

## Physicians Charged with Opioid-Analgesic Prescribing Offenses

Goldenbaum, Donald M., Ph.D., Center for Practical Bioethics  
Christopher, Myra, Center for Practical Bioethics  
Gallagher, Rollin M., M.D., M.P.H., Philadelphia V.A. Medical Center/U. Pennsylvania  
Fishman, Scott, M.D, U. California, Davis  
Payne, Richard, M.D., Duke University Divinity School  
Joranson, David, M.S.S.W., U. Wisconsin  
Edmondson, Drew, J.D., Attorney General, State of Oklahoma  
McKee, Judith, J.D., M.A., National Association of Attorneys General  
Thexton, Arthur, J.D., M.A., Wisconsin Department of Regulation & Licensing

### Corresponding Author:

Donald M. Goldenbaum, Ph.D., Director, Research, Evaluation, and Publications Program, Center for Practical Bioethics, 1111 Main, Suite 500, Kansas City, Missouri 64105-2116). Email: [dgoldenbaum@practicalbioethics.org](mailto:dgoldenbaum@practicalbioethics.org).

Word counts: abstract = 249 , text = 4,329

### ABSTRACT

**Objective.** To provide a “big-picture” overview of the characteristics and outcomes of recent criminal and administrative cases in which physicians have been criminally prosecuted or charged by medical boards with offenses related to inappropriate prescribing of opioid analgesics.

**Design:** We identified as many criminal and administrative cases of these types as possible that occurred between 1998 and 2006. Cases were identified using a wide variety of sources, including organizational and government-agency databases, published news accounts, and Websites. Factual characteristics of these cases and their outcomes, and of the physicians involved, then were further researched using additional sources and methods.

**Setting:** Study findings are intended to apply to practicing U.S. patient care physicians as a whole.

**Patients or other participants:** There were no patients or participants in this study.

**Outcome measures:** We analyzed the numbers and types of cases and physicians involved, criminal and administrative charges brought, case outcomes and sanctions, specialties and other characteristics of the physicians involved.

**Results:** The study identified 725 doctors, representing an estimated 0.1% of practicing patient care physicians, who were charged between 1998 and 2006 with criminal and/or administrative offenses related to prescribing opioid analgesics. A plurality of these

(39.3%) were General Practice/Family Medicine physicians, compared with 3.5% who were self-identified or board-certified pain specialists. Physicians in this sample were more likely to be male, older, and not board certified ( $P < 0.001$ ). DEA criminal and complaint investigations averaged 658 per year (2003-2006) and “for cause” surrenders of DEA registrations averaged 369.7 (2000-2006).

**Conclusions:** Criminal or administrative charges and sanctions for prescribing opioid analgesics are rare. In addition, there appears to be little objective basis for concern that pain specialists have been “singled out” for prosecution or administrative sanctioning for such offenses.

**Key words:** physicians, opioids, prescribing, prosecution, criminal, charges

## INTRODUCTION

Recent press accounts and articles regarding cases in which physicians have been convicted of criminal charges relating to prescribing opioid analgesics (1-5) have raised concern among prescribing doctors. Although earlier research indicates that very few physicians (fewer than 50 per year) have been charged with such criminal offenses (6-9) (3-14) that prosecutors are reluctant and unlikely to prosecute doctors for prescribing-related decisions involving controlled substances (9, 10), and that, after education about using opioids for pain, physicians become more comfortable prescribing them (11), many still fear unjustified prosecution or sanctioning. (3-14) In addition, doctors have been shown to have difficulty identifying standardized patients who deceptively claim to be in severe pain (12). Consequently they tend to under-prescribe opioids for pain (6-7, 11, 13-19). Such concerns are exacerbated by recent journalistic articles (4, 20) and news stories that suggest, without firm research evidence, that pain specialists are those most likely to be involved in such cases.

To date, no multi-year, nationwide study of actions taken against physicians so charged (3-4) and/or administratively reviewed has been available. This study was undertaken by the Center for Practical Bioethics (CPB), in partnership with the National Association of Attorneys General (NAAG) and Federation of State Medical Boards (FSMB), to answer the following kinds of questions: How many physicians actually have been criminally charged or reviewed by state medical boards for offenses related to the prescribing of opioid analgesics? What were the characteristics of these physicians? (2-1) What pleas have the physicians charged with criminal offenses, entered? Have most of the physicians involved in these cases been pain specialists?

(1-1) The following hypothetical scenarios provide examples of the types and ranges of cases addressed in this study. Representing typical offenses and charges, they indicate how physicians might become involved in cases of this type, and why they might have been charged with different, specific criminal and administrative offenses.

**Scenario 1:** Doctor A, now in his seventies, plans to retire soon from his small, rural solo practice. Most of his current patients are elderly, and many come to him complaining of

age-related minor aches and pains as well as more severe and disabling pain caused by diseases common to older populations such as cancer (and neuropathies related to its treatment), osteoarthritis, spinal stenosis and various neuropathies and neuralgias. Informed by pharmaceutical sales representatives who regularly visit his office that sustained-release, opioid-based analgesics have become available to control many types of severe pain throughout the day, Doctor A begins issuing high-dosage prescriptions of these drugs for patients whose conditions include arthritis pain and severe headaches. When one of these patients nearly dies by accidentally overdosing on her prescribed analgesics, the patient's family complains to the state medical board. Checking Doctor A's patient records, Board investigators find that many of his recent controlled-substance analgesic prescriptions appear to have been medically unnecessary and clinically inappropriate. The Board sanctions the doctor for misprescribing and for violating accepted standards of medical care. It levys a fine, puts his practice on probation, and suspends his DEA controlled-substance registration until he completes continuing medical education classes to learn proper methods of prescribing opioid-based analgesics.

**Scenario 2:** A comes to Doctor B for chronic neck and back pains. The pains were caused, he says, by an auto accident earlier in the year. The man tells the doctor that over-the-counter remedies and back exercises are providing insufficient relief, and that the accident-related pain now is keeping him from sleeping well or holding a job. Doctor B prescribes high-dosage units of oxycodone, together with a muscle relaxant. The patient keeps his scheduled follow-up appointments, during which Doctor B monitors the status of his pain and renews his prescriptions. Soon after he fills each of these prescriptions, however, the patient sells the oxycodone to a local drug dealer. When the dealer is arrested, investigators find that some of his drugs originated as prescriptions issued by Doctor B. A check of the doctor's records shows that he occasionally prescribed controlled-substance analgesics without first giving physical exams, and that in those instances, his office still billed Medicare for such exams. Satisfied on the basis of the inconsistent physical examinations and questionable billings that Doctor B probably is not really practicing medicine, the local district attorney decides that the doctor either knew or should have known that his patient's oxycodone prescriptions were ending up being sold on the street. He files criminal charges against Doctor B for drug trafficking and healthcare fraud.

**Scenario 3:** Although Doctor C has been financially successful in the past, his medical practice now is struggling. As a consequence, he is having trouble making payments on his large house, boat, and other personal debts. He decides to supplement his income by selling pre-signed, blank prescription pads and by dispensing samples of opioid-based analgesics without accompanying examinations or prescriptions, for cash, to anyone who comes to the back entrance of his clinic and requests such drugs by name. The doctor maintains his illicit inventories by removing containers of opioid-based drugs at night from the supply rooms of local hospitals. Tipped off by an informant, federal investigators send an undercover agent to Doctor C's office. As planned, the agent succeeds in purchasing the opioid-based analgesics he requests, for cash, from Doctor C without an examination or receiving a prescription. The doctor then is charged with

prescription fraud; illegally obtaining, ~~possessing~~possessing, and distributing controlled substances; and racketeering.

## **METHODS**

### **Data Sources**

Because health-professional controlled-substance (CS) cases that have received the greatest amounts of media attention have been those involving physicians, this study was restricted to criminal and administrative cases from 1998 through 2006 in which physicians, rather than nurse practitioners, pharmacists, and other health care professionals, were involved. (1-2) All physicians involved in these cases were in practice and actively involved in providing patient care at the time of their involvement. In these cases, controlled-substance medications were those identified as scheduled drugs by the Drug Enforcement Administration (DEA) on its Web site ([www.usdoj.gov/dea/pubs/scheduling.html](http://www.usdoj.gov/dea/pubs/scheduling.html)). (3-5) Because the research involved in this study was not considered research involving human subjects, the study was not subject to institutional review board or ethics committee approval.

In the absence of comprehensive sources of information on criminal and administrative cases of this type or on the characteristics of physicians (MDs and DOs) involved such cases, we used a wide variety of sources and methods to identify and research as many relevant adjudicated cases as possible. Every effort was made to identify relevant cases filed or heard during the time period; no known selection biases were imposed.

**Criminal cases.** Relevant federal and state criminal cases were identified and researched over the entire study time frame using both online and published sources, including Public Access to Court Electronic Records (PACER, <http://pacer.psc.uscourts.gov/>); Lexis/Nexis (<http://global.lexisnexis.com/us>), the *Federal Register* (<http://www.gpoaccess.gov/fr/index.html>), online historical news accounts posted by local newspapers, appellate court decisions, Websites maintained by the (2-2) patient-advocacy organizations that follow high-profile cases of physicians charged with analgesic-related offenses, the Website of the DEA, and Websites of individual federal and state criminal courts and state medical boards. In addition, because few states maintain historical lists of their criminal cases, we contacted the Attorney General's offices in forty-three states to request information on relevant cases in those states over the time period.

(3-6) These Attorney General (AG) offices are responsible for prosecuting Medicaid fraud, which often involves offenses involving the prescribing of controlled substances. Many AG offices also are responsible for, or share responsibility with, district attorneys for prosecuting drug diversion activity under their states' own controlled-substance laws.

Additional criminal cases came from medical board disciplinary records involving doctors whose licenses had been suspended or revoked because of prior criminal convictions for prescribing-related offenses. Similarly, Federal Register notices of DEA CS-registration revocations identified physicians involved in relevant criminal cases at state or federal levels. Last, investigators placed phone calls to prosecutors and defense

attorneys to request additional case details. When prosecutors and defense attorneys could not be reached, court clerks often provided needed case information.

**Administrative cases.** The Federation of State Medical Boards (FSMB) identified many relevant state medical board cases through queries of its Data Center database. FSMB staff manually reviewed flagged cases to verify that the charges actually involved prescribing of CS analgesics. We identified additional state administrative cases through *Federal Register* notices of CS registration revocations, and on the Websites of state medical boards. Some case details came from interlocutory (1-3)(intermediate or tentative) and final orders provided by individual state medical boards. “Originating” state medical board cases, i.e., those that were not responses to sanctions imposed by medical boards in other states, were flagged for analysis purposes. Information on federal administrative actions (typically, revocations of federal CS registrations) was obtained both from the DEA Website ([www.usdoj.gov/dea](http://www.usdoj.gov/dea)) and through on-line searches of the *Federal Register*.

**Physician characteristics and specialties.** We sourced physician demographic characteristics through news accounts, phone calls to appropriate state medical or osteopathic boards, and when necessary, written requests to those boards. Information on medical specialties and subspecialties, when not available from these state medical and osteopathic boards, came from Internet medical directory sites such as [www.healthgrades.com](http://www.healthgrades.com). All reported medical specialties were checked against the online database of the American Board of Medical Specialties (ABMS, [www.abms.org](http://www.abms.org)) or by staff of the American Osteopathic Association, to determine whether those specialties were board-certified. Numbers of international medical graduates in 2004 are from reference (21).

Study physicians classified as General Practice/Family Medicine specialists included those who self-identified as Family Medicine, Family Practice, or General Practice specialists, those who were board-certified as such by the ABMS, and those confirmed by the American Academy of Family Physicians to have at some time been members of that organization.

Only study physicians who self-identified as Pain Medicine specialists or who had at some point been certified by an ABMS-affiliated board in Pain Medicine were classified as such. Some self-identified Pain Medicine specialists may have been certified instead by the American Board of Pain Medicine (ABPM). (2-3) It should be noted that beyond holding a DEA controlled-substance registration, physicians who prescribe controlled-substance analgesics are not required to be board-certified by either organization in Pain Medicine.

**Data on federal investigations, CS registration revocations and voluntary surrenders.** We obtained data on total federal criminal and complaint investigations and on voluntarily surrenders of federal CS registrations from the DEA. Totals for DEA investigations were available for 2003-2006, and for voluntary registration surrenders from 2000-2006. DEA “complaint” investigations typically are undertaken as follow-

ups to state medical license actions and usually result in routine revocation of the physician's DEA CS registration, whereas DEA "criminal" investigations—(3-7) those that, after preliminary checking, are found to be substantial enough to be pursued on a formal basis—involve suspected CS-related crimes. "Out of business" registration surrenders generally indicate physician retirement or career change, whereas "for cause" registration surrenders generally follow upon the physician's medical license being suspended or revoked by a medical board, or upon being convicted in criminal court for various healthcare offenses. "For cause" surrenders included, but were not restricted to, surrenders made in connection with prescribing-related offenses. Revocations of DEA CS registrations reported in the Federal Register almost always result from medical board license actions or from criminal convictions, including those for prescribing-related offenses.

### **Statistical Analyses**

Datasets were extracted via queries of the study's Microsoft Access 2000 database. We then used Microsoft Excel 2000 pivot tables to compute category and subcategory totals and subtotals, and Excel worksheets to compute percentages and prevalence rates.

To see whether the specialties of the study physicians differed significantly from those of physicians in the U.S. workforce, we compared the numbers of study physicians holding each specialty to those of active physicians in the workforce, (1-2) i.e., physicians actively providing patient care. Analyses took into account that many study physicians held two or more specialties. Baselines for the physician workforce were taken, where available, from 2003 figures published in the 2005 edition of the AMA's annual statistical summary (22). 2003 was selected as the baseline year for these comparisons because it represents a midpoint year in the 1998-2006 time frame. We then computed prevalence rates/1,000 physicians for each of the ten specialties observed most often among study physicians over the time frame, and 95% confidence intervals for each of these prevalence rates.

Because the baseline total provided in the AMA publication for Pain Medicine specialists was dramatically small—135 for the 2003 workforce—and because this number was not consistent with the number of Pain Medicine certificates American Board of Medical Specialties reports physicians had received between 1995-2004—over 3,000—we developed an alternative estimate of the baseline number of pain specialists in the physician workforce. In 2002, 335 Ohio physicians were either self-reported pain specialists, board-certified in Pain Medicine, or both (23). These 335 physicians represented 1.04% of the estimated 24,732 Ohio patient care physicians active in Ohio in 2003. Applying this percentage to the AMA's reported 691,873 active US patient care physicians in 2003 (22), we obtained an estimate of 9,371 self-identified or board-certified pain specialists active in the US for that year.

In the demographic analyses, physician age represents the age of each individual in the year their case was filed. If a physician was involved in more than one case, this was the year of that physician's earliest case within the study time frame. To compare

demographic characteristics of study physicians to those in the U.S. physician workforce, we computed two-tailed Pearson Chi Square tests without correction for continuity. As most of the criminal and administrative cases involved multiple charges against each physician, we computed for each charge category both the percentage of total charges and the percentage of total cases involving that type of charge. Chi Square tests and confidence intervals were computed using tools provided on the Vassarstats Web site (<http://faculty.vassar.edu/lowry/VassarStats.html>).  $P < .05$  was considered statistically significant.

## **RESULTS**

### **Total cases**

We identified a total of 986 cases over the 1998-2006 study time frame in which physicians had been criminally (3-4) charged and/or administratively reviewed with offenses involving the prescribing of opioid analgesics. 335 were criminal cases (178 state, 157 federal) and 651 were administrative cases (525 state medical board cases, 126 DEA administrative actions regarding CS registrations).

### **Numbers and specialties of study physicians**

The 725 individual physicians involved in these cases over the study time period represent 0.1% of the total 691,873 patient-care physicians active in 2003, or one out of 954 physicians.

As shown in Table 1, General Practice/Family Medicine physicians comprised the largest proportion of physicians involved in the criminal and administrative cases (39.3%). Pain Medicine specialists, both self-identified and board certified, comprised 3.5% of the physicians involved in these cases.

Table 1 also shows prevalence rates/1,000 over the study period for the specialties observed most frequently among study physicians. General Practice/Family Medicine specialists had the highest nine-year prevalence rate: 3.3 per 1,000 practicing patient care physicians (95% Confidence Interval 2.9 – 3.7), or 0.4/1,000 per year. The prevalence rate for Pain Medicine specialists was lower, 2.3 per 1,000 over the study period (C.I. 1.5 - 3.5), with an average annual rate of 0.3/1,000 per year.

### **Demographic characteristics of study physicians**

Table 2 provides percentage comparisons by gender, age range, degree, country where degree was obtained, and board certification categories, for study physicians and patient care physicians in the 2003 workforce. Significantly more of the study physicians were male ( $p < .001$ ), aged 55 or over ( $p < .001$ ), and DOs ( $p < .001$ ), than in the workforce. Study physicians also were significantly less likely to be board certified in any of their specialties ( $p < .001$ ), (2-3) including those that were self- or otherwise-identified as Pain

Medicine specialists. The two groups did not differ significantly with regard to whether or not they received their medical degrees in the U.S.

### **Trends in numbers of cases, federal investigations, and registration surrenders**

Table 3 shows trends in three related measures over the study period, for years in which data were available. DEA investigations of physicians suspected of violations relating to the prescribing of CS medications (including opioid analgesics) has increased in recent years, for both “complaint” and “criminal” investigations. Between 2003 and 2006, DEA criminal investigations—those involving (3-9) prescribing- or diverting-related violations—increased 31.6%, with increases of over 15% from 2004-2005 and again from 2005-2006.

Total numbers of cases shown in Table 3, combining federal and state criminal and administrative cases, have increased over the study period, from 17 in 1998 to 147 in 2006. The decline in total cases from 2005 – 2006 is due largely to a decrease in the number of state administrative (state medical board) cases in 2006. However, the other three categories of cases decreased in 2006 as well.

Last, Table 3 shows that between 2000 and 2006 the numbers of physicians voluntarily surrendering their CS registrations has remained fairly steady, between 19,000 and 21,000 per year. Most (97.7%) of these surrenders have been due to practice-closings or career changes (what the DEA classifies as “out of business” surrenders). The remaining 2.3% of physicians voluntarily surrendered their CS registrations for what DEA classifies as “for cause,” i.e., in connection with the physician having been criminally charged or having their medical license suspended or revoked for reasons that could have included prescribing-related offenses. This “for cause” number also has remained relatively steady since 2000, fluctuating between 300 and 450 per year.

### **Criminal and administrative charges**

Table 4 shows, for each general type of criminal charge, the percentages of cases and percentages of charges represented by that type of charge. Criminal charges filed most frequently involved drug trafficking/racketeering (77.9% of cases) or fraud (33.9% of cases) rather than offenses involving direct harm to patients, such as murder or manslaughter (5.8%) or inappropriate, illegal or harmful relationships with patients (4.5%).

Table 5 similarly shows, for each type of administrative (state medical board) charge (i.e., basis for action), the percentages of such cases and charges represented by that type. Bases for action filed most frequently were falsifying or failure to maintain adequate medical records (38.3% of cases), and violating accepted standards of care or practice (26.0%). Fewer physicians were charged with misprescribing—(3-10) i.e., issuing prescriptions for which the risks outweighed the benefits—(20.2% of cases) or with prescribing to habitual users or addicts (10.1%).



## Case outcomes

Among the study physicians prosecuted in criminal courts, 79.5% pled guilty or no contest to at least one of the criminal charges brought against them. The remaining 20.5% plead not guilty to all criminal charges. 90.6% of the physicians prosecuted either pled guilty or subsequently were found guilty on at least one count. Of these, 78.8% received either a prison sentence, a monetary penalty, or both. Of the remaining 21.2% who received neither type of sanction, most (59.8%) were placed on probation.(3-4) 7.5% of the 335 criminal cases involving study physicians were either dismissed or otherwise diverted during pretrial stages.

Disciplinary orders (i.e., sanctions) imposed by state medical boards, in addition to any orders affecting the status of those physicians' medical licenses, most often required them to attend continuing medical education courses (22.0% of cases), or to pay a fine or another monetary penalty (19.8%).

License-related orders imposed by state medical boards upon physicians charged with CS-related offenses usually involved the temporary surrender or suspension of their medical license (37.8% of cases), rather than revocations or non-renewals of those licenses (17.7%). In 16.4% of cases, the medical board took no action regarding the physician's medical license.

## DISCUSSION

**Study strengths.** This research provides the most complete multi-year picture currently available of the numbers and distinguishing characteristics of U.S. physicians who actually have been prosecuted or administratively reviewed for offenses involving the prescribing of CS analgesics, and of the outcomes of those physicians' cases. It also reports totals for, and trends in, the numbers and types of such cases, and in the numbers of federal investigations and voluntary physician surrenders of DEA CS registrations in recent years.

**Study limitations.** While we were able to report numbers of federal criminal investigations of physicians for CS-related offenses, we were unable to obtain comparable data on the numbers of state criminal and medical board investigations that have taken place, a matter of considerable interest to analgesic-prescribing physicians. There is little doubt that the number of physicians investigated greatly exceeds the numbers subsequently charged.

We could not unambiguously check for relationships between charges and sanctions. Due to variations in state laws and rules, prescribing-related charges brought against physicians can be classified differently amongst states or even within a state, due to variations in individual prosecutors' inclinations or styles. For example, differences between such charges as "misprescribing" and "violating accepted standards of medical care" and other bases for actions taken by state medical boards are not rigorously established, either across jurisdictions within states, or state-to-state.

Physician characteristics we examined did not include additional, potentially-relevant measures, including years since medical school graduation, years in practice, racial characteristics, or whether there were previous sanctions, warnings, or probationary periods.

Last, the DEA-provided figures on physicians' voluntary surrenders of CS registrations "for cause" include, but are not limited to, surrenders based upon having been investigated, charged, convicted, or sanctioned specifically for prescribing-related, rather than for other CS-related offenses. Thus, these figures provide only a rough indication of the numbers of physicians who may have voluntarily surrendered their registrations in lieu of prosecution or receiving harsher sanctions.

**Conclusions.** Practicing physicians, including Pain Medicine specialists, have little objective cause for concern about being prosecuted by law enforcement or disciplined by state medical boards in connection with the prescribing of controlled-substance pain medications.

Pain Medicine specialists represent only 3.5% of the 725 physicians identified as having been involved in such cases in recent years. Although the absolute number of physicians with self-identified or board-certified specialties in General Practice, Family Medicine, or Family Practice was small—only 247 (0.3%) out of 75,414 patient care physicians in 2003 with such specialties—this group still comprised the largest percentage of the 725 physicians (39.3%) involved in the criminal and administrative cases.

**Implications.** That primary care physicians are over-represented is not surprising. Given the estimated 50 million patients in chronic pain in the US (11) and the relative shortage of pain specialists to care for them (24), long-term chronic pain care generally defaults to the primary care arena where (2-5) patients instead are served by primary care clinicians, many of whom lack specific training in pain medicine or addiction medicine.

(3-11) The low rate of physician prosecutions in our study suggest that the reasons for the reluctance of physicians to prescribe opioid analgesics are complex. The widely publicized chilling effect of physician prosecution on physicians concerned with legal scrutiny over prescribing opioids(1) appears disproportionate to the relatively few cases in which convictions and regulatory actions have occurred. Thus other causal factors must be considered.

While data from this study offer insight into the actual number of criminal and administrative cases against physicians related to CS prescribing, it was not possible to review the cases in which physicians are investigated but charges are not formally raised. Records of such medical board or other law enforcement investigations generally are not accessible, and the frequency of such investigations at state and local levels is not known.

Although physician fear of regulatory scrutiny may not always be based on real threats, its effects can lead to real changes in prescribing behaviors that may substantially

undermine the treatment of pain. The alarming public health crisis of prescription drug abuse can also stimulate fearful reactions amongst government regulators and lawmakers that may render unintended collateral damage. Irrespective of the relatively few cases identified in this study, it seems likely that physicians react to frightening or inconsistent public policy statements. Likewise, they are sensitive to experience with, or lore about, investigations that were ultimately dismissed but which disrupted a medical practice and produced fear and possibly panic. Thus, the chilling effect may, in part, be related to public relations and communications problems on the part of regulators as well as to how law enforcement handles the full number of its investigations, not just those that lead to conviction or discipline. Thus, these data may be extrapolated to suggest that regulators and law enforcement may do well to improve how they craft their public messages to physicians and how they handle routine investigations of medical practice. These phenomena deserve greater study.

How law enforcement, regulators, medicine and the public interpret the recent clash of pain and the law will almost certainly influence the future climate of pain care in America. Effective solutions to the conflicting public health crises of under-treated pain and prescription drug abuse will have to address the discordant perceptions between physicians and law enforcement, and ultimately will have to address the current state of inadequate medical education on pain and safe and effective prescribing of controlled substances, as well as inadequate research on pain and drug abuse.

**Future research.** Additional empirical studies now are needed to identify reasons underlying patterns and trends identified in this study. These should include research into reasons why, in cases of this type, General Practice/Family Medicine physicians have been involved both most frequently and most disproportionately, whether physicians involved in these cases were practicing within the specialties of their training at the time, and whether geographic locations of the physicians' practices or racial characteristics of the patient populations involved had any relationship to the incidence of charges and sanctions.

In addition, subsequent studies should examine the specific types and dosages of opioid analgesics and other drugs cited as evidence of crime or unprofessional conduct, prior histories of prescription-related offenses, the roles played by prosecutors and other law enforcement officials, types of evidence brought to bear in decisions to file charges against opioid-prescribing physicians, and the criteria that are applied in decisions to prosecute a case criminally rather than to refer it at least initially to a state medical board. Data on actual numbers of state criminal and medical board investigations might be obtained by working closely with a few, select states, and then generalizing these findings.

Last, detailed research is needed into the procedural and evidentiary reasons underlying case dismissals, not-guilty verdicts, and reversals of conviction upon appeal in the small numbers of cases with these outcomes.

## ACKNOWLEDGEMENTS

**Author Contributions.** Dr. Goldenbaum had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

*Study concept and design:* Christopher, Goldenbaum, Fishman, Joranson

*Acquisition of data:* McKee, Thexton, Goldenbaum

*Analysis and interpretation of data:* Goldenbaum, Christopher, Fishman, Thexton

*Drafting of the manuscript:* Goldenbaum, Fishman, Gallagher

*Critical revision of the manuscript for important intellectual content:* Christopher, Fishman, Payne, Joranson, Gallagher, Edmondson, McKee, Thexton

*Statistical analysis:* Goldenbaum

*Obtained funding:* Christopher, Fishman

*Study supervision:* Goldenbaum, Christopher, Fishman, Joranson

**Financial Disclosures.** Dr. Fishman reported being a consultant, serving on the speakers' bureau of, and receiving grants/research support from Elan Company, Endo Pharmaceuticals, Janssen Medical Affairs, L.L.C., Merck & Company, Inc., Pfizer, Inc., and Purdue Pharma, L.P.; and having been a consultant for Cephalon, Inc., and Eli Lilly and Company. Dr. Payne reported being a consultant to AstraZeneca, P.L.C., Elan Company, Ionix Pharmaceuticals, Johnson & Johnson, Merck & Co, Inc., Pfizer, Inc., Janssen Medical Affairs, Purdue Pharma, L.P., Rinat P.G.R.D., TheraQuest Biosciences, Endo Pharmaceuticals, Xanodyne Pharmaceuticals, Inc., TransOral Pharmaceuticals, Inc., and Applied Clinical Intelligence (Pharmaceutical Research and Manufacturers of America, PhRMA).; serving on the speaker's bureau of King Pharmaceuticals, Inc.; and being a major stock shareholder of Rinat, P.G.R.D., Xanodyne Pharmaceuticals, Inc., and Prism Pharmaceuticals. Mr. Joranson reported receiving honoraria from Abbott Laboratories, Alpharma, Inc., Cephalon, Inc., Ortho-McNeil, Inc., Purdue Pharma, L.P.; and receiving grant through the University of Wisconsin from Alpharma, Inc., Cephalon, Inc., Endo Pharmaceuticals, and Purdue Pharma, L.P. Dr. Goldenbaum, Mr. Thexton, and Ms. McKee reported being compensated by the Center for Practical Bioethics for providing consulting services.

**Funding/Support.** Research, analysis, and writing expenses associated with this study were funded, in part, by unrestricted grants to the Center for Practical Bioethics from the Greenwall, Cloud L. Cray, United Health, and the William T. Kemper Foundations, and from the Mayday Fund. Remaining expenses for conducting the study were paid by the Center for Practical Bioethics out of operating funds. Unrelated to this study, the Center for Practical Bioethics has received unrestricted funding from Purdue Pharma, L.P.

**Role of the Sponsors.** With the exception of The Center for Practical Bioethics, aside from providing funds, none of the funding organizations played a role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

**Additional Contributions.** A number of individuals and organizations contributed substantially to the planning and work that led to the preparation of this article. Organizations that voluntarily and without compensation provided data, access to such data, or technical guidance, include the FSMB, the American Pain Society and the Office of Diversion Control of the DEA. Both the American Academy of Pain Medicine (AAPM) and American Pain Society (APS) voluntarily provided data helpful in shaping final research questions. Individuals providing assistance voluntarily and without compensation in conceiving and designing the study included the following: Lynne Ross, Former Executive Director, NAAG; Will Rowe, Executive Director, American Pain Foundation; Lisa Robin, Vice President, FSMB; David Hooper, FSMB; William Marcus, JD; Annette Prince, LCSW, JD, U. of Oklahoma Health Sciences Center; Robert Twillman, PhD, University of Kansas Hospital; Peggy Compton, RN, PhD, UCLA School of Nursing; Deborah Daniels, JD, Krieg DeVault LLP; Neal Kauder, President, VisualResearch, Inc.; and Penelope Ziegler, MD, Medical Director Emeritus, William J. Farley Center. The following among these individuals also provided data or access to data, technical assistance, or both: Ross, Robin, Marcus, and Hooper.

Preliminary, embargoed versions of findings were presented to members of the Balanced Pain Policy Initiative Task Force in Kansas City, Missouri in January, 2007 and in June, 2007 at the DEA National Conference on Chemical and Drug Diversion in Ft. Lauderdale, Florida.

## REFERENCES

1. Rosenberg T. Doctor or Drug Pusher? *The New York Times Magazine*, June 17, 2007, pp. 48 & ff.
2. Hoffman DE. Criminalizing the Prescribing of Opioids: Where Should We Draw the Line? Hastings Center Report, *Bioethics Forum*, April 12, 2007. Available at: <http://www.bioethicsforum.org/treating-pain-William-Hurwitz-Controlled-Substances-Act.asp>. Accessibility verified July 9, 2007.
3. O'Reilly KB. Pain Doctor Again Found guilty of Drug Trafficking. American Medical Association, *American Medical News*. May 21, 2007. Available at: <http://www.ama-assn.org/amednews/2007/05/21/prsa0521.htm>. Accessibility verified July 9, 2007.
4. Libby R. Treating Doctors as Drug Dealers: The DEA's War on Prescription Painkillers. *Policy Analysis*. 2005; 545: 1-17.
5. Roosevelt M. Why is the DEA hounding this doctor? *Time Magazine*, 25 July, 2005.
6. Reidenberg MM, and Willis O. Prosecution of Physicians for Prescribing Opioids to Patients. *Clinical Pharmacology & Therapeutics*. 2007; 81(6): 903-906.
7. Reidenberg MM. The risk of disciplinary action by state medical boards against physicians prescribing opioids. *Journal of Pain Symptom Management*. 2005; 2: 206-212.

8. Jung B and Reidenberg MM. The risk of action by the Drug Enforcement Administration against physicians prescribing opioids for pain. *Pain Medicine*. 2006; 4: 353-357.
9. Ziegler SJ, and Lovrich NP. Pain Relief, Prescription Drugs, and Prosecution: A Four-State Survey of Chief Prosecutors. *Journal of Law, Medicine, and Ethics*. 2003; 32: 75-100.
10. Meisel A, Jernigan JC, & Yougner SJ. Prosecutors and End-of-Life Decision Making. *Archives of Internal Medicine*, 1999; 159: 1089-1095
11. Kuehn BM. Opioid prescriptions soar: increase in legitimate use as well as abuse. *JAMA*. 2007; 297 (3): 249-251.
12. Jung P, and Reidenberg, MM. Physicians Being Deceived. *Pain Medicine*, 2007; 8 (5): 433-437.
13. Scanlon MM, Chugh U. Exploring Physicians' Comfort Level with Opioids for Chronic Noncancer Pain. *Pain Research & Management*. 2004; 9(4): 195-201
14. Schmidt C. Experts Worry About Chilling Effect of Federal Regulations on Treating Pain. *Journal of the National Cancer Institute*. 2005; 97(8): 554-555.
15. Passik SD, Weinreb HJ. Managing chronic nonmalignant pain: overcoming obstacles to the use of opioids. *Advances in Therapy*. 2000; 17(2): 70-83.
16. Morley-Foster PK, Clark AJ, Speechley M, Moulin DE. Attitudes toward opioid use for chronic pain: a Canadian physician survey. *Pain Research & Management*. 2003; 8 (4): 189-194.
17. Hoffman DE, and Tarzian AJ. Achieving the right balance in oversight of physician opioid prescribing for pain: the role of state medical boards. *Journal of Law, Medicine & Ethics*. 2003; 31: 21-40.
18. Gilson AM and Joranson DE. Controlled substances and pain management: changes in knowledge and attitudes of state medical regulators. *Journal of Pain Symptom Management*. 2001; 3: 227-237.
19. Alpers A. Criminal Act or Palliative Care? Prosecutions Involving the Care of the Dying. *Journal of Law, Medicine & Ethics*. 1998; 26 (4): 308-331.
20. Libby RT. Drug cops and doctors: is the DEA hampering the treatment of chronic pain? CATO Institute, Washington, D.C. Conference, September 9, 2005. Available at: <http://www.doctordeluca.com/Library/WOD/CopsDocsCato-Libby05.pdf>. Accessibility verified July 9, 2007.

21. Akl, EA, Mustafa, R, Bdair, F, Schunemann, HJ. The United States Physician Workforce and International Medical Graduates: Trends and Characteristics. *Journal of General Internal Medicine*, 1007; 22 (2): 264-266.
22. Pasko, T, Smart, D. *Physician Characteristics and Distribution in the U.S., 2005 Edition*. American Medical Association, Chicago, IL.
23. Buenaventura, RM, McSweeney, TD, Benedetti, C, Severyn, SA, Gravlee, GP. The Qualifications of Pain Physicians in Ohio. *Anesthesia & Analgesia*, 2005: 100:1746-52.
24. Breuer, B, Pappagallo M, Tai, JY, Portenoy RK: U.S. Board-Certified Pain Physician Practices: Uniformity and Census Data of Their Locations, *Journal of Pain*, 2007, 8(3): 244-250.

## TABLES

Table 1. Prevalence Rates for Specialties Observed Most Frequently Among Study Physicians

Specialties Observed Most Frequently for Study Physicians	Study N	Study Pct	US Workforce N	US Workforce Pct	Prevalence Rate/1,000 Over Study Period	95% CI	Prevalence Rate/1000 Per Year
General Practice/Family Medicine	247	39.3%	75,414	10.9%	3.3	2.9 - 3.7	0.4
Physical Medicine & Rehab	17	2.7%	6,729	1.0%	2.5	1.6 - 4.0	0.3
Pain Medicine	22	3.5%	9,371	1.4%	2.3	1.5 - 3.5	0.3
Psychiatry	51	8.1%	35,515	5.1%	1.4	1.1 - 1.8	0.2
Internal Medicine	149	23.7%	104,397	15.1%	1.4	1.2 - 1.6	0.2
Anesthesiology	47	7.5%	35,536	5.1%	1.3	1.0 - 1.7	0.1
Emergency Medicine	33	5.3%	25,470	10.9%	1.3	0.9 - 1.8	0.1
General Surgery	32	5.1%	30,812	4.5%	1.0	0.7 - 1.4	0.1
Ob/Gyn	20	3.2%	36,738	5.3%	0.5	0.3 - 0.8	0.1
Pediatrics	18	2.9%	52,449	7.6%	0.3	0.2 - 0.5	0.0

U.S. Workforce N represents total patient care physicians active in 2003. See reference (19).



Table 2. Demographic Characteristics of Study Physicians Compared with U.S. Physician Workforce.

Physician Characteristic	Study Percent	Study Total	U.S. Percent	U.S. Total (1)	Pct. Diff.	Pearson Chi Sq	df	P (Two-tailed)
<b>Gender</b>								
Male	89.4%	633	72.9%	504,710	16.5%	9.855	1	<0.001
Female	10.6%	75	27.1%	187,163	-16.5%			
Total	100.0%	708	100.0%	691,873	-			
<b>Age Range (Broad)</b>								
<55	60.5%	328	71.8%	496,980	-11.3%	34.26	1	<0.001
55+	39.5%	214	28.2%	194,893	11.3%			
Total	100.0%	542	100.0%	691,873	-			
<b>Age Range (Detailed)</b>								
< 35	3.0%	16	17.6%	121,667	-14.6%	133.13	4	<0.001
35-44	18.1%	98	26.6%	184,294	-8.6%			
45-54	39.5%	214	27.6%	191,019	11.9%			
55-64	24.0%	130	17.1%	118,571	6.8%			
65+	15.5%	84	11.0%	76,322	4.5%			
Total	100.0%	542	100.0%	691,873	-			
<b>County Where Degree Obtained</b>								
U.S. Medical School Graduate	74.6%	305	75.4%	521,672	-0.8%	0.15	1	NS
International Medical Graduate	25.4%	104	24.6%	170,201	0.8%			
Total	100.0%	409	100.0%	691,873	-			
<b>Board Certification (2)</b>								
Board Certified in at Least one Specialty	45.4%	343	79.1%	720,538	-33.7%	227.01	1	<0.001
Not Board Certified	54.6%	285	20.9%	190,550	33.7%			
Total	100.0%	628	100.0%	911,088	-			

(1) Unless otherwise noted, U.S. totals are total patient care physicians active in 2003. See reference (19).

(2). U.S. totals and percentages are based upon 2004 data provided in reference article (18).

Table 3. Numbers of Investigations, Cases, and Registration Surrenders Per Year.

Trend	Measure	Year									Total	Avg/Yr
		1998	1999	2000	2001	2002	2003	2004	2005	2006		
DEA Criminal and Complaint Investigations Into CS-Related Offenses by Physicians	Complaint Investigations	-	-	-	-	-	415	431	448	481	1,775	443.8
	Criminal Investigations	-	-	-	-	-	193	190	220	254	857	214.3
	<b>Total Federal Investigations</b>	-	-	-	-	-	<b>608</b>	<b>621</b>	<b>668</b>	<b>735</b>	<b>2,632</b>	<b>658.0</b>
Criminal and Administrative Cases Identified, by Type and Year	Administrative--State Cases	14	20	28	35	52	81	64	130	101	525	58.3
	Administrative--Federal Cases	0	2	6	3	8	21	50	26	10	126	14.0
	Criminal--State Cases	1	10	8	12	22	35	40	34	16	178	19.8
	Criminal--Federal Cases	2	9	6	17	24	22	22	35	20	157	17.4
	<b>Total Cases</b>	<b>17</b>	<b>41</b>	<b>48</b>	<b>67</b>	<b>106</b>	<b>159</b>	<b>176</b>	<b>225</b>	<b>147</b>	<b>986</b>	<b>109.6</b>
Voluntary Physician Surrenders of DEA Registrations	"Out of Business" Surrenders	-	-	16,213	15,013	19,527	19,100	NA	20,205	18,767	108,825	18,137.5
	"For Cause" Surrenders	-	-	441	350	324	352	374	360	387	2,588	369.7
	<b>Total Voluntary Surrenders</b>	-	-	<b>16,654</b>	<b>15,363</b>	<b>19,851</b>	<b>19,452</b>	<b>374</b>	<b>20,565</b>	<b>19,154</b>	<b>111,413</b>	<b>15,916.1</b>

Table 4. Percent of Cases in Which Different Types of Criminal Charges Were Filed  
WHAT YEARS?

<b>Criminal Charge Category</b>	<b>Total Charges Filed</b>	<b>Pct of Charges</b>	<b>Pct of Cases</b>
Drug trafficking/selling/illegally distributing/racketeering	257	42.4%	77.9%
Fraud: prescription, healthcare, wire, mail, other	112	18.5%	33.9%
Illegally obtaining/possessing drugs /conspiracy to obtain	89	14.7%	27.0%
Money laundering	27	4.5%	8.2%
Other/nonspecific drug act violation	24	4.0%	7.3%
Violating standards of medical care/practice	20	3.3%	6.1%
Murder/manslaughter	19	3.1%	5.8%
Records, falsifying/failure to maintain accurate/complete	19	3.1%	5.8%
Inappropriate/illegal/harmful relationships with patients	15	2.5%	4.5%
Obstruction of justice/making false statements	9	1.5%	2.7%
Prescribing drugs/refilling prescriptions illegally	9	1.5%	2.7%
Unlicensed activity	6	1.0%	1.8%
<b>Total Charges</b>	<b>606</b>	<b>100.0%</b>	<b>-</b>
<b>Total Individual Cases</b>	<b>330</b>	<b>-</b>	<b>100.0%</b>

Table 5. Percent of State Medical Board Cases Involving Different Bases for Action  
WHAT YEARS?

<b>State Medical Board Charge Categories</b>	<b>Total Charges Filed</b>	<b>Pct of Charges</b>	<b>Pct of Cases</b>
Records/reports--falsifying, failure to maintain adequate	140	16.3%	38.3%
Standards of care/practice--violating accepted medical	95	11.1%	26.0%
Prosecution/conviction for drug-related criminal offense	83	9.7%	22.7%
Prescribing practices--inappropriate/presigning pads/nonphysician use	77	9.0%	21.0%
Misprescribing--excessive doses or amounts, refills	74	8.6%	20.2%
Other/nonspecific violations of drug act, related laws/regulations	72	8.4%	19.7%
Conduct--unprofessional, dishonest, unbecoming, harmful to public	67	7.8%	18.3%
Physical/medical exams--failure to conduct prior to prescribing	62	7.2%	16.9%
Prescribing w/o medical indication/legitimate medical purpose	50	5.8%	13.7%
Negligence or gross negligence	46	5.4%	12.6%
Physician impairment/chemical dependency	38	4.4%	10.4%
Prescribing to habitual users/addicts/potentially addicted patients	37	4.3%	10.1%
Patients--inappropriate/illegal/harmful relationships with	16	1.9%	4.4%
<b>Total Charges (Bases for Action)</b>	<b>857</b>	<b>100.0%</b>	<b>-</b>
<b>Total Individual Cases</b>	<b>366</b>	<b>-</b>	<b>100.0%</b>