

BATES NO:

FSMB00000017

PLAINTIFFS TRIAL
EXHIBIT
P-18027_00001



June 8, 2012

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

The Honorable Charles Grassley
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

Dear Senators Baucus and Grassley:

The Federation of State Medical Boards (FSMB) is pleased to respond to your letter of May 8, 2012. The FSMB agrees with the Senate Finance Committee that the abuse and misuse of opioids is a serious national problem. We remain committed to raising awareness of the problem among physicians and the public and working to reduce the risk of addiction, abuse and diversion of opioids, while ensuring that patients who suffer from pain have access to needed treatments. In this regard, we respectfully urge you to review the FSMB's Model Policies and *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..."¹

Gil Kerlikowske, Director of the Office of National Drug Control Policy (ONDCP), said during a recent speech at the 2012 FSMB Annual Conference: "There is a real gap in the amount of education and training that is provided around pain management, addiction, treatment, tolerance and dependence. We know that's an important issue. I could not be more pleased, frankly, and I could not be more proud of the work that you all have done in this area...I was just given the latest edition of the *Clinician's Guide for Responsible Opioid Prescribing* by Dr. Fishman...The second edition of this is just a wonderful, wonderful step in the right direction of putting something that is so well written in the hands of very busy professionals that need that information."²

Background

The problem of prescription drug abuse and related deaths has grown at an alarming pace in the United States. According to the Centers for Disease Control and Prevention (CDC), deaths from prescription painkillers more than tripled between 1999 and 2008, and nearly half a million emergency department visits in 2009 were due to people misusing or abusing prescription painkillers.³

At the same time, the nation faces a serious and related problem: Millions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids.⁴ Studies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life.

NATIONAL OFFICE

400 FULLER WISER ROAD | SUITE 300 | EULESS, TX 76039
(817)868-4000 | FAX (817)868-4098 | WWW.FSMB.ORG

ADVOCACY OFFICE

1110 VERMONT AVE, NW | SUITE 1000 | WASHINGTON, DC 20005
(202)530-4872 | FAX (202)530-4800

Physicians must constantly weigh these dual realities as they consider treatment options for their patients in pain. Similarly, the nation's state boards of medicine must also weigh the risks and advantages of opioid prescribing as they establish the rules and regulations under which medicine is practiced in their jurisdictions – balancing the pressing need for patient safety with the equally important need to ensure that patients have access to treatment.

This dual responsibility – ensuring public safety and access to appropriate medical treatment – is the fundamental mission and purpose of the nation's system of state medical boards. Each of the 50 states, the District of Columbia and the U.S. territories has a medical practice act that delegates to a state medical board the authority to protect the public from the unprofessional, improper, incompetent, unlawful, or fraudulent practice of medicine. With this authority, boards typically establish parameters for the safe practice of medicine, including the prescribing of medicines such as opioid analgesics.

About the Federation of State Medical Boards

Established in 1912, the Federation of State Medical Boards is the national non-profit organization that represents the 70 medical and osteopathic boards of the United States and its territories. The FSMB promotes excellence in medical practice, licensure, and regulation as the national resource and voice on behalf of the boards as they protect the public and ensure access to medical treatment. To assist its efforts, the FSMB launched the Federation of State Medical Boards Research and Education Foundation (FSMB Foundation) in 1980. The FSMB Foundation is a supporting non-profit organization to the FSMB that expands knowledge and awareness of issues of importance to state medical boards, the public and the medical profession.

The FSMB enhances the role of state medical boards in a dynamic health care environment by leading, anticipating and responding to trends in medical regulation; serving as an informational and educational resource for the boards; and assisting the boards in developing and using consistent standards, language, definitions, and tools to regulate the practice of medicine.

The FSMB helps state medical boards adapt and respond as medicine evolves and various new issues emerge that impact the public. In the constantly changing environment of medical practice, the FSMB plays a key role as a thought leader and shaper of policy. In recent years, its work has helped the medical community respond to emerging issues such as outpatient surgery, use of the Internet in medical practice, maintenance of licensure, re-entry to practice, and physician impairment. In addition, the FSMB has been the recipient of multiple license-portability grants, authorized under the Public Health Service Act, and coordinated with the U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA), to develop and expand multi-state cooperation between licensing boards and to create and implement state policies that will also help facilitate telemedicine, and improve access to care.

FSMB Activities Related to Treatment of Pain and the Misuse, Abuse and Diversion of Opioids

Until the mid 1990s, physicians and state medical boards struggled with a lack of consistent policies related to the treatment of pain, which contributed to the dual public health issues of the under-treatment of pain and the improper use of controlled substances in addressing pain. Increased public demand for improvement in the medical management of pain and advances in medical knowledge regarding the use of controlled substances (including opioids), combined with a lack of physician awareness of the laws and regulations governing the prescribing of these substances, led the FSMB to launch a series of initiatives. The FSMB's goal was to provide a policy framework that would bring consistency to differing regulatory processes and to encourage states to clarify their guidelines and laws addressing pain management and appropriate and responsible prescribing.

Since its first major initiative related to pain and opioid prescribing in 1997, the FSMB and its state medical board partners have sought to balance efforts to ensure patient access to appropriate pain care with efforts to reduce the

potential for prescription drug misuse, abuse and diversion. These multi-pronged efforts have included policy-making, educational outreach, and collaboration with key federal and state agencies, physician organizations, foundations, academia, and many other stakeholder groups.

Throughout its work on these issues, the FSMB has sought to raise awareness with physicians and the public of the risks that opioids pose – in addition to their benefits for patients in need – while striving to bolster safeguards for their appropriate use. The FSMB’s policies and educational materials do not advocate for opioid therapy by physicians; rather, they offer a framework to ensure that physicians who choose to prescribe opioids do so responsibly and safely, and remain in compliance with legal regulations regarding their use.

The FSMB has worked vigorously with the physician community to raise awareness of these issues and has worked closely with state and federal policy-making and law enforcement agencies to develop strategies aimed at addressing the misuse, abuse and diversion of all controlled substances.

Model Guidelines for the Use of Controlled Substances for the Treatment of Pain

The FSMB’s efforts began in 1997 with the development of its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Developed with a grant from the Robert Wood Johnson Foundation, the guidelines were created to address the dual issues of under-treated pain and improper prescribing of controlled substances, providing physicians with best practices to ensure safe and responsible prescribing and public access to appropriate and effective pain relief.

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.

The *Model Guidelines* stressed that all physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances. They stipulated that all prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state and federal law. The *Model Guidelines* set forth state medical boards’ expectations for physicians to incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances, including thorough examinations; the use of written treatment plans and maintenance of accurate records; the critical importance of discussing both risks and benefits of controlled substances with patients; and the need for periodic review of treatment goals.⁵

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).

In 2004, the *Model Guidelines* were revised and updated at the direction of the FSMB's 70 state member boards, with language intended to ensure they were consistent with emerging medical insights regarding pain management and the use of controlled substances. They were also renamed the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* to better reflect the practical use of the document.⁶

The FSMB subsequently hosted a series of regional educational workshops titled "Promoting Balance and Consistency in the Regulatory Oversight of Pain Care," for members and staff of state medical and pharmacy boards. The objectives of the workshops were to create a regulatory environment that supports accessible and appropriate pain care; to define controlled substances abuse and diversion and the appropriate regulatory responses to these issues; to distinguish between criminality and negligence and acceptable medical practices; and to define key terms and concepts related to pain and addiction. The workshops were accredited by the University of Texas Southwestern Health Science Center.

In March 2012, the FSMB, in collaboration with SAMHSA's Center for Substance Abuse Treatment (CSAT), brought together experts in pain management, addiction medicine, law enforcement, pharmacology, psychiatry, public health, medical regulation and other disciplines to once again review and update the *Model Policy*. The review process will be completed this year, with the goal of an updated and revised policy in 2013.

National Clearinghouse on Internet Prescribing

The FSMB has been a leader in addressing the problem of illegal prescribing through "rogue" Internet pharmacy sites, which operate without appropriate licensing and allow anonymous physicians to prescribe medications based only upon online questionnaires completed by patients never seen by the physician. In 2000, the FSMB launched an initiative creating a clearinghouse for the collection and dissemination of information to state and federal regulatory authorities on the operation of rogue Internet pharmacy sites – leveraging its formal relationship with all state medical boards in the United States and its well established lines of communication with state and federal agencies and the national pharmacist community.

This program gathered valuable information about illegal online activities for state and federal regulatory authorities, identifying more than 1,000 questionable Web sites as a part of its activities. The program received an Award of Excellence from the American Society of Association Executives for its results benefiting the American public. It supplied or assisted with information about 122 illegal prescribing cases on the federal level and 178 cases on the state level. The Clearinghouse was cited in multiple pieces of federal legislation, including: *H.R. 1298/S. 525, Pharmaceutical Market Access and Drug Safety Act of 2009* (March 4, 2009); *S. 3415, Fair Pricing For Prescription Drugs Act* (May 25, 2010); and *S. 319, Pharmaceutical Market Access and Drug Safety Act of 2011* (February 10, 2011). Among their provisions, these federal legislative initiatives called for the Department of Health and Human Services to partner with the FSMB Clearinghouse. Additionally, the FSMB supported a number of federal legislative proposals to address the problem of rogue internet pharmacies by writing endorsement letters and providing testimony at hearings.

Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office

In 2002, the FSMB House of Delegates adopted the *Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office*. These guidelines were intended to directly address the issue of opioid addiction, one of the key components of the FSMB's work related to opioid prescribing.

Developed with substantial funding from SAMHSA, the guidelines encourage state medical boards to adopt consistent standards, promote public health by helping direct opioid-addicted patients to appropriate treatment, and educate physicians and others on new modalities in the treatment of addiction. Following their adoption in 2002, the

FSMB and SAMHSA hosted a series of regional educational programs to help build awareness and visibility of the need for new policies to address opioid addiction treatment.

Responsible Opioid Prescribing: A Physician's Guide

Among the FSMB's educational initiatives has been the development and distribution of a guidebook intended to help physicians recognize the risks of opioids and follow responsible and safe prescribing standards. The first edition of *Responsible Opioid Prescribing: A Physician's Guide* was released in 2007, and later accredited by the University of Wisconsin School Of Medicine and Public Health and designated for 7.25 AMA PRA Category 1 Credits™. Written by one of the nation's leading experts in pain medicine, Scott M. Fishman, MD, the book offers practical steps for reducing the risk of addiction, abuse and diversion of opioids, and for achieving improved patient outcomes. The book was developed with the assistance of an advisory board, which included a diverse range of physicians, academicians and health-policy experts who reviewed its content.

From its release in 2007 through January 2012, the book has been distributed in each of the 50 states and the District of Columbia. The book has been widely acknowledged and supported in the medical community as an important educational resource for physicians, and has been used extensively by state regulators and others to address the need for safer, more responsible and better-informed opioid prescribing.

The North Carolina Medical Board, for example, has sent a copy of the book to any physician who demonstrated deficits in knowledge of prescribing issues. It has also provided the book at educational seminars given to local physicians, emergency department personnel and county social service workers. The State of Michigan Bureau of Health Professions has made the book available annually, and has distributed more than 40,000 copies to physicians, physician assistants and other prescribers.

In Maine, every practicing physician in the state received a copy. Similarly, in Washington, more than 14,000 copies were distributed to the state's licensed physicians and physician assistants. Virginia distributed 20,000 copies of the book to all of its licensees. In Iowa, physicians seeking renewal of a medical license must complete two hours of accredited training on chronic pain management; the Iowa Board of Medicine provides free copies of the book to help physicians fulfill this requirement. In 2011, the FSMB sent 1,500 copies to the Iowa Board of Medicine, which offered the book free of charge to physicians. Montana received 1,800 copies of the book in 2008 for distribution to all licensed physicians in the state. More than 9,000 copies of the book were sent to Florida for distribution to licensed physicians, and more than 5,000 copies were distributed in West Virginia.

In a letter describing the Virginia Board of Medicine's use of the book to raise awareness of opioid prescribing issues, its executive director stated: "I write on behalf of the Virginia Board of Medicine in support of the Federation's efforts to educate the nation's physicians on the safe prescribing of opioids...From a regulatory board standpoint, education of physicians and other prescribers is first and foremost. Knowing the drugs one is writing, their hazards, and the red flags for abuse, addiction and diversion are critical. The more a prescriber knows, the safer his/her patients will be, and so will the public."⁷

In 2010, Maine Attorney General Janet Mills described the book as "...recommended reading for all primary care doctors and pain specialists." Attorney General Mills also noted: "As a non-physician reading that book, what I found most cogent was the emphasis on measuring progress through documented improvements in life *functions*, if and when prescription opioids are required for treatment of a serious and chronic condition. Documentation of concrete progress in specific areas such as work, sleep and social interaction will improve the patient's life, minimize the risk of addiction and keep your practice within the professional standard of care."⁸

As cited above, Gil Kerlikowske, Director of the ONDCP, has also praised the second edition of the book and the FSMB's efforts to promote responsible opioid prescribing.⁹

In April 2012, recognizing the continuing growth of the nation's prescription drug abuse epidemic, an updated version of the book, now titled *Responsible Opioid Prescribing: A Clinician's Guide*, was published, with new statistics and data on opioid addiction that were not available in 2007. The new edition, funded in part by SAMHSA, is accredited by the University of Nebraska Medical Center and again offers 7.25 AMA PRA Category 1 Credits™. Copies of the first edition are no longer being distributed; its CME activity expired in March 2012.

The expanded 2012 edition of the book is closely aligned with two important federal initiatives: the U.S. Food and Drug Administration (FDA) proposed Risk Evaluation and Mitigation Strategies (REMS) for Long-Acting/Extended-Release Opioid Class-Wide content guidelines for prescriber education¹⁰ and the ONDCP's action plan to address the national prescription drug abuse epidemic, adopted in 2011.¹¹ Among its recommended strategies, the ONDCP's action-plan calls for a collaborative effort with state medical boards to raise awareness of the safe and appropriate use of opioids to treat pain, while minimizing the risk of addiction and substance abuse, as a part of continuing medical education and instruction in health professional schools. Recommendations in the book are designed to address the key elements of these federal initiatives, including support of prescription drug monitoring programs (PDMPs), more effective disposal methods of unused medications, improved education for healthcare providers and patients, and reducing the prevalence of "pill mills" and doctor shopping through enforcement efforts.

Responsible Opioid Prescribing: A Clinician's Guide reminds physicians that they have vitally important duties when prescribing: to become well versed in the latest guidance on how to evaluate and select patients for whom opioids are appropriate, and to monitor carefully their treatment. It provides a renewed warning to physicians that opioids are potentially dangerous, that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society, and that such medications must be used with great caution. The book is a key supporting resource for the educational efforts of state medical boards as they seek to raise awareness of the risks associated with prescribing opioids.

The Online Prescriber Education Network (OPEN)

In 2006, the FSMB became one of 24 recipients of the Attorney General Consumer and Prescriber Education Grant Program, designed to provide physicians with tools for accessing unbiased sources of information about drugs and to help them recognize improper pharmaceutical industry marketing practices.

As a part of the FSMB's overall efforts to ensure the highest standards of prescribing behavior, the FSMB developed and implemented an internet-based portal, the Online Prescriber Education Network (OPEN). OPEN provides accredited CME courses developed by universities and other educational institutions. Among the nearly 50 CME courses available at the site are modules on clinical practice guidelines for drug therapy, evidence-based medicine, and pharmacologic management of acute pain, as well as modules designed to help physicians recognize improper pharmaceutical marketing practices.

In addition, the portal provides access to relevant state and federal statutes, unbiased databases of information about the safety and efficacy of prescription medicines, and tools and strategies for evidence-based prescribing.

Since its inception in 2006, OPEN has provided guidance to physicians on how to be safer, more responsible prescribers, and how to recognize improper marketing of drugs by pharmaceutical companies. Since 2008, the OPEN modules have been accessed by approximately 10,745 learners with 5,260 completing one or more activity for CME credit.

Policy Brief on Balance, Uniformity and Fairness in Law Enforcement

The FSMB co-produced a policy brief with the Center for Practical Bioethics and the National Association of Attorneys General (NAAG) in 2009, aimed specifically at the issue of prescription drug diversion, titled: "Balance, Uniformity and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice."¹²

The brief summarized discussions of the Balanced Pain Policy Initiative Law Enforcement Roundtable, made up of leaders from the law enforcement and health care communities focused on ensuring that patients who need pain medications have access while preventing these drugs from becoming a source of harm and abuse.¹³ The FSMB played a key role as one of the convening organizations, with the goal of helping foster stronger working partnerships between law enforcement and health care on these issues. Among the participants were: Mark Caverly, Chief, Liaison & Policy Section, U.S. Drug Enforcement Administration; Myra Christopher, President and CEO, Center for Practical Bioethics; Adam Clark, PhD, Director of Health Policy, Lance Armstrong Foundation; Drew Edmonson, Attorney General, State of Oklahoma; Cathy Gallagher, Associate Section Chief, Liaison & Policy Section, U.S. Drug Enforcement Administration; Richard Roper, U.S. Attorney, Northern District of Texas; William Sorrell, Attorney General, State of Vermont; Charles Cichon, Executive Director, National Association of Drug Diversion Investigators; Craig Watkins, District Attorney, Dallas County, Texas; and others.

Roundtable participants agreed on six strategies intended to seek balance as law enforcement agencies focus on sources of illegal drug diversion – to ensure that these efforts do not negatively impact appropriate medical practice and patient care. The strategies, ranging from distinguishing between criminal behavior and medical negligence to promoting the use of PDMPs, were publicly distributed in February 2009.

Roundtable participants agreed that the FSMB's *Model Policy for the Use of Controlled Substances for the Treatment of Pain* forms a strong foundation for educating health-care providers about issues related to opioid diversion and that "state boards in all states should learn, study, adopt and promote this Model Policy."¹⁴ Moreover, the brief declared: "the short primer on record keeping and other aspects of pain medicine in Scott Fishman's book, *Responsible Opioid Prescribing: A Physician's Guide*, is another excellent resource for doctors."¹⁵

National Collaboration to Better Utilize Health Information Technology Related to Prescribing

In 2012, the FSMB announced a collaborative effort with the Office of the National Coordinator for Health Information Technology, ONDCP, SAMHSA, major pharmacy chains and other stakeholder organizations to promote the use of health information technology to reduce prescription drug abuse. Under this project, the FSMB will work with partner organizations to improve access to database information on prescribers and dispensers of controlled substances found in PDMPs. The project will put an emphasis on increasing timely access to PDMP data at the point of care, at the point of dispensing, and in hospital emergency departments.¹⁶

Initiatives with Federal Agencies and Other Organizations

An integral component of the FSMB's efforts related to opioid prescribing and the under-treatment of pain is its collaboration with various government agencies and other stakeholder organizations. Among the organizations the FSMB has worked with are SAMHSA's Center for Substance Abuse Treatment, the Drug Enforcement Administration (DEA), the FDA, ONDCP, and the National Institute on Drug Abuse – all of whom are helping the FSMB update and revise its *Model Policy for the Use of Controlled Substances for the Treatment of Pain*.

FSMB leaders continue to meet with their counterparts in federal agencies to assist with the development of national policy, including the ONDCP's new prescription drug abuse plan. Among the FSMB's recent outreach activities:

- In December 2010, FSMB leaders met with Dr. Janet Woodcock, Director, and Douglas Throckmorton, Deputy Director of the FDA's Center for Drug Evaluation and Research (CDER) to discuss REMS, CME, and the FSMB's efforts on behalf of responsible opioid prescribing as they relate to state medical and osteopathic boards.
- In March 2011, the FSMB representatives were invited by U.S. Surgeon General Regina Benjamin, MD, MBA, to participate in the Summit on Prescription Drug Abuse in Youth. Following the conference, the FSMB submitted comments to the U.S. Surgeon General's Office, which sought additional input on ways to reduce prescription drug abuse in the nation's youth population.
- In June 2011, the FSMB participated in the White House Summit on Health Information Technology and Prescription Drug Abuse. The roundtable, hosted by the Office of the Vice President of the United States, ONDCP, Office of the National Coordinator for Health Information Technology, and the Office of Science and Technology Policy, engaged approximately two dozen leaders across the public safety, healthcare, and technology sectors to address a variety of topics, ranging from use of PDMP data at the point of care to facilitate appropriate prescribing to leveraging PDMP data in emergency rooms through health information exchanges. The FSMB is currently serving on the Office of the National Coordinator for Health Information Technology's Law and Policy Work Group for the Enhancing Access to Prescription Drug Monitoring Programs (PDMPs) Project.
- In July 2011, the FSMB CEO met with Thomas Frieden, MD, MPH, Director, Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR), in Atlanta, GA. Among items for discussion were opportunities for the CDC and the FSMB to collaborate on opioid prescribing education. Following the meeting with Dr. Frieden, the FSMB's CEO met with other CDC senior leaders to continue the discussion, exploring ways in which the CDC and FSMB can collaborate to address prescription drug abuse, including opportunities available with the promotion of provider and patient education, PDMPs, and identifying state disciplinary trends for opioid prescribing.
- Also in July 2011, the FSMB's senior staff attended a meeting of the FDA Industry Working Group (IWG), which includes the branded and generic manufacturers charged by the FDA to develop REMS for long acting and extended release opioids. As a key component of the REMS, the IWG is required to develop an educational program for prescribers and patients and provide the educational materials either directly or through accredited continuing medical education (CME) providers. In November 2011, the IWG submitted a REMS draft blueprint for prescriber education, to which the FDA requested stakeholder input. The FSMB submitted comments in support of the REMS blueprint.
- In November 2011, FSMB leaders met with ONDCP Director Gil Kerlikowske at the 2011 American Medical Association (AMA) Interim Meeting in New Orleans, LA. ONDCP requested the meeting in order to identify ways in which state medical and osteopathic boards can serve as an education resource to the physician community regarding responsible opioid prescribing. In addition, ONDCP sought to explore mechanisms whereby state boards can be of assistance in monitoring prescribing patterns to identify fraudulent providers and patients who are 'doctor shopping.'
- In March 2012, FSMB senior staff served as faculty for a DEA training program, Pharmaceutical Investigations and Prosecution Seminar, in Philadelphia, PA.
- In 2011-2012, the FSMB continued to participate in SAMHSA's Center for Substance Abuse Treatment Open Dialogue Meetings, a forum to discuss the non-therapeutic use of prescription medications, and

strategies to reduce their misuse. Among the participants are experts from the medical community, federal agencies, consumer organizations, and the pharmaceutical industry.

- The FSMB continued to serve as a member of the FDA Opioid Patient Prescriber Pain Treatment Agreement Working Group, assisting with the development of model provider patient agreements for long-term opioid therapy as well as other prescriber resources.
- The FSMB is a sponsor of the DEA's National Prescription Drug Take-Back Day program, promoting the safe disposal of pain medications among state medical and osteopathic boards.

Throughout the last year, the FSMB also maintained an ongoing dialogue and partnership activities regarding prescription drug abuse with a wide variety of other stakeholders, including the National Council of State Boards of Nursing (NCSBN), the National Association of Boards of Pharmacy (NABP), the National Association of State Controlled Substances Agencies (NASCA), the National Council on Patient Information and Education (NCPPIE), the Alliance of States with Prescription Drug Monitoring (ASPDM), and the American Pain Society (APS).

Additional Information Regarding the *Responsible Opioid Prescribing* book and the FSMB's Model Policies

As noted earlier, the book *Responsible Opioid Prescribing* educates physicians about FSMB policy on the use of controlled substances for the treatment of pain, seeking to reduce the risk of diversion and abuse of prescription opioids while balancing the need for patient access to these medications. The book distills the principles of FSMB's *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, which were adopted by the FSMB in 2004. The guidelines offer a balanced approach to opioid prescribing, acknowledging the legitimate medical uses of controlled substances for patients in need, while stressing the critical responsibility that physicians have in safeguarding against abuse and diversion.

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.

The book's title emphasizes the need for prescribers to act responsibly – to educate themselves about the risks of opioids, to focus on their patients' behaviors and risk factors, and to monitor carefully and document the success or failure of treatment to achieve functional outcomes.

The book was recently revised, with a new title (*Responsible Opioid Prescribing: A Clinician's Guide*) and new information about the risks associated with opioids as well as safety and risk management. The new information and additional sections support the original – and still-central – theme of the book, which continues to be that the use of opioids must be grounded in solid risk-management and caution by prescribers.

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.

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.

The Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (1998), the Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office (2002), the Model Policy for the Use of Controlled Substances for the Treatment of Pain (2004), and the two editions of Responsible Opioid Prescribing provide guidance for physicians to ensure that a balance is struck between the dual realities of opioid misuse, abuse and diversion and the legitimate medical needs of millions of Americans who suffer from pain. The FSMB believes the appropriate role for the regulatory community is to ensure that, in seeking this balance, physicians are apprised of their responsibility to manage the inherent risks of opioids and to remain in full compliance with laws and regulations governing their use, should they choose to prescribe them. While there can be divergent views within the medical community on the best way forward in this area of medical practice, as in others, we believe the guidelines, policies, and books we have developed, with consensus from stakeholders, provide a prudent framework for patient safety as our understanding of pain management and opioid use continues to evolve.

Turning to the questions in the May 8, 2012 Senate Finance Committee letter, to the best of our knowledge, after reasonable due diligence and good faith efforts and to comply with the information requested, the following is provided in response to the questions contained in that letter.

Question 1:

Provide a detailed account of all payments/transfers received from all organizations that develop, manufacture, produce, market, or promote the use of opioid-based drugs from 1997 to the present. For each payment identified, provide:

- i. Date of payment
- ii. Payment description (CME, royalty, honorarium, research support, etc.)
- iii. Amount of payment
- iv. Year end or year-to-date payment total and cumulative total payments for each organization or individual.
- v. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.

Answer 1:

The requested payments/transfers received by the Federation of State Medical Boards (FSMB) and the Federation of State Medical Boards Research and Education Foundation (FSMB Foundation) from 1997 to the present are:

Payer Organization	Date	FSMB Fiscal Year (5/1 – 4/30)**	Payment Description	Amount of Payment	Percent of Total Revenue (Consolidated)
		Total for FY 1997		\$0.00	0.00%
		Total for FY 1998		\$0.00	0.00%
		Total for FY 1999		\$0.00	0.00%

		Total for FY 2000		\$0.00	0.00%
Purdue Pharma	7/14/2000	2001	Purchase of Copies of FSMB Pain Model Guidelines	\$28,324.56	
Pfizer Corp.	8/4/2000	2001	Support for the FSMB National Clearinghouse on Internet Prescribing	\$50,000.00	
Purdue Pharma	9/27/2000	2001	Support for the FSMB National Clearinghouse on Internet Prescribing	\$10,000.00	
		Total for FY 2001		\$88,324.56	1.09%
Purdue Pharma	1/29/2002	2002	Support for the FSMB National Clearinghouse on Internet Prescribing	\$10,000.00	
Pfizer Corp.	2/6/2002	2002	Support for the FSMB National Clearinghouse on Internet Prescribing	\$10,000.00	
		Total for FY 2002		\$20,000.00	0.23%
Purdue Pharma	1/24/2003	2003	Purchase of Copies of FSMB Pain Model Guidelines	\$25,180.50	
Purdue Pharma	3/26/2003	2003	Grant in Support of 2003 FSMB Annual Meeting Session	\$60,000.00	
		Total for FY 2003		\$85,180.50	0.76%
Purdue Pharma	4/27/2004	Total for FY 2004	Grant for Project to Update <i>FSMB Model Guidelines for the Use of Controlled Substances in the Treatment of Pain</i> ; Educate FSMB Member Boards; and Assess Changes in Knowledge and Attitudes of FSMB Member Boards, as Assessed by Surveys (5 Total Payment Installments)	\$87,895.00	0.53%
Purdue Pharma	11/24/2004	2005	Grant for Continued Support of Aforementioned Project	\$112,000.00	

Purdue Pharma	3/31/2005	2005	Grant for Continued Support of Aforementioned Project	\$132,000.00	
		Total for FY 2005		\$244,000.00	1.50%
Purdue Pharma	7/29/2005	2006	Grant for Continued Support of Aforementioned Project	\$132,000.00	
Purdue Pharma	12/13/2005	2006	Grant for Continued Support of Aforementioned Project	\$75,000.00	
		Total for FY 2006		\$207,000.00	1.05%
Endo Pharmaceuticals	6/22/2006	2007	Grant in Support of <i>FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management</i>	\$40,000.00	
Purdue Pharma	7/6/2006	2007	Grant in Support of <i>FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management</i>	\$50,000.00	
Abbott Laboratories	8/16/2006	2007	Support of <i>FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management</i>	\$30,000.00	
Cephalon	9/5/2006	2007	Donation	\$30,000.00	
		Total for FY 2007		\$150,000.00	0.75%
Alpharma	8/28/2007	2008	Grant to Support the Distribution of <i>Responsible Opioid Prescribing</i> to State Medical Boards (SMBs)	\$100,000.00	
Endo Pharmaceuticals	9/11/2007	2008	Grant to Support the Distribution of <i>Responsible Opioid Prescribing</i> to SMBs	\$100,000.00	
Cephalon	9/11/2007	2008	Grant to Support the Distribution of <i>Responsible Opioid Prescribing</i> to SMBs	\$100,000.00	
Purdue Pharma	11/8/2007	2008	Grant to Support the Distribution of <i>Responsible Opioid Prescribing</i> to SMBs	\$100,000.00	

		Total for FY 2008		\$400,000.00	2.10%
King Pharmaceuticals	6/17/2008	2009	Grant to Support the Distribution of <i>Responsible Opioid Prescribing</i> to SMBs	\$100,000.00	
Endo Pharmaceuticals	12/4/2008	2009	Grant to Support the Distribution of <i>Responsible Opioid Prescribing</i> to SMBs	\$100,000.00	
Alpharma	1/15/2009	2009	Purchase of 20 Copies of <i>Responsible Opioid Prescribing</i>	\$238.23	
		Total for FY 2009		\$200,238.23	1.18%
King Pharmaceuticals	12/15/2009	Total for FY 2010	Support for the Distribution of <i>Responsible Opioid Prescribing</i> to SMBs	\$75,000.00	0.32%
Mallinckrodt* (*a Covidien Company)	8/18/2010	2011	Grant to Support the Distribution of <i>Responsible Opioid Prescribing</i> to SMBs	\$100,000.00	
Cephalon	11/10/2010	2011	Donation to Support the Distribution of <i>Responsible Opioid Prescribing</i> to SMBs	\$50,000.00	
Endo Pharmaceuticals	1/28/2011	2011	Grant for Proposed CME Activity Related to FDA Opioid REMS	\$125,000.00	
Covidien	4/15/2011	2011	Grant for Proposed CME Activity Related to FDA Opioid REMS	\$85,000.00	
		Total for FY 2011		\$360,000.00	1.60%
Endo Pharmaceuticals	7/1/2011	Total for FY 2012	Purchase of 6,000 Copies of <i>Responsible Opioid Prescribing</i>	\$46,620.00	0.24%
Totals		Total for FY 1997 – 2012		\$1,964,258.29	0.81%

**The FSMB's Fiscal Year was changed in 1999 from Dec 1 – Nov 30 to May 1 – April 30.

Question 2:

Identify any grants or financial transfers used to fund the production of the book, "Responsible Opioid Prescribing" by Dr. Scott M. Fishman. Provide the date, amount, and source of each grant.

Answer 2:

Payment Description	Payer Organization	Date	Amount of Payment
Grant to Support the <i>FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management</i>	Endo Pharmaceuticals	6/22/2006	\$40,000.00
Grant to Support the <i>FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management</i>	Purdue Pharma	7/6/2006	\$50,000.00
Payment to Publisher, Waterford Life Sciences	FSMB Foundation	7/10/2006	\$40,000.00
Payment to Publisher, Waterford Life Sciences	FSMB Foundation	7/18/2006	\$50,000.00
Support for <i>FSMB Physician Education Initiative on Safe & Effective Prescribing Practices in Pain Management</i>	Abbott Laboratories	8/16/2006	\$30,000.00
Payment to Publisher, Waterford Life Sciences	FSMB Foundation	9/20/2006	\$25,000.00

Question 3:

How much revenue was generated by sales of "Responsible Opioid Prescribing?" Provide amounts by year, state, and total.

Answer 3:

Revenue from sales includes a combination of retail, in-house and external bulk orders, online sales, and royalties. The following chart reflects revenue based on retail, in-house sales and bulk orders. It should be noted that the amounts listed below are not necessarily an indication of where the books were distributed. For example, JBS International, based in Maryland, is a contractor for SAMHSA, and purchased thousands of copies of the book to distribute at SAMHSA/CSAT educational workshops around the country. The revenue provided by state is based on the origin of the payment.

State & Year	Revenue
Alabama	
2008	\$38.85
2009	\$42.95
Arizona	
2008	\$217.45
2010	\$16.80
California	
2009	\$1,541.35
2010	\$1,213.80
Colorado	
2011	\$111.00
Connecticut	
2010	\$16.80
Delaware	
2010	\$572.74
Florida	
2008	\$142.45
Georgia	
2008	\$25.90
2009	\$621.15
Illinois	
2008	\$55.00
2010	\$16.80
Indiana	
2009	\$149.00
Iowa	
2009	\$260.44
Kansas	
2008	\$383.47
2009	\$4,678.00
2010	\$137.80
Kentucky	
2008	\$12.95
2009	\$245.80
Maine	
2009	\$270.35
2011	\$137.80
Maryland	
2008	\$35,799.44

2009	\$787.12
2010	\$9,547.51
2011	\$5,379.80
Massachusetts	
2008	\$25.90
Michigan	
2010	\$16.80
Minnesota	
2008	\$51.80
2009	\$3,133.25
2010	\$1,560.91
2011	\$1,932.00
Missouri	
2008	\$38.85
Nebraska	
2008	\$12.95
New Hampshire	
2008	\$51.80
2010	\$264.12
New Jersey	
2009	\$3,368.20
2010	\$17.24
2012	\$16.80
New York	
2008	\$103.60
2010	\$287.47
North Carolina	
2008	\$29.75
2010	\$90.02
Ohio	
2008	\$38.85
2009	\$16.70
Oklahoma	
2008	\$30,000.00
2009	\$6,300.00
2011	\$137.01
Oregon	
2009	\$16.80
Pennsylvania	
2010	\$1,165.87

2011	\$47,595.66
Rhode Island	
2010	\$70.00
South Carolina	
2008	\$12.95
Tennessee	
2008	\$12.95
2009	\$1,054.36
2011	\$306.30
Texas	
2009	\$3,750.00
Utah	
2008	\$25.90
Virginia	
2008	\$729.99
2009	\$332.75
2010	\$15,455.47
Washington	
2008	\$12.95
Wisconsin	
2008	\$77.70
2009	\$97.60
2010	\$33.80
2012	\$16.80
Wyoming	
2010	\$14,825.07
Total (2008-2012):	\$195,509.46

Additional Sales

Year	Revenue
2008	\$262.95
2009	\$7,875.16
2010	\$657.60
2011	\$137.80
Total (2008-2011):	\$8,933.51

The following chart provides online sales of *Responsible Opioid Prescribing* through Midpoint National, an online order fulfillment company, and includes advanced purchases for the 2nd edition of the book. The sales revenue listed below accounts for the charges deducted by Midpoint National for its fees.

Year	Total Revenue
2009	\$11,469.80
2010	\$14,352.50
2011	\$14,715.29
2012	\$12,557.73
Total (2009-2012):	\$53,095.32

The following chart provides royalties received from the *Responsible Opioid Prescribing* publication:

Year	Total Revenue
2008	\$13,437
2009	\$4,779
2011	\$3,629
Total (2008-2011):	\$21,845

Question 4:

List each state that has distributed copies of “Responsible Opioid Prescribing” and the number of copies distributed.

Answer 4:

The following is a chart of state-level distributions of *Responsible Opioid Prescribing*. Books were distributed directly by state medical boards or in conjunction with and support from state/federal health departments and agencies, and non-profit organizations.

State	# Books Distributed
Alabama	450
Arizona	100
Connecticut	1,130
District of Columbia	4,140
Florida	9,100
Georgia	18,121
Illinois	500
Iowa	1,550
Maine	3,840
Michigan	42,366
Minnesota	900
Montana	1,800
New Hampshire	4,100
New Mexico	4,500

North Carolina	2,000
North Dakota	300
Oklahoma	6,000
Pennsylvania	601
Rhode Island	6,006
South Carolina	8,070
Vermont	4,412
Virginia	20,000
Washington	15,395
West Virginia	5,200
Wyoming	2,550
Total:	163,131

Question 5:

Provide the names of any people or organizations, other than Federation of State Medical Boards employees or Dr. Scott M. Fishman, involved in writing or editing the content of “Responsible Opioid Prescribing.”

- i. For each person or organization identified, list any financial transfers between the identified person or organization and the Federation of State Medical Boards.
- ii. For each individual or organization identified, provide a description of the involvement.

Answer 5:

The following individuals participated in advising, writing, and/or editing the content of the first or second edition of *Responsible Opioid Prescribing*. The job title presented below corresponds with the participant’s position held at the time of the production of each edition of *Responsible Opioid Prescribing*.

The following individuals did not receive monetary compensation or an honorarium from the FSMB or its Foundation for their participation in the production of *Responsible Opioid Prescribing*.

Several individuals serving on the Advisory Board, including then FSMB Chair and current U.S. Surgeon General Regina M. Benjamin, MD, MBA, and William L. Harp, MD, Executive Director of the Virginia Board of Medicine, have served the FSMB and its Foundation in various capacities (i.e. Board and Committee leadership, workgroups, educational faculty, etc.), and some may have received travel reimbursements and/or stipends in connection with other FSMB-related activities. Such financial transfers were not related in any way to the production of the book.

Responsible Opioid Prescribing: A Physician’s Guide (2007)

Advisory Board:

Upon the author’s completion of the manuscript of ‘Responsible Opioid Prescribing’, the Advisory Board was charged with reviewing content and making recommendations as deemed necessary.

Regina M. Benjamin, MD, MBA

Bayou Clinic
 Bayou La Barre, AL
 Chair, FSMB Board of Directors

Anton C. Bizzell, MD
Immediate Past Medical Officer
Center for Substance Abuse Treatment
Division of Pharmacologic Therapies
Substance Abuse & Mental Health Administration

Myra Christopher
President/CEO
Center for Practical Bioethics

Perry G. Fine, MD
Professor of Anesthesiology
University of Utah, School of Medicine

Rollin M. Gallagher, MD, MPH
Director, Center for Pain Medicine, Research & Policy
University of Pennsylvania

Aaron Gilson, PhD
Co-Director for U.S. Policy Research
Pain & Policy Studies Group/WHO Collaborating Center
University of Wisconsin-Madison

William L. Harp, MD
Executive Director
Virginia Board of Medicine

Rebecca A. Kirch
Associate Director of Policy
American Cancer Society

Michael Moskowitz, MD
Assistant Professor, Anesthesiology and Pain Medicine,
School of Medicine, University of California, Davis

David Thornton
Immediate Past Executive Director
Medical Board of California

Medical Writer:
The medical writer assisted the author with writing and editorial support.

Stephen Braun

Associate Editors
The Associate Editors reviewed the full manuscript and offered suggested edits and identified any content concerns.

Perry G. Fine, MD
Rollin M. Gallagher, MD, MPH
Aaron Gilson, PhD

Michael Moskowitz, MD, MPH

Responsible Opioid Prescribing: A Clinician's Guide (2012)

Advisory Board

Roger Chou, MD

Associate Professor, Departments of Medicine and Medical Informatics & Clinical Epidemiology
Oregon Health & Science University School of Medicine, Portland, OR

Rollin M. Gallagher, MD, MPH

Clinical Professor of Psychiatry and Anesthesiology
Director, Center for Pain Medicine, Research & Policy University of Pennsylvania
Deputy National Program Director for Pain Management, Veterans Affairs Health System

Marc B. Hahn, DO

Dean and Senior Vice President for Health Affairs, University of New England, Biddeford & Portland, Maine,
College of Osteopathic Medicine, Biddeford, ME

William L. Harp, MD

Executive Director, Virginia Board of Medicine, Perimeter Center, Henrico, VA

Scott G. Kirby, MD

Medical Director, North Carolina Medical Board, Raleigh, NC

Sandrine Pirard, MD, PhD, MPH

Medical Officer, Division of Pharmacologic Therapies, Center for Substance Abuse Treatment, Substance Abuse
and Mental Health Administration, Rockville, MD

Janelle Rhyne, MD, MA, MACP

FSMB Chair, Medical Director, Cape Fear Health Net, Health Net Clinic, Wilmington, NC

Medical Writer

Stephen Braun

Question 6:

Please identify the name, job title, job description, and dates employed of any Federation of State Medical Boards
employees who worked on distributing this book.

Answer 6:

The following employees of the Federation of State Medical Boards (FSMB) served in some capacity in the
development and/or distribution of the *Responsible Opioid Prescribing* publication.

Last Name	First Name	Job Title	Job Description	Dates of Employment
Alfred	Kelly	FSMB Director, Education Services	Under the supervision of the Chief Advocacy Officer, the Director of Education Services manages all functions of the Education Department. This includes the development and delivery of educational services, programs and products, providing educational assistance to state medical boards, and collaborating with external entities in the interest of state medical boards.	3/2/98-present
Austin	Dale	FSMB Senior Vice President and Chief Operating Officer (Interim Executive Vice President 2001-2002)	Reporting directly to the President as Chief Executive Officer (CEO), the Senior Vice President serves as the Federation's Chief Operating Officer (COO). Under guidelines and parameters established with the President, the Senior Vice President is responsible for management and oversight of all internal operations of the Federation's national office, both administrative and programmatic. This person maintains a cohesive work force in an effective organizational structure based on teamwork and accountability. Through appropriate executive and management staff, the Senior Vice President oversees implementation of new and enhanced work processes and resource allocations that more efficiently and effectively accomplish the mission, goals and objectives of the Federation and promote a positive working environment for all employees.	2/20/95-11/30/08
Bransford	Denise	Manager, IMIS Solutions	The Manager of IMIS Services plans, maintains and ensures the accessibility of the FSMB's member services database and member services products to the FSMB and our member boards. Responsibilities include collecting dues, subscriptions and orders; invoicing; ensuring data integrity and accessibility; internal and external user support; managing customer relationships with member boards; data gathering; and meeting internal customer reporting requests.	5/5/97-present
Chaudhry, DO, FACP	Humayun	FSMB President and Chief Executive Officer	Under the general direction of the Board of Directors, the President/CEO for the Federation of State Medical Boards (FSMB) is responsible for the overall leadership and corporate direction of the organization's activities. The President/CEO serves as the primary spokesperson and represents the FSMB to the leadership of other organizations as the premier organization concerned with medical licensure and discipline. The President/CEO has the ultimate responsibility for carrying out the mission of the FSMB and achieving all of its	10/19/09-present

			goals in a manner that is in keeping with the core values of the organization. Key partnerships include those with the National Board of Medical Examiners, the Education Commission for Foreign Medical Graduates, the American Medical Association, the Association of American Medical Colleges, and the American Osteopathic Association.	
Jagoda	Jonathan	Director, Federal Government Relations	The Director of Federal Government Relations is a position within the Federation of State Medical Boards (FSMB) Washington, D.C. Advocacy Office that reports directly to the Chief Advocacy Officer. The position contributes to the overall success of the FSMB's Washington, D.C. Advocacy Office in achieving advocacy and policy goals.	7/28/10 – present
McCullough	Randy	Senior Director, Finance	The Sr. Director of Finance is responsible for presenting and analyzing all pertinent financial information in an accurate and understandable format. This information is reported directly to the executive staff and includes the preparation of financial statements, quarterly variance reports, and the tracking of investments. In addition, the Sr. Dir of Finance is heavily involved in the budgeting process for the Federation.	1/11/88-present
Paxton	Bill	Director, Legislative Services	The Director of Legislative Services has responsibility for the management of all functions of the organization's legislative services and government relations, including: research, review, and monitoring of federal and state legislation and regulations relating to FSMB policies and medical licensure and regulation; communicating with and providing assistance to state medical boards on legislative issues and strategies; coordinating operation of the Internet Clearinghouse; coordinating interaction with government relations firms and legislative tracking service. The Director works closely with senior staff and provides administrative support to special committees and workgroups in developing policy. The Director develops relationships and seeks to collaborate with external entities on issues that affect medical regulation and impact public health and safety.	7/12/04-12/1/06
Robin	Lisa	FSMB Chief Advocacy Officer	The Chief Advocacy Officer (CAO) directs the FSMB's Washington, DC advocacy office and directly oversees and manages a wide range of services on behalf of and promoting state medical and osteopathic boards and the FSMB. These include: state and federal legislative services, advocacy and outreach activities, public policy, education, and public affairs and other projects as	8/24/94 – present

			assigned by the President/CEO. The CAO oversees the FSMB federal and state public policy strategy, which entails formulating and implementing the FSMB's legislative and regulatory agenda on behalf of FSMB member boards and the FSMB.	
Schneidman, MD	Barbara	FSMB President	Under the general direction of the Board of Directors, the President/CEO for the Federation of State Medical Boards (FSMB) is responsible for the overall leadership and corporate direction of the organization's activities. The President/CEO serves as the primary spokesperson and represents the FSMB to the leadership of other organizations as the premier organization concerned with medical licensure and discipline. The President/CEO has the ultimate responsibility for carrying out the mission of the FSMB and achieving all of its goals in a manner that is in keeping with the core values of the organization. Key partnerships include those with the National Board of Medical Examiners, the Education Commission for Foreign Medical Graduates, the American Medical Association, the Association of American Medical Colleges, and the American Osteopathic Association.	1/1/09-10/16/09
Still	Sheila	Administrative Assistant, Education	The Administrative Assistant for Education Services is a shared position of responsibilities that consists of administrative duties relating to the functions of the Education department and the Director of Education Services, and the FSMB Librarian. The Administrative Assistant will perform a variety of complex administrative duties requiring a thorough knowledge of office procedures and will possess the ability to work independently as well as the ability to interact with FSMB executive leadership and staff.	6/5/00 - present
Thompson, MD	James	FSMB President and Chief Executive Officer	Under the general direction of the Board of Directors, the President/CEO for the Federation of State Medical Boards (FSMB) is responsible for the overall leadership and corporate direction of the organization's activities. The President/CEO serves as the primary spokesperson and represents the FSMB to the leadership of other organizations as the premier organization concerned with medical licensure and discipline. The President/CEO has the ultimate responsibility for carrying out the mission of the FSMB and achieving all of its goals in a manner that is in keeping with the core values of the organization. Key partnerships include those with the National Board of Medical Examiners, the Education	3/4/02-10/31/08

			Commission for Foreign Medical Graduates, the American Medical Association, the Association of American Medical Colleges, and the American Osteopathic Association.	
Turner	Michelle	FSMB Director, Professional Development and Member Data Services	The Director is responsible for the design, development, and implementation of educational programs for the professional growth and development of FSMB's leadership and support staff.	7/16/99-present
Winn, MD	James	Executive Vice President	Under the general direction of the Board of Directors, the President/CEO for the Federation of State Medical Boards (FSMB) is responsible for the overall leadership and corporate direction of the organization's activities. The President/CEO serves as the primary spokesperson and represents the FSMB to the leadership of other organizations as the premier organization concerned with medical licensure and discipline. The President/CEO has the ultimate responsibility for carrying out the mission of the FSMB and achieving all of its goals in a manner that is in keeping with the core values of the organization. Key partnerships include those with the National Board of Medical Examiners, the Education Commission for Foreign Medical Graduates, the American Medical Association, the Association of American Medical Colleges, and the American Osteopathic Association.	10/1/94-9/11/01

Conclusion

The FSMB, and the state medical boards it represents, are committed to helping address the nation's dual public health issues of under-treated pain and opioid prescription misuse, abuse and diversion. The FSMB shares the Committee's concern over the problems stemming from addiction to opioid medications. The FSMB has launched a wide range of activities in response, ranging from educational initiatives for physicians to close collaboration with federal health care and law enforcement agencies and strong efforts to expand tools such as prescription drug monitoring programs.

At the center of the FSMB's work is the belief that the prescribing of medications that are FDA-approved for pain management, such as long-acting and extended release opioids, should involve a careful balance by physicians between the benefits of these medications to control pain and suffering, and the rising concerns associated with their misuse, abuse and diversion.

The FSMB supports educating physicians about these concerns and emphasizing responsible and appropriate prescribing when a decision is made to use this class of drugs.

The FSMB and state medical boards' efforts to educate physicians about the responsible prescribing of opioids do not advocate for opioid therapy; but rather, ensure that those who do choose to prescribe FDA-approved pain medications do so in a medically appropriate way that properly manages risk and reduces adverse outcomes.

- The FSMB's efforts give physicians the knowledge and understanding of best practices and guidelines so they have the confidence to prescribe in a manner that ensures patient safety and is in compliance with federal regulations. This is in direct alignment with the FSMB's mission and purpose of protecting the public and the integrity of medical practice while ensuring access to medical treatment.

The FSMB joins other medical organizations in acknowledging the need for more robust data on opioid use and effectiveness. Until more data is available, we must ensure that physicians fully understand and adhere to best-practice guidelines for the proper prescribing of these drugs. In a major report on pain in 2011, the IOM concurred, writing: "Health professions education and training programs, professional associations, and other groups that sponsor continuing education for health professionals should develop and provide educational opportunities for primary care practitioners and other providers to improve their knowledge and skills in pain assessment and treatment, including safe and effective opioid prescribing."¹⁷ The FSMB is committed to filling this vital need as a part of its service to the nation.

We urge you to read these documents in their entirety and full medical context. We stand ready to provide any additional information, if needed, and welcome the opportunity to discuss these questions further with you personally. We would also be pleased to engage in a full discussion with you regarding the FSMB Model Policies and our publication, *Responsible Opioid Prescribing*.

Respectfully,



Humayun J. Chaudhry, DO, FACP
President and CEO

Enclosures

- 1) *The Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (1998)
- 2) *The Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office* (2002)
- 3) *The Model Policy for the Use of Controlled Substances for the Treatment of Pain* (2004)
- 4) *Balance, Uniformity and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice*. (2009)
- 5) *Responsible Opioid Prescribing: A Clinician's Guide* (2012)

References

1. American Medical Association. *AMA Policy H-120.944: Standards, Laws, and Regulations Addressing Pain Medications and Medical Practice*. <https://ssl3.ama-assn.org/apps/ecom/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-120.944.HTM>. Accessed May 30, 2012.
2. Gil Kerlikowske, Director of the Office of National Drug Control Policy. From a speech delivered at the Federation of State Medical Boards Annual Meeting, Forth Worth, Texas, April 26, 2012. Mr. Kerlikowske's full comment: "There's a real gap in the amount of education and training that is provided around pain management, addiction, treatment, tolerance, dependence, etcetera. We know that that's an important issue...and I am going to talk about that in particular. Because I could not be more pleased, frankly, and I could not be more proud of the work that you all have done in this area...I was just given the latest edition of the *Clinician's Guide for Responsible Opioid Prescribing* by Dr. Fishman, boy, I could not be more proud of what you are doing with that. The second edition of this, being distributed across literally by the tens of thousands, I'm sure, is just a wonderful, wonderful step in the right direction of putting something that is so well written in the hands of very busy professionals that need that information. I commend you and my hat is off to you for doing that...So we could not be more pleased or proud of the cooperation and collaboration that we have with all of you. I am truly in awe of the work that you have done and the way you have taken this on."
3. Centers for Disease Control and Prevention. *Prescription Painkiller Overdoses in the U.S.* November, 2011. <http://www.cdc.gov/Features/Vitalsigns/PainkillerOverdoses/>. Accessed May 22, 2012.
4. Institute of Medicine of the National Academies. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*; June 2011.
5. Federation of State Medical Boards of the United States. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*; May 1998.
6. Federation of State Medical Boards of the United States. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*; May 2004.
7. William L. Harp, MD, Executive Director, Virginia Board of Medicine. Letter of endorsement to the Federation of State Medical Boards, July 29, 2011.
8. Janet Mills, Attorney General, State of Maine. Remarks to the Maine Medical Association Practice Education Seminar, June 3, 2009. http://www.mainemed.com/spotlight/2009/AttorneyGeneral_Speech_PracticeEducationSeminar.pdf. Accessed May 22, 2012.
9. Gil Kerlikowske, Director of the Office of National Drug Control Policy. From a speech delivered at the Federation of State Medical Boards Annual Meeting, April 26, 2012.
10. United States Food and Drug Administration. *Draft Blueprint for Prescriber Education for the Long-Acting/Extended-Release Opioid Class-wide REMS*. November 4, 2011. <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM277916.pdf>. Accessed May 22, 2012.
11. United States Office of National Drug Control Policy. *Epidemic: Responding to America's Prescription Drug Crisis*. 2011.

12. Federation of State Medical Boards of the United States, Center for Practical Bioethics, National Association of Attorneys General. *Balance, Uniformity and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice*. February 2009.
13. Ibid.
14. Ibid., p. 11
15. Ibid.
16. Federation of State Medical Boards of the United States. "FSMB Announces Opioid Prescribing Initiative." News release, Feb. 17, 2012. <http://www.fsmb.org/pdf/nr-opioid.pdf>. Accessed May 22, 2012.
17. Institute of Medicine of the National Academies. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*; June 2011.