



**Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd.,  
Cephalon, Inc., and Actavis Generic Defendants'**

# **Cross Examination of David Herzberg, PhD**

**May 31, 2022**

# Cephalon's Products Until October 2000: Provigil & Gabitril

5/29/22, 11:23 AM

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<TYPE>425  
<SEQUENCE>1  
<FILENAME>a425.txt  
<DESCRIPTION>FORM 42  
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accretive to Cephalon's revenues and earnings in 2001 and beyond. Cephalon develops and markets products to treat sleep and neurological disorders, and cancer. Anesta is a leader in the development and commercialization of products for the management of cancer pain and other therapeutic applications using its patented oral transmucosal system (OTS-TM-) for drug delivery.

Exchange Act of 1934  
Commission File No.: 0-19119  
Subject Company: Anesta Corp.

THE FOLLOWING IS A PRESS RELEASE DISSEMINATED BY CEPHALON, INC. ON JULY 17, 2000

CONTACT: SHERYL WILLIAMS  
Cephalon, Inc.  
610-738-6450

FOR IMMEDIATE RELEASE

CEPHALON AND ANESTA  
PHARMACEUTICAL BUSINESS

West Chester, Ohio  
Cephalon, Inc. (NASDAQ: CEPH) and Anesta Corp. (NASDAQ: ANES) have agreed to combine their companies into a new entity. The combined company will have three key marketed products in the United States: PROVIGIL-R- (modafinil) Tablets [C-IV] is marketed for the treatment of excessive daytime sleepiness associated with narcolepsy, and is being developed for other potential uses; ACTIQ-R- (oral transmucosal fentanyl citrate) is marketed for the treatment of breakthrough cancer pain, and pending regulatory clearance will be launched in Europe through licensees Elan, Grupo Ferrer, Laboratoire Lafon and Swedish Orphan; GABITRIL-R- (tiagabine hydrochloride) is marketed under a co-marketing and co-development agreement with Abbott Laboratories for the adjunctive treatment of partial seizures associated with epilepsy.

Upon completion of the merger, Cephalon will own approximately 0.4765 shares of new common stock. Based on the total number of shares outstanding, the total value of the transaction is approximately \$31.45 million, or \$31.45 per share, based on the closing price of Cephalon common stock on July 17, 2000.

The boards of directors of Cephalon and Anesta have approved the proposed merger, and regulatory agencies are expected to complete the merger agreement, and the transaction is expected to close in the third quarter of 2000.

Cephalon believes the combination of the two companies will create a unique and rapidly growing company with a highly capable and experienced management team. Cephalon believes the combination will give Cephalon another high-growth product, complete our commercial integration in oncology and enable us to apply Anesta's novel drug delivery technology to the development of new products in both oncology and neurology."

<https://www.sec.gov/Archives/edgar/data/873364/0000091205700032179/a425.txt>

1/5

<https://www.sec.gov/Archives/edgar/data/873364/0000091205700032179/a425.txt>

# Cephalon - Anesta Merger (October 2000)

- October 10, 2000 -

Contact: Sheryl Williams  
610-738-6493  
[swilliam@cephalon.com](mailto:swilliam@cephalon.com)

FOR IMMEDIATE RELEASE

## Cephalon Completes Merger with Anesta

West Chester, PA – Cephalon, Inc. announced that shareholders of the merger of the two companies. After the close of trading today on NASDAQ and the company

Under the terms of the merger agreement, Anesta shareholders will receive one share of Cephalon common stock for each share of Anesta they owned as a pooling of interests.

The merger creates a combined company with pain management and more than 200 sales and marketing professionals.

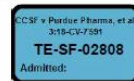
The combined company has strong sales in their respective markets. Cephalon's lead product, PROVIGIL® (modafinil) Tablets, is currently marketed in six countries for the treatment of excessive daytime sleepiness associated with narcolepsy. Anesta's lead product, ACTIQ® (oral transmucosal fentanyl citrate), a treatment for breakthrough cancer pain, is marketed in the U.S. and today received regulatory approval in the United Kingdom.

Cephalon plans to re-open its company on Thursday, November 2, 2000, at a conference call scheduled for 10:30 a.m. EST on November 2 by calling 913-981-4901, and referring to Conference Code Number 477989.

Confidential

TE-SF-02808.00001

TEVA\_MDL\_A\_08476493



TE-SF-02808

# Declaration of David Herzberg, PhD

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 1 of 15

Word count: 4286

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2 YVONNE R. MERE, State Bar #173594  
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acting by and through San Francisco City Attorney David Chiu.

10  
11 UNITED STATES DISTRICT COURT  
12 NORTHERN DISTRICT OF CALIFORNIA  
13 THE CITY AND COUNTY OF SAN FRANCISCO, CALIFORNIA and THE  
14 PEOPLE OF THE STATE OF CALIFORNIA, Acting by and through San  
15 Francisco City Attorney DAVID CHIU,  
16 Plaintiff,  
17 vs.  
18 PURDUE PHARMA L.P., et al.,  
19 Defendants.  
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4870-7922-2817.v1

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 3 of 15

1 medical consensus that opioids should not be used for less severe or, especially, chronic  
2 pain.  
3 5. Beginning in the early 1900s, this medical consensus was supported by federal  
4 and state laws and regulations limiting the prescribing and dispensing of opioids in medical  
5 practice. San Francisco passed the first of such laws with an 1875 municipal ordinance

6. In at least two instances, drug manufacturers attempted to push back against the conservative consensus, each time claiming that their new drug was less addictive than other opioids; in both cases, they were proved sadly wrong. The first of these involved

18 Dilaudid, a semi-synthetic derivative of morphine first produced by Merck in Germany in  
19 1924 and introduced in the United States by Bilhuber-Knoll Corporation in 1932. Bilhuber-  
20 Knoll launched Dilaudid with a marketing campaign built around the positive assessment of  
21 prominent Mayo Clinic physician Walter C. Alvarez ("Alvarez"), who described the drug as  
22 an "ideal analgesic" that "no one has yet become habituated to." Bilhuber-Knoll circulated  
23 Alvarez's sunny take in its marketing materials and in the popular media. Most of these  
24 quoted Alvarez's claim that Dilaudid was "five times stronger than morphine" but "not  
25 habit-forming" because it lacked morphine's "pleasurable sensations." Bilhuber-Knoll also  
26 mailed advertisements to thousands of physicians claiming that Dilaudid did not produce  
27  
28

DECLARATION OF DAVID HERZBERG, PH.D. - 3:18-cv-07591-CRB  
4870-7922-2817.v1

- 2 -

Declaration of David Herzberg, PhD p. 2:15-17

# Declaration of David Herzberg, PhD “Opioid Manufacturers” (1980s and 1990s)

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 1 of 15

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9 *Attorneys for Plaintiff The People of  
acting by and through San Francisco*

11 UNITED STATES OF AMERICA  
12 NORTHERN DISTRICT OF CALIFORNIA

13 THE CITY AND COUNTY OF SAN  
FRANCISCO, CALIFORNIA and THE  
14 PEOPLE OF THE STATE OF  
CALIFORNIA, Acting by and through  
15 Francisco City Attorney DAVID CHIU

16 Plaintiff,

17 vs.

18 PURDUE PHARMA L.P., et al.,  
19 Defendant

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4870-7922-2817.v1

11. In the 1980s and 1990s, opioid manufacturers made substantial progress in overturning the primary element of the conservative opioid system – the robust medical consensus – by amplifying the views of a small, fringe minority of pain reformers and industry-supported medical experts (also known as key opinion leaders (“KOLs”)), who advocated for the long-term use of opioids to treat chronic pain. Undermining the primary

Declaration of David Herzberg, PhD p. 3:25-4:2

# Declaration of David Herzberg, PhD

## Examples of Purdue's Conduct (1980s-2000s)

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 1 of 15

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Francisco City Attorney DAVID CHIU,  
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Case No. 3:18-cv-07591-CRB  
DECLARATION OF DAVID  
HERZBERG, PH.D.

4870-7922-2817.v1

traditional role as opioid watchdogs into opioid boosters. The first company to seize the opportunity and pioneer these marketing campaigns was Purdue Pharma (“Purdue”), which worked with consultant Fleishman-Hillard in 1998 to develop a playbook of strategies to remove what it described as “barriers” to opioid prescribing. The strategy involved building alliances with “third party groups” and “local champions” to promote loosening of opioid guidelines and policies while launching a broad-spectrum campaign of public and medical education to spread awareness of the new pro-opioid gospel. While Purdue was the first to

Declaration of David Herzberg, PhD p. 5:6-12

14. An important early example of this campaign involved the 1997 “Consensus Statement” of the APS and AAPM. The joint APS/AAPM committee charged with writing the statement was chaired by Haddox, employed Portenoy as its sole consultant, and boldly

Declaration of David Herzberg, PhD p. 5:16-18

Research Group (“PRG”). The PPSG received its funding from the opioid manufacturers, including \$1.4 million from Purdue from 1997 to 2009; tens of thousands of dollars from

Declaration of David Herzberg, PhD p. 6:6-7

individually and as head of the AAPM. Documents also show that Ferrell gave 37 Purdue-funded talks between 1997 and 2002.<sup>10</sup>

Declaration of David Herzberg, PhD p. 8:2-3

# Declaration of David Herzberg, PhD APS/AAPM Consensus Statement (1997)

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 1 of 15

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14 PEOPLE OF THE STATE OF CALIFORNIA, Acting by and through San  
15 Francisco City Attorney DAVID CHIU, Case No. 18-cv-07591-CRB  
DECLARATION OF DAVID HERZBERG  
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17 vs.  
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4876-7922-2817.v1

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 6 of 15

1 2012 and 2018).<sup>3</sup> In all, as the U.S. Senate reported in 2017, five opioid manufacturers  
2 provided nearly \$9 million to 14 such pain and opioid organizations between 2012 and 2017

14. An important early example of this campaign involved the 1997 “Consensus Statement” of the APS and AAPM. The joint APS/AAPM committee charged with writing the statement was chaired by Haddox, employed Portenoy as its sole consultant, and boldly challenged the conservative opioid consensus in a manner that closely followed the industry line, downplaying risks of addiction and overdose while advocating the use of opioids for chronic pain. Both the APS and AAPM subsequently received vast sums from opioid manufacturers, including Purdue, Endo, Cephalon, and Teva.

2 / groups (2017).

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DECLARATION OF DAVID HERZBERG, PH.D. - 3:18-cv-07591-CRB  
4876-7922-2817.v1

- 5 -

Declaration of David Herzberg, PhD p. 5:16-22

# APS: Funded By Purdue Pharma (1997-2012)

Response to Request 1)

Summary of payments by Name and Year (1997 - May 8, 2012) <sup>1, 2</sup>

Name	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
AMERICAN PAIN FOUNDATION			250,000		606,500	15,000	461,055	250,087	251,210	177,037	231,150	375,000
AMERICAN ACADEMY OF PAIN MEDICINE	36,800	25,000	32,200	37,600	80,273	198,824	382,295	572,462	17,000	14,000	159,100	78,500
AMERICAN PAIN SOCIETY	48,501	75,960	391,520	108,065	211,211	383,530	606,332	311,603	154,050	102,858	80,690	121,430
AMERICAN GERIATRICS SOCIETY	11,985	24,481	38,248	78,446	127,850	68,750		1,950			6,000	
PAIN & POLICY STUDY GROUP	75,000	75,000			175,000	85,024	280,000	279,500	275,388		50,000	75,000
THE ALLIANCE OF STATE PAIN INITIATIVES								2,720	395,000	152,500	92,500	
CENTER FOR PRACTICAL BIOETHICS INC			40,000	25,000	17,500	270,000	250,000	250,000	250,000	201,500	100,000	510,176
BETH ISRAEL MEDICAL CENTER				118,542	25,000	185,615	96,334	62,679	447		4,190	5,000
JOINT COMMISSION ON ACCREDITATION				560,000	981,359	582,649						
FEDERATION OF STATE MEDICAL BOARDS			12,549	75,362	36,410	6,345	85,181	199,895	339,000	50,000	100,000	
RUSSELL PORTENOY MD	4,357	4,105	1,000	1,554				2,039				
SCOTT FISHMAN MD	24,750	2,497	5,843	9,392								
PERRY G FINE MD		805				700						5,148
LYNN WEBSTER MD (c/o Lifetree Clinical Research)							245,487	1,006,232	148,236	750	4,890	
ROLLIN GALLAGHER MD				2,500								
WILLIAM MCCARBERG MD	2,500	6,974	7,375	12,212	7,939	4,929	2,964	6,062				
MARTIN GRABOIS MD												
MYRA CHRISTOPHER												

## Footnotes:

1.) These figures do not include grants to entities other than those listed in Request 1(a) that sponsored medical education conferences or programs at which one or more individual listed in 1(b) may have been a speaker. In such cases, current *Standards for Commercial Support: Standards to Ensure Independence in CME Activities* promulgated by the Accreditation Council for Continuing Medical Education (ACCME) prohibit any involvement by commercial entities like Purdue in the selection of faculty, selection or presentation of content, or other aspects of the administration of accredited medical education programs. Accordingly, Purdue's reasonably available records do not reflect whether a portion of Purdue's educational grants in support of such programs may have been paid indirectly to an individual listed in Request 1(b).

Name	1997	1998	1999	2000	2001
AMERICAN PAIN FOUNDATION			250,000		606,500
AMERICAN ACADEMY OF PAIN MEDICINE	36,800	25,000	32,300	37,600	80,273
AMERICAN PAIN SOCIETY	48,501	75,960	391,520	108,065	211,211
AMERICAN GERIATRICS SOCIETY	11,985	24,481	38,248	78,446	127,850
PAIN & POLICY STUDY GROUP	75,000	75,000			175,000
JOINT COMMISSION ON ACCREDITATION				560,000	981,359
FEDERATION OF STATE MEDICAL BOARDS			12,549	75,362	36,410
RUSSELL PORTENOY MD	4,357	4,105	1,000	1,554	
SCOTT FISHMAN MD	24,750	2,497	5,843	9,392	
PERRY G FINE MD		805			
LYNN WEBSTER MD (c/o Lifetree Clinical Research)					
ROLLIN GALLAGHER MD				2,500	
WILLIAM MCCARBERG MD		2,500	6,974	7,375	12,212

1.) These figures do not include grants to entities other than those listed in Request 1(a) that sponsored medical education conferences or programs at which one or more individual listed in 1(b) may have been a speaker. In such cases, current *Standards for Commercial Support: Standards to Ensure Independence in CME Activities* promulgated by the Accreditation Council for Continuing Medical Education (ACCME) prohibit any involvement by commercial entities like Purdue in the selection of faculty, selection or presentation of content, or other aspects of the administration of accredited medical education programs. Accordingly, Purdue's reasonably available records do not reflect whether a portion of Purdue's educational grants in support of such programs may have been paid indirectly to an individual listed in Request 1(b).

Confidential: Senate Finance Committee letter request dated May 8, 2012

PLAINTIFFS TRIAL  
EXHIBIT  
P-08386\_00001

P-08386\_00001

P-08386 fn.1

# Declaration of David Herzberg, PhD

## Funding Beginning in the 1990s

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2 City At  
3 YVON  
4 Chief D  
5 SARA  
6 Chief o  
7 OWEN  
8 JAIMIE  
9 JOHN  
10 Deputy  
11 Fox Pla  
12 1390 M  
13 San Fra  
14 Teleph  
15 jaimie.h  
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4870-7922-2

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 8 of 15

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 9 of 15

1 McCarberg as a particularly significant recipient of opioid manufacturers' funding  
2 individually and as head of the AAPM. Documents also show that Ferrell gave 37  
3 funded talks between 1997 and 2002.<sup>10</sup>

4 20. Results of these collaborations between manufacturers and their  
5 groups and consultants included, for example, elimination of California's  
6 prescribing requirement for Schedule II controlled substances, which the manufac  
7 opposed as an impediment to easier opioid prescribing, and widespread distri  
8 Fishman's industry-funded 2007 publication, "Responsible Opioid Prescribing,"<sup>11</sup>  
9 influential in persuading doctors that the risks of opioids had been exaggerated  
10 opioids were appropriate for chronic pain.

11 21. A central vehicle for the campaign to remove guardrails from Ca  
12 conservative opioid prescribing laws was the PPSG's project to evaluate each sta  
13 regulations, and professional guidelines as a way to publicly shame them and prod  
14 making changes. The PPSG had been mentioned in the original proposal by  
15 consultant, Fleishman-Hillard, as an organization whose effort to "direct the at  
16 policy makers and the general public to the need to remove the obstacles to provid  
17 care" presented Purdue with an "opportunity."<sup>11</sup>

18 22. The PPSG's campaign very closely echoed Fleishman-Hillard's langu  
19 a focus on "barriers" to pain treatment and a call for "balance" in pain policy. The  
20 was also funded by a long list of opioid manufacturers, including Purdue, Endo, C  
21 and others, that piggybacked on a massive grant from the Johnson Foundation,<sup>12</sup> v  
22 affiliated with Janssen. In California, the PPSG's campaign led to changes in med

<sup>10</sup> P-29979.

<sup>11</sup> P-29977.

<sup>12</sup> RWJF grants, see P-29974; P-43071. For Purdue's funding of the PPSG, see P-08  
PPSG received contributions ranging from \$5,000 to \$50,000 at a time from a long li  
companies, including Cephalon, Endo, Janssen, and others (readers may search for compa  
spreadsheet P-23785).

19. Opioid manufacturers, including Purdue, Endo, Janssen, Cephalon, and Teva, played an integral role in advancing radical changes to California's laws and policies that encouraged widespread opioid prescribing through the funding of front groups and retention of KOLs beginning in the 1990s. These efforts included financial sponsorship of the PRG, which became the PPSG at the University of Wisconsin, and its leader, Joranson, a noted opioid advocate, as well as the APS, AAPM, and their individual members/leaders, including Portenoy, Fine, Bill McCarberg ("McCarberg"), Fishman, Betty Ferrell ("Ferrell"), Haddox, and Bill Marcus. The Senate Finance Committee Report of December 2020 identified McCarberg as a particularly significant recipient of opioid manufacturers' funding, both individually and as head of the AAPM. Documents also show that Ferrell gave 37 Purdue-funded talks between 1997 and 2002.<sup>10</sup>

# Declaration of David Herzberg, PhD PPSG Funding

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 1 of 15

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15 Francisco City Attorney DAVID CHIU, Case No. 3:18-cv-07591-CRB  
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16 Plaintiff,

17 vs.

18 PURDUE PHARMA L.P., et al.,

19 Defendants.

4876-7922-2817.v1

Case 3:18-cv-07591-CRB Document 1387 Filed 05/26/22 Page 7 of 15

1 15. The Vice Chair of the APS/AAPM Consensus Committee was David Joranson  
2 ("Joranson"), an opioid advocate. Joranson focused on reforming state laws, regulations, and

Research Group ("PRG")). The PPSG received its funding from the opioid manufacturers, including \$1.4 million from Purdue from 1997 to 2009; tens of thousands of dollars from Purdue competitors Faulding, Cephalon, Endo, and Janssen; and over \$2 million from the Robert Wood Johnson Foundation ("Johnson Foundation"). Indeed, Purdue's original

18 any efforts to impose surveillance or limits on opioid prescribing that might – according to  
19 the PPSG – intimidate physicians into inadequate use of opioids. These efforts, along with  
20 other campaigns by opioid manufacturers, were successful; and states did change their opioid  
21 guidelines and regulations, protecting or even encouraging opioid prescribing.

22 17. In 1998, for example, the Federation of State Medical Boards ("FSMB") issued  
23 new "Model guidelines for the use of controlled substance for the treatment of pain,"  
24 developed with the help of the AAPM, the APS, and the PPSG, among others.<sup>6</sup> The FSMB,

25 <sup>5</sup> P-08386; P-23785; P-28698.

26 <sup>6</sup> Federation of State Medical Boards of the United States, Inc., Model Policy for the Use  
27 of Controlled Substances for the Treatment of Pain, at 1 (2004),  
28 [https://dprfiles.delaware.gov/medicalpractice/Model\\_Policy\\_Treatment\\_Pain.pdf](https://dprfiles.delaware.gov/medicalpractice/Model_Policy_Treatment_Pain.pdf).

DECLARATION OF DAVID HERZBERG, PH.D. - 3:18-cv-07591-CRB  
4876-7922-2817.v1

- 6 -

Declaration of David Herzberg, PhD p. 15:6-9

# PPSG Funding: Cephalon Total = \$25,000 (2001, 2004)

1	REGENTS NOTICES DEC 1999 - FEB 2008 5/27/2010								
2	All for 533415								
3									
4	Today's Date: 05/27/2010								
5	Fun	Acc	Award Da	Begin Da	End Dat	Amount	PI Name	Donor Description	Project Description
6	133	AW32	20000126			\$15,000.00	DIRECTOR	ROXANE LABORATORIES	PAIN COMMUNICATIONS
7	133	AW32	20000630	19960812		\$10,000.00	DIRECTOR	ANESTA CORPORATION	PAIN COMMUNICATIONS
8	133	AW32	20001117	19960812		\$5,000.00	DIRECTOR	FAULDING LAORATORIES	PAIN COMMUNICATIONS
9	133	AW32	20010108	19960812		\$10,000.00	DIRECTOR	CEPHALON, INC.	PAIN COMMUNICATIONS
10	133	AW32	20010215	19960812		\$10,000.00	DIRECTOR	BASF CORPORATION	PAIN COMMUNICATIONS
11	133	AW32	20010305	19960812		\$10,000.00	DIRECTOR	ENDO PHARMACEUTICALS, INC.	PAIN COMMUNICATIONS

1	REGENTS NOTICES DEC 1999 - FEB 2008 5/27/2010								
2	All for 533415								
3									
4	Today's Date: 05/27/2010								
5	Fun	Acc	Award Dat	Begin Dat	End Date	Amount	PI Name	Donor Description	Project Description
9	133	AW32	20010108	19960812		\$10,000.00	DIRECTOR	CEPHALON, INC.	PAIN COMMUNICATIONS
31	133	AW32	20040326	19960812		\$5,000.00	DIRECTOR	CEPHALON, INC.	PAIN COMMUNICATIONS
51	133	AW33	20040730	19960828		\$10,000.00	DIRECTOR	CEPHALON, INC.	PAIN POLICY STUDIES
72									

25	133	AW32	20030408	19960812		\$3,500.00	DIRECTOR	PURDUE PHARMS	PAIN COMMUNICATIONS
26	133	AW32	20030523	19960812		\$4,000.00	DIRECTOR	AMERSHAM HEALTH	PAIN COMMUNICATIONS
27	133	AW32	20031112	19960812		\$5,000.00	DIRECTOR	PURDUE PHARMA LP	PAIN COMMUNICATIONS
28	133	AW32	20040114	19960812		\$5,000.00	DIRECTOR	PURDUE PHARMA LP	PAIN COMMUNICATIONS
29	133	AW32	20040212	19960812		\$15,000.00	DIRECTOR	ENDO PHARMACEUTICALS INC.	PAIN COMMUNICATIONS
30	133	AW32	20040302	19960812		\$5,000.00	DIRECTOR	PURDUE PHARMA	PAIN COMMUNICATIONS
31	133	AW32	20040326	19960812		\$5,000.00	DIRECTOR	CEPHALON, INC.	PAIN COMMUNICATIONS
32	133	AW32	20040406	19960812		\$5,000.00	DIRECTOR	ASTRA ZENECA	PAIN COMMUNICATIONS
33	133	AW32	20040525	19960812		\$40,000.00	DIRECTOR	JOHNSON & JOHNSON SERVICES, INC.	PAIN COMMUNICATIONS

P-23785, PSG Funding

# PPSG Funding: Other Organizations

Today's Date: 05/27/2010

Fund	Acct	Award Date(yyyymmdd)	Begin Date(yyyymmdd)	End Date(yyyymmdd)
133	KH27	20071123	20080101	
133	AW32	20000126		
133	AW32	20000630	19960812	
133	AW32	20001117	19960812	
133	AW32	20001117	19960812	
133	AW32	20010108	19960812	
133	AW32	20010124	19960812	
133	AW32	20010215	19960812	
133	AW32	20010305	19960812	
133	AW32	20010420	19960812	
133	AW32	20010523	19960812	
133	AW32	20010702	19960812	
133	AW32	20010702	19960812	
133	AW32	20010622	19960812	
133	AW32	20011001	19960812	
133	AW32	20011001	19960812	
133	AW32	20010831	19960812	
133	AW32	20020129	19960812	
133	AW32	20020115	19960812	
133	AW32	20020415	19960812	
133	AW32	20020516	19960812	
133	AW32	20020531	19960812	
133	AW32	20021105	19960812	
133	AW32	20021105	19960812	
133	AW32	20021204	19960812	
133	AW32	20030108	19960812	
133	AW32	20030408	19960812	
133	AW32	20030523	19960812	
133	AW32	20030604	19960812	
133	AW32	20031112	19960812	
133	AW32	20040114	19960812	
133	AW32	20040212	19960812	
133	AW32	20040302	19960812	
133	AW32	20040326	19960812	
133	AW32	20040406	19960812	
133	AW32	20040525	19960812	
133	AW32	20041027	19960812	
133	AW32	20050106	19960812	
133	AW32	20051204	19960812	
133	AW32	20060126	19960812	
133	AW32	20070109	19960812	
133	AW32	20070306	19960812	
133	AW32	20070426	19960812	
133	AW32	19991101		
133	AW32	19991215		
133	AW33	20010214	19960828	
133	AW33	20010411	19960828	
133	AW33	20010517	19960828	
133	AW33	20011218	19960828	
133	AW33	20020624	19960828	
133	AW33	20020618	19960828	

pharma original (+)

1 Today's Date: 05/27/2010

Fund	Acct	Award Date(yyyymmdd)	Begin Date(yyyymmdd)	End Date(yyyymmdd)	Amount	PI Name	PI UDC	Agency	Donor Description	Project Description
88	133	CG93	19991203		10000	JORANSON, DAVID E	A533415		WORLD HEALTH ORGANIZATION	WHO GUIDELINES ASSESSMENT
94	133	FC47	20020701	20020701	5075	JORANSON, DAVID E	A533415	WHO	WORLD HEALTH ORGANIZATION	REPORT ON PALLIATIVE CARE AND LONG TERM CARE
95	133	FC47	20021212	20020701	5074	JORANSON, DAVID E	A533415	WHO	WORLD HEALTH ORGANIZATION	REPORT ON PALLIATIVE CARE AND LONG TERM CARE
106	133	HT92	20060223	20060201	20060331	18900	JORANSON, DAVID E	A533415	WHO	PROMOTION OF RATIONAL ACCESS TO AND USE OF PSYCHOACTIVE MEDICINES: ENHANCEMENT OF PPSG/WHOC INTERNATIONAL WEBSITE AND ADDITIONAL TRANSLATIONS OF WHO GUIDELINES-ACHIEVING BALANCE IN NATIONAL OPIOIDS CONTROL POLICY
107	133	HT93	20060223	20060201	20060331	29000	JORANSON, DAVID E	A533415	WHO	PROMOTION OF RATIONAL ACCESS TO AND USE OF PSYCHOACTIVE MEDICINES: SPECIAL ISSUE OF CANCER PAIN RELEASE ABOUT 20TH ANNIVERSARY OF WHO 3-STEP ANALGESIC LADDER
108	133	HU80	20060309	20060227	20060331	5100	JORANSON, DAVID E	A533415	WHO	PROMOTION OF RATIONAL ACCESS TO AND USE OF PSYCHOACTIVE MEDICINES: SPECIAL ISSUE OF CANCER PAIN RELEASE IN RUSSIAN ABOUT 20TH ANNIVERSARY OF WHO 3-STEP ANALGESIC LADDER

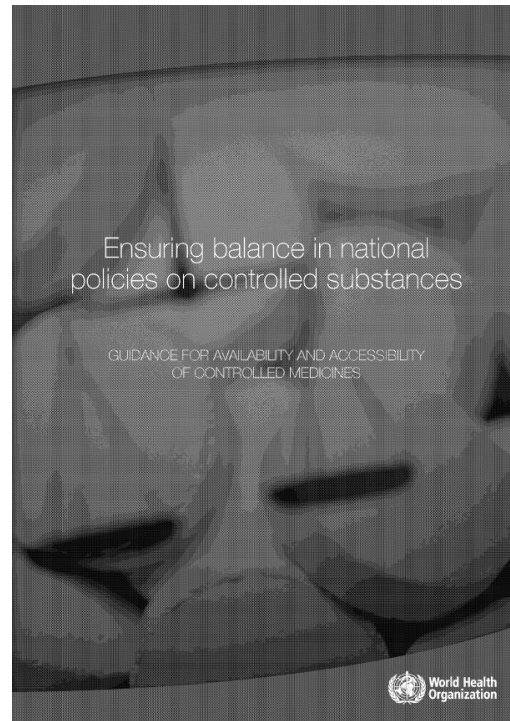
40000 DIRECTOR A533415 J & J PHARMA PAIN COMMUNICATIONS

71	133	HR20	20060109	20060115	20070114	99056	GILSON, AARON M	A533415	LANCE ARMSTRONG FOUNDATION	BENCHMARKING STATE POLICIES FOR CANCER PAIN AND PALLIATIVE CARE
72	133	HR20	20070101	20060115	20080114	82681	GILSON, AARON M	A533415	LANCE ARMSTRONG FOUNDATION	BENCHMARKING STATE POLICIES FOR CANCER PAIN AND PALLIATIVE CARE
73	133	HS33	20060110	20060101	20081231	300000	GILSON, AARON M	A533415	AMERICAN CANCER SOCIETY, INC	BENCHMARKING STATE POLICIES FOR CANCER PAIN AND PALLIATIVE CARE
74	133	JF53	20060818	20060101	20090331	296076	GILSON, AARON M	A533415	KOMEN (SUSAN G) BREAST CANCER FOUNDATION	BENCHMARKING STATE POLICIES FOR CANCER PAIN AND PALLIATIVE CARE

77	133	KK55	20061221	20060801	20090731	16112	GILSON, AARON M	A533415	UNIVERSITY OF CALIFORNIA - DAVIS	IMPACT OF DRUG CONTROL POLICY ON PAIN TREATMENT IN CALIFORNIA: ARE PHYSICIANS UNWILLING TO PRESCRIBE NEEDED MEDICATIONS?
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P-23785, PPSG Funding

# World Health Organization: Opioid Guidelines (2011)



DEF-MDL-12690.00001

FSMB\_001826

WHO - Public Domain, n.d. CC BY  
DEF-MDL-12690  
Submitted

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DEF-MDL-12690.00038

FSMB\_001863

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DEF-MDL-12690.00070

FSMB\_001895

These policy guidelines were produced by the World Health Organization, Department of Essential Medicines and Pharmaceutical Policies, Access to Controlled Medicines Team, as an update of the WHO guidelines *Achieving balance in national opioid control policy*. The original version was developed for WHO by the WHO Collaborating Centre for Policy and Communications in Cancer Care at the Pain and Policy Studies Group, University of Wisconsin, Madison WI, United States of America in 2000.<sup>o</sup>

When balancing drug control legislation and policies, it is wise to leave *medical decisions* up to those who are knowledgeable on medical issues. Therefore, the amount of medicine prescribed, the appropriate formulation and the duration of treatment should be the practitioner's decision, based on individual patient needs and on sound scientific medical guidance (e.g. national or WHO treatment guidelines). An example of how this rule may sometimes be violated is the legal restriction on the maximum daily dosage of strong opioids. Another example is the limitation of the use of strong opioids only to certain conditions such as cancer pain or terminal cancer pain, while other moderate to severe pain remains unaddressed.

#### Observer

Mr Pavel Pachta, Deputy Secretary of the Board and Chief, Narcotics Control and Estimates Section, Secretariat of the International Narcotics Control Board, United Nations Office on Drugs and Crime, Vienna, Austria

#### WHO Staff

Dr James Cleary, WHO Collaborating Centre for Pain and Palliative Care, Pain & Policy Studies Group, Paul P. Carlsone Comprehensive Cancer Center, University of Wisconsin, Madison WI, United States of America (Temporary Adviser)

<sup>o</sup> Currently, WHO Collaborating Centre for Pain and Palliative Care.

DEF-MDL-12690.00038, 00070

# Senate Finance Committee: Other Manufacturers (1997-2012)

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STEVE DAINES, MONTANA  
TODD YODanis, NEVADA  
BEN Sasse, NEBRASKA

United States Senate  
COMMITTEE ON FINANCE  
WASHINGTON, DC 20510-4020

To: Members of the Senate Finance Committee  
From: Senator Chuck Grassley, Chairman of the Senate Finance Committee  
Date: December 16, 2020  
Re: Findings from the Investigation of Opioid Manufacturers' Financial Relationships with Patient Advocacy Groups and other Tax-Exempt Entities

Dear Colleagues:

As the nation continues to respond to the COVID-19 pandemic, attention has been turned back to another concerning public health matter: opioid overdoses. Over the past several years, more than 450,000 lives in the United States have been lost to opioid overdoses. Preliminary data from the Centers for Disease Control and Prevention (CDC) indicates that opioid overdoses have increased significantly since the beginning of the year.<sup>1</sup> Indeed, COVID-19 has increased risk factors associated with substance use disorders (SUDs) and opioid-use disorders (OUDs) like feelings of anxiety, depression, loneliness, and an ongoing sense of uncertainty.<sup>2</sup> For individuals suffering from these diseases, COVID-19 has even presented additional barriers to treatment and social support services as people are urged to stay-at-home and social distance.<sup>3</sup> We are concerned that this will only worsen as our country continues to battle COVID-19 and as social isolation and lack of access to SUD and OUD treatment persists.

As the opioid epidemic and its impact on programs within the Finance Committee's jurisdiction shows no signs of abating, we write to provide you with an update on the

<sup>1</sup> Opioid Overdose, Data Analysis and Resources, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/drugoverdose/data/analysis.html> (last viewed Dec. 10, 2020).

<sup>2</sup> Alex Edelman, *Overdose deaths appear to rise amid coronavirus pandemic in U.S.*, NBC News (Oct. 20, 2020), <https://www.nbcnews.com/health/health-news/overdose-deaths-appear-rise-amid-coronavirus-pandemic-u-s-12444024>; Jon Kamp and Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL ST. J. (Sept. 8, 2020), <https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401>.

<sup>3</sup> Jon Kamp and Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL ST. J. (Sept. 8, 2020), <https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401>. See also DEP'T OF HEALTH AND HUMAN SERVS., OFF. OF INSPECTOR GEN., OPIOID TREATMENT PROGRAMS REPORTED CHALLENGES ENCOUNTERED DURING THE COVID-19 PANDEMIC AND ACTIONS TAKEN TO ADDRESS THEM (Nov. 2020), [https://oig.hhs.gov/oas/reports/region9/92001001.asp?utm\\_source=web&utm\\_medium=web&utm\\_campaign=covid-A-09-20-01001](https://oig.hhs.gov/oas/reports/region9/92001001.asp?utm_source=web&utm_medium=web&utm_campaign=covid-A-09-20-01001).

## Endo/Johnson & Johnson/Purdue Payments (1997-2004)

P-18565\_00020-21

## Endo/Johnson & Johnson/Purdue Payments (2005-2012)

P-18565\_00022-24



19

## Testimony from AAPM Representative

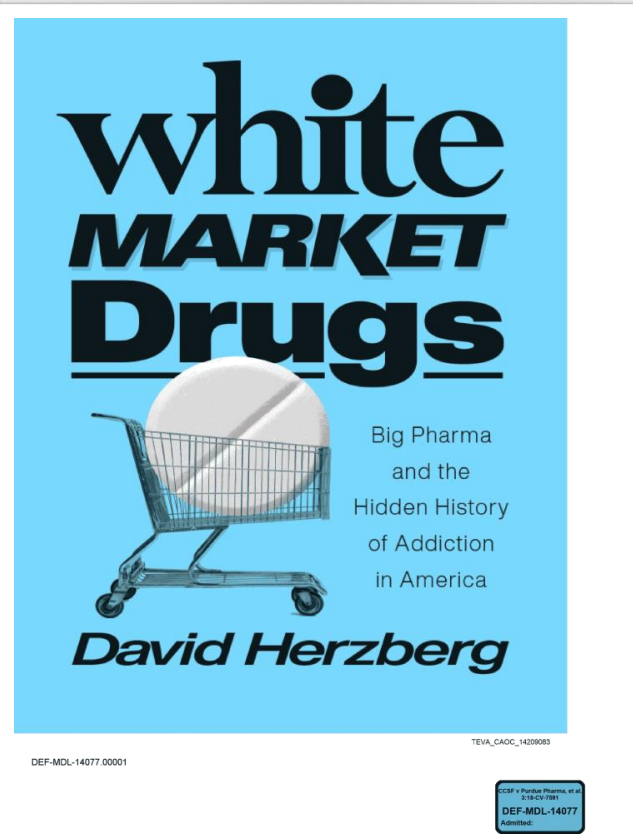


**Dr. Philip Saigh**  
Executive Director  
AAPM

Q. Has that -- and should I use -- Has that money ever influenced any publications that the AAPM has put out?

THE WITNESS: I can't describe what any individual would have thought when he or she wrote a publication and submitted it, for example, to our journal, how that person formed his or her opinions. But I can say to you that the academy has never published anything on behalf of the academy that was influenced by pharmaceutical company dollars or industry dollars, I should say.

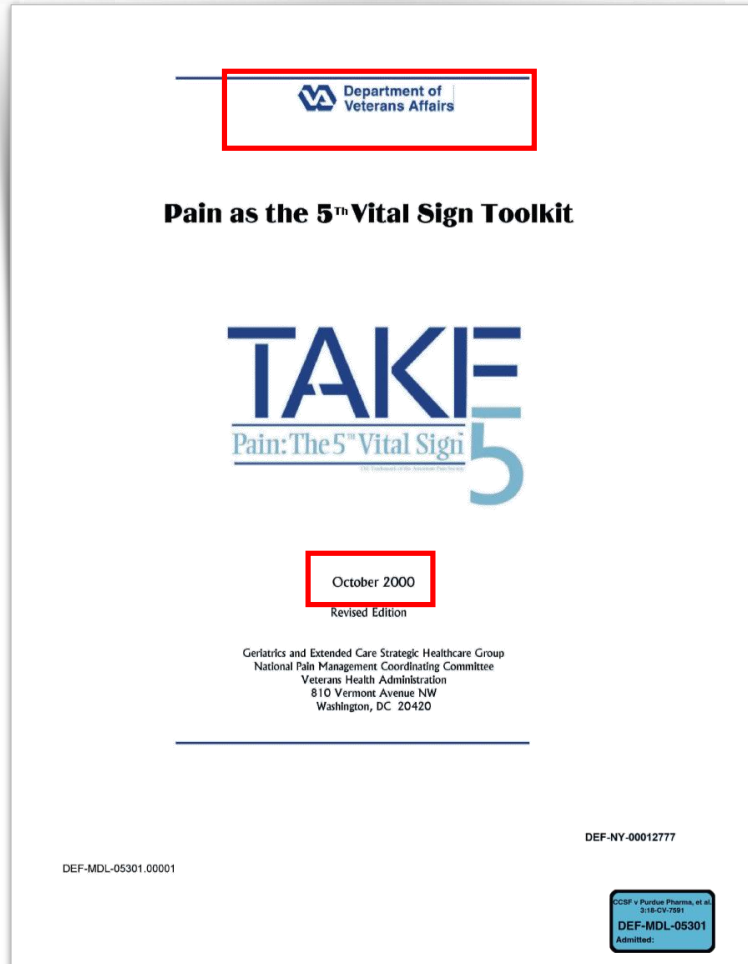
# Purdue's Exclusive Relationship With JCAHO



the Joint Commission on the Accreditation of Healthcare Organizations, collaborated with PPSG to produce hospital accreditation standards for pain and opioids—required, not recommended, practices.<sup>115</sup> Issued in 2001, the new standards described pain as the “Fifth Vital Sign,” required that all patients be asked to rate their pain on a numeric scale of 1 to 10, and required caregivers to reduce pain to the low end of the scale.<sup>116</sup> This was a bonanza for opioid manufacturers. **Purdue won an exclusive agreement to help the Commission develop materials to educate hospitals and the public about the new standards**—campaigns that, the company noted, provided its sales force with “many door-opening opportunities.”<sup>117</sup> Internal Purdue documents described the “Fifth Vital Sign” campaign as “an important promotional initiative.”<sup>118</sup>

David Herzberg, “White Market Drugs” (2020)  
DEF-MDL-14077

# VA: Pain as the 5th Vital Sign (2000)



October 2000

DEF-MDL-05301

# Federation of State Medical Boards (FSMB)

## Letter to Senate Finance Committee



June 8, 2012

The Honorable Max Baucus  
United States Senate  
511 Hart Senate Office Building  
Washington, DC 20510

Dear Senator Baucus and Grassley:

The Federation of State Medical Boards (FSMB) is pleased to re-agree with the Senate Finance Committee that the abuse and misuse of opioids remain a national public health crisis. We are committed to raising awareness of the problem among physicians, ensuring that patients receive the care they need, and ensuring that the medical community is equipped to manage the crisis. In this regard, we respectfully urge you to review the *Opioid Prescribing* publication, described within this letter.

The FSMB is actively addressing the important issues surrounding opioid abuse through a variety of federal agencies and leading health care organizations (AMA), for example, has adopted formal policy specific to opioids and seeks to improve them, based on the Federation of State Medical Boards' guidance.

Dr. Korlikowski, Director of the Office of National Drug Control Policy, stated at the 2012 FSMB Annual Conference: "There is a real gap in the way we manage pain, addiction, tolerance and dependence. It could not be more planned, frankly, and I could not be more proud if we just given the latest edition of the *Clinician's Guide for Responsible Opioid Prescribing*. This is just a wonderful, wonderful step in the right direction. It is written in the hands of every busy professional that need that information."

### Background

The problem of prescription drug abuse and related deaths has tripled between 1999 and 2008, and nearly half a million emergency room visits are caused by prescription drug misuse or abuse.

At the same time, the nation faces a serious and related problem: millions of people who suffer from chronic pain are often under-treated in the United States, creating a public health crisis.

NATIONAL OFFICE  
400 TULSA WISER ROAD | SUITE 100 | DALLAS, TX 75219  
(817) 868-4000 | FAX (817) 868-4091 | WWW.FSMB.ORG

ADVOCACY  
1110 VANDERBILT  
(202) 331-0000

The guidelines represent an extensive effort at achieving consensus on these important topics. They were formulated with input from a diverse group of major stakeholders, ranging from pain and addiction specialists and medical societies to federal law enforcement agencies, many of whom participated in an invitational symposium hosted in March 1998, where they were able to provide formal testimony.

Before the model guidelines were finalized and formally adopted as Federation policy at the FSMB House of Delegates meeting in May 1998, a copy of the draft guidelines were distributed to more than 300 individuals, representing state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, state and federal regulatory agencies, and representatives from pharmacy and nursing regulatory boards for additional review and comment. The result was a set of guidelines that represented consensus from key national stakeholders.

Since their adoption, the *Model Guidelines* have been extensively distributed to state medical boards, medical professional organizations, other health care regulatory boards, and patient advocacy groups, as well as state and federal regulatory, law enforcement and other agencies, including the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) and U.S. Drug Enforcement Administration (DEA). They have been endorsed or supported by a variety of organizations, including the American Medical Association (AMA) and the National Association of State Controlled Substances Agencies (NASCSA).

Confidential

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P-18027\_00004

# Federation of State Medical Boards (FSMB)

## Letter to Senate Finance Committee



June 8, 2012

The Honorable Max Baucus  
United States Senate  
511 Hart Senate Office Building  
Washington, DC 20510

Dear Senator Baucus and Grassley:

The Federation of State Medical Boards (FSMB) is pleased to re-agree with the Senate Finance Committee that the abuse and misuse of opioids remain a national public health crisis. The FSMB remains committed to raising awareness of the problem among physicians and the public, while ensuring the safe and effective use of opioids for needed treatments. In this regard, we respectfully urge you to review the FSMB's *Responsible Opioid Prescribing* publication, described within this letter.

The FSMB is actively addressing the important issues surrounding opioids on multiple levels. These efforts include collaborations with a variety of federal agencies and leading health care organizations. The American Medical Association (AMA), for example, has adopted formal policy specifying that "...states should examine their pain policies and seek to improve them, based on the Federation of State Medical Boards Model Policy."<sup>1</sup>

Gil Korlikowski, Director of the Office of National Drug Control Policy, stated at the 2012 FSMB Annual Conference: "There is a real gap in the information around pain management, addiction, treatment, tolerance and dependence. It could not be more planned, frankly, and I could not be more proud of what we have just given the latest edition of the *Clinician's Guide for Responsible Opioid Prescribing*. This is just a wonderful, wonderful step in the right direction, written in the hands of every busy professional that need that information."

### Background

The problem of prescription drug abuse and related deaths has tripled between 1999 and 2008, and nearly half a million emergency room visits are caused by abusing prescription painkillers.<sup>2</sup>

At the same time, the nation faces a serious and related problem: Millions of people suffer from chronic pain, which can be relieved through the use of opioids. Chronic pain is often under-treated in the United States, creating a productivity and quality of life.

NATIONAL OFFICE  
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1115 VERMONT AVE., NW | SUITE 1000 | WASHINGTON, DC 20005  
(202)330-4972 | FAX (202)330-4000

Confidential

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P-18027\_00002

The first edition of *Responsible Opioid Prescribing* was one of the first books to not only highlight the heightened risks of opioids, but to call upon physicians to measure the efficacy and safety of opioid therapy against tangible and measurable functional outcomes in addition to the subjective feedback of their patients.

P-18027\_00010

The FSMB firmly stands behind the integrity of the book, the development of which was overseen by an advisory board of respected medical and policy experts and which presents an unbiased and impartial view of opioid prescribing. All revenue generated from the sale of the FSMB's *Responsible Opioid* guides was dedicated to support the development and distribution of these materials. Funding contributors had no input or influence on its content.

P-18027\_00010

It is important to note that contributions and support for the book have come from non-industry sources, such as the Lance Armstrong Foundation and the Mayday Fund, and that a wide variety of not-for-profit organizations have supported the book's distribution through their independent purchases of it. Examples include SAMHSA, the American Academy of Family Physicians, Kaiser Permanente, the American Cancer Society, the New Jersey Academy of Family Physicians, the Pennsylvania Medical Society, Vanderbilt University Center for Professional Health and the U.S. Department of Veterans Affairs.

P-18027\_00010-11

# Substance Abuse and Mental Health Services Administration

The screenshot shows the SAMHSA website. At the top, it says 'U.S. Department of Health & Human Services' with the SAMHSA logo. Navigation links include Home, Site Map, and Contact Us. A search bar is present. A dark blue menu bar contains links: Find Treatment, Practitioner Training, Public Messages, Grants, Data, Programs, Newsroom, About Us (highlighted), and Publications. Below the menu, a breadcrumb trail shows 'Home » About Us'. The 'About Us' section title is underlined. The main text describes SAMHSA's mission. To the right, a 'Contact SAMHSA' box provides location information and a link to 'Contact Us'. At the bottom, a footer contains three columns of links: 'Offices & Centers' and 'Laws & Regulations' in the first column; 'National Advisory Council' and 'Center for Substance Abuse Prevention National Advisory Council' in the second; and 'EEO / No Fear Act of 2002' and 'Information Quality Act' in the third.

U.S. Department of Health & Human Services

**SAMHSA**  
Substance Abuse and Mental Health  
Services Administration

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Find Treatment Practitioner Training Public Messages Grants Data Programs Newsroom **About Us** Publications

[Home](#) » About Us

**About Us**

The Substance Abuse and Mental Health Services Administration (SAMHSA) is the agency within the U.S. Department of Health and Human Services that leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities.

**Contact SAMHSA**

SAMHSA headquarters is located in Rockville, MD. [Visit "Contact Us"](#) to connect with SAMHSA and find answers to your questions.

» [Offices & Centers](#)  
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[National Advisory Council](#)  
» [Center for Substance Abuse Prevention National Advisory Council](#)

» [EEO / No Fear Act of 2002](#)  
» [Information Quality Act](#)

The Substance Abuse and Mental Health Services Administration (SAMHSA) is the agency within the U.S. Department of Health and Human Services that leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities.