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.*

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**BILLING CODE 4410–09–P**

## 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.

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]

[15] According to the stipulated facts, Mr. Mudri is a retired DEA Diversion Investigator.

[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. 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]

[22] This is page 5 of the exhibit.

[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