STATE MEDICAL BOARD RESPONSES TO AN INQUIRY ON PHYSICIAN RESEARCHER MISCONDUCT

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ABSTRACT

Misconduct in clinical research jeopardizes the integrity of medical science. Physician researcher misconduct that produces flawed results has consequences, including the subsequent inability of other physicians who rely on erroneous data to provide informed consent and/or accurate assessment of pharmaceutical and medical device efficacy and safety. This deviation from acceptable medical practice can directly harm patients. How state medical boards address this clinical problem is uncertain. To examine this issue, we asked 51 U.S. medical boards to search their databases for disciplinary action in response to physician researcher misconduct (PRM) from 1996 thru early 2007. We compared their responses with data from federal agencies responsible for disciplinary actions against clinical researchers. Our results demonstrated: i) a high percentage (45 percent) of U.S. medical boards indicated that they did not have or could not provide access to data adequate to address whether or not disciplinary action for PRM had been levied in their states and ii) of respondents able to make relevant information available, we identified only 13 cases of physician disciplinary action for PRM. In contrast, several dozen examples of disciplinary action against physicians for serious clinical research misconduct could be readily documented in publicly accessible data from federal regulatory agencies.

INTRODUCTION

Misconduct in the design, approval, conduct, reporting or reimbursement of clinical research involving physicians has broad implications for the integrity of the medical community, public health policy and the overall quality of health care in the United States.[1-5] Physician researcher misconduct (PRM) may further erode the public's faith in the medical-scientific community at a time when general concern and skepticism as to the quality and affordability of the U.S. health-care system are high.[6-10] PRM does not necessarily translate directly into compromised patient care, but lack of integrity in this regard cannot be considered a victimless crime.

Public awareness of disciplinary action for PRM is usually limited to media-exposed cases. In 1996, for example, a psychiatrist, formerly affiliated with the Medical College of Georgia, was convicted of flagrant clinical research misconduct comprising fraudulent representation of researcher affiliations, diversions of millions of dollars from corporate sponsors, falsification of research data and direct harm to patient-subjects. This resulted in surrender of his medical license and substantial jail term.[11,12] This well publicized case, however, is not unusual. Reports from the U.S Public Health Service's Office of Research Integrity (ORI), the U.S. Food and Drug Administration's Division of Scientific Investigation (DSI) and other sources clearly indicate that physician involvement in various forms of research misconduct is chronic, with evidence of increased attention to these and related problems in recent years.[13-21] Likewise, the Department of Health and Human Service's Office of Human Research Protections (OHRP), which sets standards and monitors compliance with institutional review board-based agreements, frequently issues warning letters that raise concern about PRM.[22]

Taken together, these sources of information provide strong indication that various forms of PRM may be more widespread in the medical community than is commonly appreciated, and therefore potentially of increased concern to state medical boards. However, information pertaining to physician disciplinary action by state medical boards can be difficult to obtain in general[23,24] and the complexity of the issues surrounding PRM in particular

may present additional barriers to transparency of reporting.[25,26] We sought to explore the responses of medical boards to a specific query on disciplinary action for PRM in their states.

METHODS

The medical boards of all 50 U.S. states plus the District of Columbia were canvassed between March and May, 2007. Each query letter was addressed to the official(s) involved in board disciplinary orders.

We introduced ourselves as a physician led group "conducting a research project for publication examining public records regarding the number of licensed individuals who have faced discipline (sanction, reprimand, suspension or revocation of license) due to engaging in research fraud or other forms misconduct related to conducting clinical trials." We further requested that the medical board officials "provide a list of all licensed individuals, including the date and the punishment administered, who have been disciplined for the above forms of conduct from 1996 to the present. If there have been no such actions by your licensing authority, please respond in writing to that effect."

We did not specify the particular types of documents that may have been involved in disciplinary action, having anticipated variability from state to state, and to encourage a broader overall response. When we received responses from state medical boards with inadequate details pertaining to the criterion used in our study, we utilized both state board Internet sites and additional formal requests to obtain further documentation or clarification. We then derived simple descriptive statistics to organize the responses that we had received, and to the extent possible abstracted the circumstances, dates and type of disciplinary action taken.

Comparable information about disciplinary action for PRM over the same time-frame (1996 to the present) was obtained from the U.S. Public Health Service's Office of Research Integrity (ORI), the U.S. Food and Drug Administration's Division of Scientific Investigations (DSI) and the Department of Health and Human Service's Office of Human Research Protections (OHRP) for purposes of comparison. Data from these agencies was obtained almost entirely from publicly available internet websites, but we made telephone contact with agency officials in a few cases to obtain clarification. We systematically examined all of the sequentially published reports from those agencies on disciplinary action, but only abstracted information pertaining to action(s) against physicians related at least in part to the design, approval, conduct, reporting or reimbursement of clinical research. Our work was privately funded. The cost of this research project was modest, estimated at less than $1,000. No IRB was required since there was no human experimentation. All of our primary data and sources are available for review.

RESULTS

The State Medical Board Responses

We received official responses – typically in the form of a return letter on state medical board stationary – from 46 of the 51 addresses (90 percent). We did not receive responses from five states (follow-up letters were sent out after a three-month waiting period). The responses were put into the following categories with the number of disciplinary actions in parentheses next to each state listed.

1a. Complete responders (positive; definite documentation of disciplinary action for PRM) – Maryland (n=1), Minnesota (n=1), New York (n=3), North Carolina (n=2), Ohio (n=1), Rhode Island (n=1), Louisiana (n=1) [14 percent of the all responders] (see table 1 below for details).

1b. Complete responders (indefinite or pending action(s)) — Alabama (n=1), Louisiana (n=2) [four percent of all responders] (see table 1 below for details).

1c. Complete responders (negative; no evidence of disciplinary action for CRM) — Alaska, Delaware, District of Columbia, Florida, Hawaii, Idaho, Indiana, Iowa, Kansas, Maine, Mississippi, Montana, New Hampshire, New Mexico, North Dakota, Oklahoma, South Dakota, Tennessee, Vermont, West Virginia [39 percent of all responders].

2. Incomplete responders (no available database or no access) — Arizona, Arkansas, California, Colorado, Connecticut, Georgia, Kentucky, Massachusetts, Michigan, Missouri, New Jersey, Pennsylvania, Texas, Utah, Virginia, Washington, Wisconsin, Wyoming [35 percent of all responders].

Federal Agency Databases

Systematic Review of ORI records covering the past 10 years revealed 22 instances of formal disciplinary action against physicians for research misconduct, although

Table 1. Characterization of Disciplinary Actions for PRM by State Medical Boards (subgroups 1a & 1b) 1996-2007

State	Brief Description of PRM	Date of Action	Action Taken
Maryland (1)	A Md. physician diverted more than $30,000 for personal use from a fund intended for 'treatment and research on cancer patients'.	May 2002	reprimand; ordered to take an ethics course
Minnesota (1)	A Minn. physician was accused of gross profesional misconduct, including:	July 1996	Temporary suspension of license
	The mismanagement of patients enrolled in clinical trials involving psychoactive medications; the complaints cited against him extended more than 50 pages in the board's 'stipulation and order' document;	July 1998	Allowed to practice under supervision
	The same physician was reprimanded again, several years after regaining a non-probated medical license, for writing prescriptions under false names and failing to provide requested medical records.	June 2006	Corrective order re: need to demonstrate knowledge of relevant statues; no further actions taken
New York (3)	N.Y. Physician A performed variations on a face lift procedure, involving use of different techniques on the left and right sides of face (!) under an assumed clinical research protocol with no informed consent plus failure to keep relevant records.	March 2002	Public censure and reprimand
	N.Y. Physician B performed variations on a face lift procedure, involving use of different techniques on the left and right sides of face under an assumed clinical research protocol with no informed consent plus failure to keep relevant records.	Feb 2002	Public censure and reprimand
	N.Y. physician C misrepresented himself as holding a Ph.D. on medical and scientific documents; he fabricated animal research results submitted to medical journals.	Nov 2001	License placed on probation plus 100 hrs. public service
North Carolina (2)	N.C. physician A misrepresented clinical credentials and engaged in fraudulent animal research funded by the N.I.H.	Oct 2005	Entered into a Consent Order, reported to National Practitioner Data Bank
	N.C. physician B failed to follow post-surgical care protocols and fabricated follow-up visit data in a pediatric ENT research project.	Dec 2002	6-month suspension of medical/surgical license
Ohio (1)	An Ohio physician pleaded guilty to five felony counts of aggravated grand theft in connection with misuse of funds owned by the Cleveland Clinic Foundation, in part related to clinical research.	Jan 1996	Min. 5 years probation of medical license
	The same physician was later disciplined for repeatedly providing false information as to his specialty board certification.	Feb 2003	Medical license permanently revoked
Rhode Island (1)	A R.I. psychiatrist was practicing under a restricted medical license because of prior sexual misconduct and was then disciplined for not abiding the supervision of an assigned professional monitor and conducting research on patients not as part of any research protocol, i.e., no I.R.B.-involvement, no informed consent.	Aug 1998	Medical license revoked
Alabama (1)	An Ala. physician is alleged to have provided inadequate medical care to patients engaged in a clinical research trial.	April 2007	Case under review
Louisiana (3)	La. physician A was disciplined in a reciprocal action after he had been suspended by his employer for clearing patients for entry into a research protocol in a manner that was deemed inappropriate.	1990s	Suspension of license
	La. physicians B and C currently are under federal indictments for Medicaid and Medicare fraud and, evidently also clinical research fraud; the executive director of the Louisiana State Board of Medical Examiners indicated in his correspondence that any future La. board disciplinary actions will hinge on the circumstances of the prosecutions for Medicaid and Medicare fraud.	Current	Cases under review; pending concomitant federal prosecution

Disciplinary Action for CRM = 10; Cases Under Current Review = 03; To tal = 13

Guide to Table 1. This is a summary of disciplinary action for PRM during a 10-year period. It includes a description of the specific offenses, the dates of action taken and the type and/or extent of punishment. Next to each state that provided us with a 'positive' response, the number of licensed practitioners receiving disciplinary action(s) for research misconduct in that state is listed in parentheses.

Table 2. Brief summary of disciplinary actions taken for PRM or warnings made to physicians by federal agencies that oversee clinical research (ORI, FDA and OHRP), 1996-2007.

Agency	# Actions against physicians	Type of actions
ORI	22	Public reprimands, requests for additional oversight and/or training, exclusion from access to future federal funding
FDA	20	Exclusion from access to investigational products and future research funds
OHRP	76	"determination letters", serving as warnings; reminders as to prior "assurance of compliance" agreements

about half of these cases involved misconduct that could not be construed as directly involving patient care (e.g., plagiarism or dishonesty in reporting clinically relevant research data, misuse of funds, affiliated bench research misconduct, etc.)[13,14] (see Table 2). Similarly, the FDA's disciplinary arm (DSI) reported actions against an additional 20 physician-investigators during the past 10 years. Federally mediated sanctions were not infrequently severe and included total debarment or long-term exclusion from future access to federal resources, criminal charges through the Department of Justice and demands for restitution in cases of outright financial fraud.

The review of OHRP records over the same time frame is more difficult to place in context because there were literally hundreds of "determination letters" sent out to physician-investigators over the 10 years in question.[22] Even in the case of the more egregious alleged research practice violations, these letters from OHRP served as warnings only and were not predictably followed by formal investigation or disciplinary action. Nonetheless, we were able to identify 76 warning letters from OHRP to physician-investigators that raised concern about clinical research misconduct, the significance of which was indicated by the fact that most of these were related to issues of patient safety and informed consent.

DISCUSSION

In our query of state medical boards, we obtained clear evidence of disciplinary action for PRM in only 13 cases distributed over approximately 10 years. Of interest, three of these 13 were cases under current and active review, perhaps indicating a recent increase in attention to this problem by some state medical boards. Several of these PRM cases involved only public reprimand. There were two instances of revocation of licensure, and six instances of suspension of licensure, with or without probationary arrangements. It is noteworthy that disciplinary action for PRM is much less common than other types of state board disciplinary actions, less than 0.1 percent of the total.[27,28]

In contrast, federal agencies that oversee clinical research have publicly made available dozens of examples of disciplinary action and warnings that express concern about PRM over the same 10-year period that we examined. Such actions by federal authorities are clearly increasing.[7,29] These observations and reports from the federal agencies are consistent with recent anonymous surveys of senior researchers,[2,19-21] indicating that medical research fraud and misconduct may be much more widespread than is generally appreciated.

One of the major findings of our survey was the wide variation in data access to the medical board officials themselves, with obvious implications for public access to information and transparency. We received no response from 10 percent of the 51 jurisdictions queried, and incomplete responses (most often indicating of no access to relevant data) from an additional 35 percent. A few state medical boards have a policy of not publicly releasing information concerning some disciplinary actions against physicians, policies evidently maintained to protect physician privacy. This relative lack of transparency is consistent with the observations of a physician-led patient advocacy group which monitors public access to information related to general disciplinary actions against licensed physicians.[23,24]

Barriers to Greater Medical Board Involvement

The extent of involvement of licensed physicians in clinical research misconduct is not fully known and may not be discoverable at this time given the current legal, structural and administrative obstacles to disclosure. What are some of the barriers to potentially greater medical board involvement in pursuing and reporting disciplinary action for PRM?

1. The charters of the various state medical boards are limited by the statutes and mandates of the respective state legislatures. Medical boards have traditionally handled individual inquires and complaints, particularly in response to clinical practice concerns, abili-

ties of physicians to practice safely, mandated investigations regarding felony convictions, DUIs, drug and alcohol problems and sexual boundary violations.[28] These make up the vast majority of disciplinary actions across the country.

2. As would be expected in any form of professional discipline, acceptable definitions of PRM vary, and considerable discretionary latitude exists in the exercise of particular disciplinary actions.

3. State medical boards vary substantially with respect to staffing and resources committed to the development of databases and dissemination of information. Apart from the propensity of a given board to prosecute, considerable variability in the use of user-friendly computerized databases clearly exists.[23]

4. Most clinical trials in the United States are financed privately (about 80 percent by current estimates),[31] and state medical boards have no clear-cut jurisdiction in the case of PRM in proprietary clinical research, unless patient-subject care was demonstrably compromised.

5. Neither private nor federal sponsors of clinical trials have codified reporting requirements or disciplinary protocols when it comes to the state medical boards.

Our study was limited in particular by the third area of consideration enumerated above. While a few of the boards responded to our query with detailed recounting of disciplinary actions, including full transcripts of the consent orders and/or full case histories (e.g., New York, Rhode Island), most of our "complete" respondents — subgroups 1a and 1b — provided only the names, dates involved and brief description of the final action. Furthermore, many of the negative responses we received from "complete" responders (i.e., 'no instances of disciplinary action for PRM over the time period in question') do not imply an exhaustive or even adequate database search by those particular state medical boards.

The Big Picture

Clinical trials have assumed a much larger role in our medical culture over the past two decades, both from the standpoint of their influence on emerging clinical practice standards and on resource commitment.[31-33] Spending on clinical trials in the United States was an estimated $25 billion in 2006 and it is expected to reach about $32 billion by 2011; most spending on clinical trials in the Unites States comes from private industry, with federal funding assuming a considerably smaller yet substantial second place position (the NIH budgeted $3.0 billion for clinical trials for 2006). However, since public resources support the federal approval process necessary for bringing a pharmaceutical agent, biological product or medical device to market, demarcation between private and public financial resources is blurred.[34]

Licensed physicians are frequently – in fact, almost always – involved in the conduct of both publicly and privately financed clinical trials and other forms of clinical research. They often assume leadership roles that extend beyond the planning and execution of the trials in the FDA-approval process to subsequent participation in various post-marketing efforts. The latter effort includes promulgation of research results to other practicing physicians and potential consumers in various public forums, design and implementation of follow-up studies (phase IV studies which usually focus on extending safety data) and scholarly publications. In particular, it is through these latter activities that PRM may be translated directly into flawed patient care and misguided standards of practice.[18,26,36-41] Because physicians assume enormously influential positions with respect to the quality, cost and general direction of health care policy in the states in which they practice and to the patients who are recipients of that care, greater attention to PRM seems justified.

CONCLUDING COMMENTS

When we consider the major implications of PRM for standards of clinical practice and patient safety, the current reality of disciplinary action against physician-investigators appears weak and inconsistent. Because physician-investigators often recruit patients as research subjects from the states where they practice, we believe that state medical boards should consider taking a more active role in monitoring and responding to infractions, even in cases where demonstrable harm to individuals is not available. This approach would be in line with the current policies of most medical boards involving physicians with mandated investigations regarding clinical incompetence, felony convictions, sexual boundary violations, DUIs and drug problems, who are identified and sanctioned in large part out of concern that these physicians may – in the future – harm patients. Similarly, a physician investigator with a history of PRM may directly or indirectly harm a multitude of patients.

A simple, consistent definition of PRM is suggested for

future adoption by the medical community, in line with a recent report from a representative of the US Department of Justice.[7] We suggest: *The knowing breach of the standard of good faith and fair dealing as understood in the community, involving deception or breach of trust ... by a physician engaged in the design, approval, conduct, reporting or reimbursement of clinical research.* In future efforts we will explore the various forms of PRM, the complex legal basis of disciplinary action and those issues that more directly address responsibility and corrective actions.

AUTHOR AFFILIATIONS

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