Editorial

Sham Peer Review and the National Practitioner Data Bank

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The National Practitioner Data Bank (NPDB), which began in 1990, was created by a federal law passed in 1986 known as the Health Care Quality Improvement Act (HCQIA). The stated purpose of the NPDB and HCQIA was to prevent incompetent physicians from moving from one location to another to continue to practice medicine.

In congressional hearings in 1986, Rep. Henry A. Waxman (D-CA-33), a co-sponsor of the bill (H.R. 5540, HCQIA), stated:

As you know, the essential feature of H.R. 5540 is its reporting system. Under our bill, doctors who have lost their hospital privileges, or who have paid malpractice claims, will be reported to a central data bank. This information will be available to the peer review community on an ongoing basis—ending forever, we hope, the ability of bad doctors to hide their unsavory pasts.²

Concerns were raised at the time that the strong immunity HCQIA provided would invite abuse of the peer review process and ruin or end the careers of physician whistleblowers and other physicians for purposes unrelated to professional competence or conduct. However, Rep. Waxman, who retired from the U.S. House of Representatives in 2014, provided strong reassurances that those concerns were unwarranted, and that the law would not protect what is known as sham peer review:

As I understand it, one of the main purposes of this morning's hearing is to permit doctors who believe that they were victimized by improper peer review procedures to testify about their experiences. Of course, I do not know the details of the cases that will be described today. I want to make it clear, however, that we fully agree that we <u>cannot</u> [emphasis in original] tolerate abuses of the peer review system, and that H.R. 5540 was never intended to protect any such abuses.

This is true whether the concern is with anticompetitive activities, with actions based on race, or <u>any other</u> [emphasis in original] prejudicial or discriminatory factors. We have emphasized this throughout our discussions of this bill within the Energy and Commerce Committee and with the staff of the Judiciary Committee.

To reiterate: <u>nothing</u> [emphasis in original] in H.R. 5540, as currently drafted, would protect the type of abuse that I have referred to....

I appreciate that any form of immunity raises concerns about the potential for mischief that might be visited by doctors on their colleagues for improper reasons. But, let me say that we have had numerous—some might say endless—discussions with those interested in, and affected by our bill, to remove such cause for alarm....

Let me also say that I believe our bill is so tightly worded that it could not possibly bar a doctor victimized because of his or her race, age or sex from pursuing all [emphasis in original] remedies currently available under our civil rights laws. Nor could it be used to shield actions to harass physicians who are willing to blow the whistle on their incompetent colleagues. If there are any [emphasis in original] lingering doubts on these points, I am prepared to add yet more language clarifying that competence and conduct under H.R. 5540 cannot [emphasis in original] be judged on the basis of matters that would violate our civil rights laws or that would deter whistle blowers.²

Unfortunately, as a result of the strong immunity provided by HCQIA, combined with the judicial doctrine of non-review and case law (the "objective test"), the limited and qualified immunity intended by Waxman has been transformed into nearly absolute immunity.³ Widespread abuse of the peer review process, sham peer review, is well-known and has often been shielded by immunity provided by HCQIA. Improper motives underlying sham peer review have included, but are not limited to, anti-competitive motives, retaliation against physician whistleblowers, and discrimination based on race, ethnicity, sex, and age.

Accuracy of NPDB Reports Questioned

Because an Adverse Action Report in the NPDB can ruin or end a physician's medical career, the accuracy of information contained in NPDB reports is of paramount importance. However, since its beginning in 1990, the NPDB has been plagued with questions about operational efficiency, effectiveness, and accuracy of information.

A report of a General Accounting Office (GAO) study, published in November 2000, stated:

Because NPDB information can affect a practitioner's reputation and livelihood, the integrity of the data bank's information has been of great concern.

Since its beginning in 1990, questions have arisen about NPDB's operational efficiency and effectiveness....

In addition, various organizations representing the health care industry have periodically questioned the accuracy of information submitted to NPDB....

Problems that we identified in the data submitted to NPDB during September 1999 raise concerns about the effectiveness of HRSA's management of the data bank and of the two mechanisms—practitioner notification and dispute resolution—that are intended to ensure the <u>quality</u> [emphasis in original] of reported information.⁴

Incredibly, the GAO report also found that one-third of the adverse action reports in the NPDB were inaccurate: "We also found inaccurate information in about one-third of the 79 clinical privilege restriction reports we reviewed." 4

The GAO study also reported: "HRSA officials acknowledged that there are problems with the accuracy and completeness of the data and that they have been working with consultants to revise the way information reported to the data bank is coded." However, no follow-up GAO study has apparently been done to determine whether proposed improvements have resulted in actual improvements in accuracy.

Problems with the accuracy of information contained in Adverse Action Reports in the NPDB continue, largely because of legal limitations imposed on the scope of review performed by the data bank.

NPDB Determination of Accuracy Highly Flawed

In making a determination regarding the reportability and accuracy of information provided by a hospital to the NPDB, for instance, NPDB only evaluates the documentation submitted by the hospital (e.g. meeting minutes, hearing panel and appeals findings and reports, etc.), and if the documentation even minimally supports the action taken, then NPDB assumes it is "accurate." If the documentation provided by a hospital supports the reportability according to NPDB guidelines, then it is judged to be reportable. In effect, the fox is put in the position of guarding the chicken coop.

Law review articles put it this way:

The HCQIA, from which the National Practitioner Data Bank was born, has been said to be "a club, a sword that allows hospitals to do whatever they want to do: lie, cheat, embellish, ameliorate, alter records [and] commit fraud..." Ironically, the HCQIA, which was intended to achieve many of the same objectives as the PSQIA [Patient Safety and Quality Improvement Act], has led to illegitimate disciplinary action against physicians who have done nothing but try to improve the safety and care of their patients.

The NPDB is the mechanism that converts an adverse action, taken as a result of sham peer review at the local level, to a professional death sentence for a physician's career at the national level. False and defamatory information provided by a hospital to NPDB is published and disseminated by the data bank, to the detriment of physicians who have done nothing wrong.

Irreparable Harm Done by Adverse Action Report in NPDB

Professor Katherine A. Van Tassel, J.D., details the irreparable harm done by an adverse action report in the NPDB.

The NPDB reporting and publication system has the intended impact on the targeted physician as, once the NPDB has published a negative report on a physician, the physician's reputation is irreparably damaged. Physicians report that a negative report is a "career ender" because it is difficult, if not impossible, to find a new position after a negative report...

Once a physician has had his hospital staff privileges terminated or curtailed at one hospital, a second hospital is highly unlikely to allow the physician staff privileges as, in so doing, the second hospital places itself at risk of being sued for negligent credentialing.⁷

Prof. Van Tassel goes on to delineate how an adverse action taken by a hospital can lead to an investigation by a medical board, putting the physician's license in jeopardy, as well as difficulties obtaining liability insurance and listings on insurance panels.⁷

Another law review article noted not only the severe irreparable harm done by an adverse action report, but also the enormous social waste when patients are subsequently deprived of the services of a good physician when the physician is excluded from insurance networks:

Further, when these improperly severe disciplinary measures are reported to the NPDB, such reports can seriously damage a physician's ability to practice medicine, as employers and health insurance companies may be reluctant to hire or utilize practitioners with such adverse reports....

In enacting the HCQIA, Congress was far more concerned with reducing improper leniency than with reducing improper severity. The immunity in the HCQIA, and in parallel state statutes, allows peer review bodies to impose discipline without much fear of litigation, even though this immunity makes it easier to conduct sham peer review. The NPDB system spreads reports of discipline nationwide, even though this reporting system magnifies the effect of sham peer review and may drive good doctors out of the profession.⁸

Judge Brad Newman, in the case of Jesse Cole, M.D., v. St. James Healthcare, concluded in his ruling: "An adverse report to the Data Bank is akin to a 'scarlet letter' that could permanently harm a physician's professional reputation." 9

In yet another case, Yelena Levitin v. Northwest Community Hospital, Judge Mary Ann Mason stated the following in her ruling on a motion seeking injunctive relief: "Finally, I find that Plaintiff is likely to sustain irreparable harm in the absence of injunctive relief because once the termination of her privileges at Northwest Community [Hospital] are reported to the National Practitioner Data Base, there is a domino effect on Plaintiff's reputation and ability to practice elsewhere." 10

And, in response to a hospital's argument that an NPDB adverse action report would not result in irreparable harm to the physician because the report could be voided in the future if necessary, the Court in the case of *John Doe, M.D., v. Community Medical Center*, wrote: "[T]he fact is that a ringing bell cannot be unrung." 11

It's also well-known that an adverse action report in the

NPDB has a much more devastating effect on a physician's career than reports of malpractice verdicts or settlements posted in the data bank. The 2000 GAO report on the data bank noted: "Industry experts also agree, pointing out that disciplinary actions taken by health care providers and states are better indicators of professional competence than medical malpractice."

Removing a Wrongful Adverse Action Report from the NPDB is Nearly Impossible

Once a wrongful, inaccurate adverse action report has been filed with the data bank, there really is no good mechanism to get it removed. Even when charges against a physician are found to be totally without merit, the adverse action report may remain in the data bank, plaguing the physician for the remainder of his career.

Prof. Van Tassel noted this same severe problem in the law review article she authored:

Finally, there does not appear to be any mechanism to remove negative peer review reports in light of a subsequent finding by medical licensure boards that there is no merit to hospital charges of incompetence, even though medical licensure board proceedings are far more rigorous than private peer review and are conducted by disinterested third parties in keeping with due process requirements.⁷

The 2000 GAO report on the NPDB also noted that agency officials recognized the difficulty of getting wrongful reports removed from the NPDB: "Agency officials also realize that practitioners can face difficulties in correcting reported information."

As Prof. Van Tassel noted, alleged sexual predators and terrorists receive more due process protection before being blacklisted in a federal database than do physicians accused of incompetence or professional conduct deficiencies.⁷

Successful Challenges to Wrongful NPDB Reports

The internal administrative procedures of the data bank are largely ineffective in getting an adverse action report based on sham peer review removed from the NPDB.

In rare instances, wrongful and inaccurate adverse action reports have been removed from the NPDB as the result of litigation. Successful legal arguments have included violation of the Federal Privacy Act (5 U.S.C. § 552a (1974)) and violation of the Administrative Procedure Act (Pub.L. 79–404, 60 Stat. 237 (1946)).

In a 2004 case, *Doe v. Thompson*, the Court held that: "prior to disseminating any record about any individual to any person other than an agency, [the government agency] must make reasonable efforts to assure that such records are accurate, complete, timely, and relevant for agency purposes." ¹²

In a case in 1998, Simpkins v. Shalala, the Court rejected the HHS Secretary's argument that the government did not need to review the accuracy of the NPDB report, and that simply noting that there was a dispute and offering the physician the opportunity to post a statement disagreeing with the action was sufficient to remedy the matter. The Court stated:

Defendants appear to argue that they did not need to review the accuracy of the information submitted to the Data Bank. The defendants phrase this argument as support for the contention that plaintiff was given meaningful notice or opportunity to contest his listing in the Data Bank. Nevertheless, this court disagrees with the implication of defendant's argument, namely that the Secretary could resolve all concerns about a Data Bank report by simply "noting that a dispute exists about the accuracy of the information and including a brief statement by the physician or practitioner setting forth the disagreement regarding the information." ¹¹³

The Court also found that the hospital involved did not follow its own medical staff bylaws in conducting peer review of Dr. Simpkins, and that the HHS Secretary's failure to consider this fundamental deficiency rendered the Secretary's actions arbitrary and capricious, warranting the directed removal of the wrongful adverse action report from the data bank. The Court stated:

The "review" of Dr. Simpkins did not follow this D.C. General procedure...nor was "an investigating committee" appointed as required by the Bylaws. These deviations from the Bylaws were not minor but rather fundamental in nature and indicate that these actions cannot be reasonably found to constitute an investigation by D.C. General.

The Secretary's failure to follow these authorities or from all appearance even consider these provisions renders the Secretary's actions arbitrary and capricious. In light of these facts, this court cannot sustain the Secretary's decision. It does not amount to an exercise of reasoned decision making. Guided by the deference to which HHS's decision is entitled, this court nevertheless is convinced that the Adverse Action Report concerning plaintiff should be removed from the Data Bank due to the arbitrary and capricious action of the defendants.¹³

The ability of a physician to post a written rebuttal statement on the NPDB, disagreeing with the validity of the action taken against him, does not alter the devastating impact the adverse action report has on his career. The content of an adverse action report and the fact there is a dispute and a rebuttal statement is largely irrelevant. It is the mere existence of the adverse action report in the NPDB that ruins or ends the physician's career.

Interview with NPDB Director David Loewenstein

In an effort to obtain the NPDB view of sham peer review as it relates to the data bank, the *Journal* conducted an interview with the current director of the NPDB on Jul 28, 2017.

David Loewenstein has been the director of the National

Practitioner Data Bank (NPDB) for about six months. Before that, he worked in the Division of Practitioner Data Bank as the compliance branch chief a few years ago.

Loewenstein described his main duties as director as follows:

Primarily the director's duty is to make sure that we are running a good program. We make sure our system is meeting all the IT needs that our user's needs are met but primarily that we are implementing the statutes and regulations that underpin the NPDB.

Written questions were provided to Director Loewenstein before the interview so he would have the opportunity to research the answers to questions as needed.

Journal: Question #1: Are you aware of something called "sham peer review"?

Loewenstein: Yes, I am aware. As you know Congress had specific concerns when it established HCQIA in 1986, concerns of protecting patients from incompetent physicians and so it was believed that effective peer review was the best way to resolve that, and they outlined that in HCQIA both in subchapter 1 with promotion of professional peer review and in subchapter 2 with reporting of actions to the NPDB.

Journal: Right, and at the time, when they were holding hearings in October of 1986, former Congressman Henry Waxman provided assurances that this HCQIA law would not be subject to abuse of the peer review process and, of course, unfortunately, the strong immunity provided by HCQIA has basically invited abuse which is now pretty much widespread.

Question #2: Are you aware that an Adverse Action Report filed by a hospital against a physician who is a victim of sham peer review either totally ruins or ends the doctor's career? Agree, disagree, any comment?

Loewenstein: We don't collect any data on sham peer review, but I can speak in general with NPDB reports. I wouldn't agree that it would necessarily ruin a doctor's career. We believe the NPDB to be a valuable workforce tool. We provide information to entities when they make their hiring, credentialing, licensing, etc. decisions. It's primarily designed to be a flagging system that alerts those entities as part of a comprehensive review of the qualifications and background of the health care practitioner. It is not intended to be used on its own. So, it should be used in combination with other sources that entity would receive. We are not a sole source verification tool. We ask that those entities do more research when seeing an NPDB report. And, we have done some research to show that is indeed what they are doing. We did a survey a few years ago and it showed about 2/3 of health care entities the next step they take when seeing an NPDB report is that they seek additional information, which is just what we would ask them to do to try to find out exactly the entirety of the story to help them make a good decision.

Journal: I should clarify that I know there are different kinds of reports made to the National Practitioner Data Bank, those involving malpractice verdicts and settlements and Adverse Action Reports. And, the type I'm talking about is the Adverse Action Reports. And, it has certainly been my experience over the past 13 years or so that the Adverse Action Report is, in fact, a flagging mechanism. It provides a red flag for any hospital that is considering putting a physician on medical staff. As you know, they are required by law to query the data bank before putting someone on staff and then every two years thereafter for renewal of privileges. And, we know from testimony of hospital administrators that they don't look much farther than the fact that there is an Adverse Action Report when they deny privileges. So, the content doesn't matter so much as the fact that there is an Adverse Action Report. And, in the case of physicians who are incompetent,...it eliminates their ability pretty much to get privileges anywhere else, which is a good outcome. But in the case of physicians who have done no wrong and have been victims of false accusations and improper peer review, it does destroy their career. In fact, a judge in Montana referred to it as a "scarlet letter," and he recognized that it does pretty much permanent damage. And, I certainly know of some physicians that have an Adverse Action Report, who had done nothing wrong. They were victims of sham peer review, usually meaning false information was brought against them, and the hospital rigged the peer-review process. And, some of those physicians have committed suicide as a result.... I have calls from physicians every week or contacts by email.... I don't know of too many that have been able to get any medical staff privileges after having an Adverse Action Report in the data bank even when they put their rebuttal information as to the fact that there were false charges, etc.

Question #3: In the experience of the NPDB, how common are Adverse Action Reports based on bad faith peer review?

Loewenstein: I really don't have any way to answer that question since we don't collect that kind of data, and it's really not the role of the NPDB to investigate the underlying merits of the peer-review process. We get about 100,000 reports. Last year we got about 100,000 reports, and we don't substantively examine the reports unless they are disputed by the subject of the report. The subject, as you mentioned, can add a written narrative to tell their side of the story or challenge the assertions that are made in the report. We also forward them that dispute resolution process to elevate that report. And, it is really at that time when we review the report. But, it is important to note that through statute and regulations the review is limited to two things: whether the report was submitted in accordance with NPDB reporting requirements, including the fact that it must be a professional review action related to professional competence or conduct, and the other thing we look at is the factual accuracy of the information based on the records we receive. So, we do not review the underlying merits of

the action that was taken nor do we have the authority to substitute our judgment for that of the reporting entity.

Journal: Right, and I was aware of that legal limitation. There was a former associate director of what is called Research and Disputes Division there, I think it was Mr. Robert Oshel,... who answered some similar questions in a book entitled Sham Peer Review by attorney Gregory Piche, and so his answers are in the last section of that book. And, he said that he was in a position of basically reviewing the Secretarial Reviews that were requested, and he was aware of the fact that there were some bad faith peer reviews, but in his opinion, the only thing that they could do from the data bank's standpoint was to pressure the hospital to withdraw the report. But, they didn't really have any leverage or legal authority to require [the hospital] to do so.

Loewenstein: And, that's not even an element that we evaluate because we don't have that authority. And, I really can't speak for Mr. Oshel.

Journal: Question #4: What does the Health Resources and Services Administration (HRSA) do when it suspects an Adverse Action Report is based on a bad faith peer review? So, suppose the doctor has provided you with documentation and information that shows that the charges were totally false against him and he didn't get due process in peer review, and you can kind of see that there might be something wrong with that even though you don't have the legal authority to do anything about it as far as investigating merits or lack thereof. But, you might suspect there is a problem. What does the HRSA do in those instances?

Loewenstein: The first thing we do in any instance of a dispute is we look at all the materials we receive, and we evaluate the two elements I told you about. If the report submitted is not factually accurate according to the record that was created by, say the hospital, we would certainly instruct that to be corrected or voided depending on what the outcome was. But, other than that, like I said, we really don't evaluate those underlying merits. So, if that is what the physician was telling us, and it could be any practitioner, but a physician in this case, that they were the victim of a bad faith peer review, we would let them know that's outside the scope of our review authority and they should look into that via a different venue, be it with the reporting entity or some other venue.

Journal: So, although you would recommend to the hospital in those cases where it doesn't look as if the factual evidence supports what was done that the hospital should withdraw the report, you don't have any legal authority to do that, right? To force the hospital to withdraw it?

Loewenstein: If it is not reportable to the NPDB, certainly we would instruct them to do so and if they didn't do it,

we would do it ourselves. If the report is not supported by those underlying records...[say] if the report tells us that they suspended a doctor's clinical privilege for a period of six months and the records they show us don't demonstrate that occurred, we would absolutely instruct them to void that report and if they refused, we would do it ourselves.

Journal: I'm going to jump down to question #7 because it kind of ties in here.

According to your website, reporting entities such as hospitals are responsible for the accuracy of the information in Adverse Action Reports. Isn't that a little like asking the fox to guard the chicken coop?

Loewenstein: I don't think so. We're operating the NPDB according to statute and regulation. We do provide practitioners multiple avenues to insist in making sure that that report is factually accurate. We do notify practitioners when they are the subject of a report. We provide them the opportunity to query us at any time for a fee of only \$4. They can add that subject statement we referred to earlier to tell their side of the story. And, then also we talked about our dispute resolution process, that if it is not factually accurate they certainly can come to us and we will evaluate the accuracy of the report versus the record of the entity.

Journal: But, when you say accuracy of the report I think the data bank presumes that the information, provided by the hospital in meeting minutes or whatever, is factually accurate, right? I mean, it's a presumption on the part of the data bank, and there isn't anything else really that you would do to see whether that was true or not?

Loewenstein: Yes, that would be outside the scope of our review to look at the underlying merits of the action.

Journal: Right, and just so you know I have seen testimony by a hospital CEO, who testified that he altered the records basically to make the doctor look incompetent. He admitted that in sworn testimony and really found no problem with that. So, the information the hospital provided at least in that case was false information and there would be no way to really do anything about that.

Returning to Question #5: Under what circumstances can HRSA void an Adverse Action Report in the NPDB?

Loewenstein: So, one thing I also want to mention is there are corrections as well, so if something is wrong we would instruct it to be corrected. But in terms of a void there's really three reasons that we would void a report and/or direct an entity to void a report. There are really only three reasons an entity should void a report on their own. Number one, it was submitted in error. It was not intended to be submitted, and they would void that immediately. The second reason would be that the action wasn't reportable because it didn't meet the statutory and regulatory reporting requirement.

And, the third reason would be that action that was taken was overturned on appeal. So, essentially that action is no longer valid, that report would be voided.

Journal: Question #6: Is there a mechanism for removal of an Adverse Action Report when a physician obtains a jury verdict, finding that a hospital violated its medical staff bylaws and failed to provide due process in conducting peer review? Or, for example, a physician is exonerated by an internal review proceeding in a hospital—a summary suspension, for example, where a hearing is held after the punishment is administered and the hospital, finding that there is no merit to uphold the summary suspension, immediately lifts it.

Loewenstein: Those are really two different questions. I'll handle them separately if you don't mind. First with regard to the jury verdict, what we have to do is, we have to review how that verdict affected the underlying action that the hospital, for example, took. So, if that underlying action would be overturned by the jury verdict, then it would fall into that void situation I just talked about earlier. So, that action no longer would exist. In terms of a physician being exonerated by an internal review proceeding, so any action is overturned on appeal, that would need to be voided.

Journal: So, I've known a case, I'm not naming names, but I've known a case where the doctor was summarily suspended and within a two-week period or so, he received his due process. There was an investigation conducted, and it went to the medical executive committee, and they found that there was no merit to the summary suspension, which was immediately lifted [summary suspension lasting more than 30 days]. However, the attorney representing the hospital said that the hospital had no legal obligation to remove the Adverse Action Report that reported the summary suspension. What's your thought on that?

Loewenstein: So, each situation is individual here because the report that should be voided is one that either does not meet reporting requirements or has been overturned. If it has changed—so, if there was a suspension that lasted for 60 days, and we do get these on occasion, and then it's ruled that that suspension is being lifted after 60 days, that would still meet reporting requirements, and so that would be reported to us. But the other key part there is that they would also be required to report a revision saying that the suspension lasted 60 days, and after that 60 days it was lifted. So, the difference [is] between revising what happened versus overturning the original action. [Clarification provided by Director Loewenstein on 08/03/2017: In describing the 60-day example, I was referring to a summary suspension that was lifted after 60 days, not necessarily one that was intended to last for 60 days.]

Journal: Right. And, I guess my comment on that would be that, so in the case of like a summary suspension that lasts

more than 30 days, which is reportable, and the doctor then is exonerated by the internal peer review process, it results in a revision to that data bank report. So, at that point the doctor has two Adverse Action Reports, one a revision. And, I will tell you that the effect of that is very negative. Again, the hospitals don't look much beyond the fact that the doctor has an Adverse Action Report, and the fact that one of them was revised and found to have no merit for the first report in the first place, doesn't have much of a helpful effect for the physician involved. Any comment on that?

Loewenstein: Just that we require the revisions and we certainly expect that our hospitals that are querying are looking at all of the reports. Everything we do is according to the statute and regulations of the NPDB to make sure that information is available.

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