method of payment does the practitioner accept (cash, insurance, Medicare) and what is the ratio of each?
- Has the practitioner ever been disciplined by any state or federal authority?
- How many patients does the practitioner see each day? What is his weekly average?
- Does the practitioner prescribe as well as dispense?
- Why does the practitioner prefer to dispense as opposed to prescribe?
- Who was the practitioner's previous supplier? Are they still ordering from this supplier? If not, why are they looking for a new supplier?
- Do the hours of operation and the facility accommodate the type of practice being conducted?
- Does the practitioner's office have security guards on-site? If so, why?

- Are all applicable state, federal, local licenses current and are they issued for the registered address at which the practitioner is practicing?
- Does the practitioner see out of state patients? If so,
    - From what states,
    - How many,
    - Approximate ratio of out of state compared to local, and
    - Why, specifically, they travel so far to see him?

- Can the practitioner provide a blank copy of an agreement which they enter into with a patient, specifying the course of treatment, the patient rights and responsibilities, and reasons for termination of treatment?
- Does the practitioner conduct random unannounced drug testing?
- What measures does the practitioner employ and/or monitor to prevent addiction and diversion of controlled substances?
- Are there more than one practitioner dispensing controlled substances from the registered location?
- Do you order for just yourself or for the whole clinic?
- What controlled substances are you currently dispensing? (If only one or two controlled substances are being ordered, have the practitioner fully explain why he administers or dispenses only these specific controlled substances).
- In what dosage levels is the practitioner dispensing (2 tablets, 4 times a day, for 30 days, or 90, 120, 240 a week, month).
- Does the practitioner prescribe as well as dispense to his patients?
- Does the practitioner prescribe the same controlled substances as were dispensed to the patient?
- How many patients is the practitioner presently treating (day, week, and month)?

Should you have any additional questions, concerns, or issues beyond what has been presented; it is strongly recommended you contact your local DEA Office.