Medical Board Launches Malignant Attack Against Oncologist

Parvez Dara, M.D.

A single blank shot from Vladimir Lenin's pistol started the Bolshevik Revolution. The emblem of that revolution still flies above the Kremlin. It is the hammer-and-sickle flag, which was meant to symbolize the union of the two working classes that represented the masses. Over time, the true meaning of the Communist cause became apparent. The iron hand of the Politburo (the hammer) oppressed all (the workers using the sickle) that dared rise against the central planners in Lenin's Soviet Union.

It seems far away, but it is not. It seems on distant shores, but it is not. It seems so alien to us in the United States, but it is not. What's happening here has the potential to result in what happened there.

My story, like that of Dr. William Summers,[1] is an example of accusation without proof, the unjustified accusation of physicians, all in the name of some "larger good."

Case Summary

In January 2009, I diagnosed hepatitis B in a patient who had finished her chemotherapy 6 weeks earlier. According to my standard protocol, I consulted the gastroenterologist and turned that part of the patient's care over to him. The patient recovered fully from the illness several weeks later.

In early March 2009, my family and I left for a Colorado ski vacation. During my absence, as was my routine, I called twice a day, each day of my absence from the office, even though I had physician coverage, to check for any patient calls and see whether I could answer questions or ameliorate problems. My family and I know that we could only enjoy our vacation days when my mind was at ease about my patients.

One Tuesday when I called, I was informed that there were 10 individuals from the health department in my office, an overwhelming and intimidating force for the two employees in the office. The Public Health Investigative Team (PHIT) carried laptop computers, legal pads, cameras, and a portable copy machine. I was told that they were going through the patient charts and copying them at will, using the guise of public safety to override considerations of confidentiality. Accompanying them was the chief of police, in case there should be any resistance to entering my office. It was later revealed from the hearing transcript that they knew that I would be on vacation. All this was done without a search warrant.

By the time my attorney arrived, the initial investigation was mostly completed. I was told to continue my vacation, and that the investigators would return the following week.

Upon my return I met with my attorney, who advised me to open the office and see my patients. I declined because I wanted to see any problems resolved before reopening my practice.

Several telephone calls took place between my attorney and the assistant commissioner of health regarding the patient-centered need to open the office. Additionally, the PHIT came back to review protocols and interview the personnel in my office.

After that meeting I was informed by the PHIT that four out of the 6,000 active patients were confirmed to be infected with hepatitis B virus (HBV). This result was obtained through their CDRSS (Communicable Disease Reporting and Surveillance System). I'm a medical oncologist, and all my patients were referrals. They all had had procedures elsewhere, and most had had blood transfusions, owing to their their diagnosis of malignancy or anemia. Others had previously diagnosed HBV in some of the patients. None of these facts mattered. It only mattered that they were identified as being in my practice. The New Jersey Department of Health and Human Services (NJDHSS) determined that investigation of other facilities (office practices, local hospitals, or the community at large) was not indicated or necessary in spite of the contrary opinion of its own epidemiologist.

Shortly thereafter, the assistant commissioner of health called a meeting at the Ocean County Health Department (OCHD). Her opening remarks were: "Dr. Dara, we must tell you that this is not a witch hunt." The meeting closed with a demand to supply the NJDHSS with the names of all current and former patients of my practice dating back to 2000. She stated that if I wanted to enclose a brief letter to my patients, along with their letter, I would be accommodated. However, without waiting for my letter, the NJDHSS mailed letters to 2,860 patients and an additional 3,000 letters shortly thereafter. The second letter implied that my office was responsible for spreading HBV. Immediately, there was a storm of media reaction. The *Asbury Park Press*, which covers Monmouth County and Ocean County, New Jersey, initiated it, and soon thereafter all the television channels lined up to vilify and demonize my name and practice. Television news trucks parked outside my office for four days, interviewing any patients that arrived or left the office.

The assistant commissioner of health agreed to the reopening of my office. Within 24 hours, after a flurry of phone calls, a two-member committee of the 21-member Board of Medical Examiners (BME) held an emergency meeting on Apr 3, 2009, and immediately suspended my license. This led to another flurry of media coverage.

The BME president stipulated at the hearing that Dr. Dara must have no involvement in transferring the care of his patients. This would be managed by his office staff. Subsequently, a letter from the prosecuting deputy attorney general (DAG) was sent to my office staff, advising them not to speak with my attorneys or me, and if a contact was made, that the DAG should be notified immediately.

Hearings

In December 2009, the DAG scheduled a management conference 2 weeks before a hearing in an effort to resolve issues.

He suggested that I forgo the hearing, and I agreed. However, following the conference, the BME offered a 5-year license suspension with an admission of guilt, which I declined to accept.

In April 2010, the DAG scheduled a management conference 2 weeks before a hearing. Again I accepted the suggestion to attend the management conference and forgo the hearing. But I declined the 4-year revocation including the 1 year already served, with an admission of guilt, which the committee tendered as its final decision.

In September 2010, the DAG advised my attorneys, by email, to forgo a hearing and resolve the matter via a different judge's binding decision without a hearing. I declined.

In September 2010, the Office of the Administrative Law (OAL) held a hearing that lasted 6 months. The OAL judge rendered his decision in June 2011.

In September 2011, a hearing was held before the BME. Before the final official decision by the BME, the DAG counsel representing the BME suggested a resolution in private for a 3-year revocation and admission of guilt. I declined. Shortly thereafter the BME made a ruling of revocation for 4 years and reapplication following completion of an ethics course. On the second day of the 3-day course, the attendee must write a one-page document admitting guilt. All the information gathered by the organizer of the ethics course is shared with the BME.

The Science of Hepatitis B

Hepatitis B is a HepaDNA virus with 3,400 base pairs in its genome. It is widely distributed in the world, affecting almost 3 billion people. There are an estimated 350,000,000 people with chronic hepatitis.[2] The genotype is region-based, with a growing mix occurring due to travel.[3,4] The virus is estimated to be 1 million to 6 million years old, and is thought to have originated in a woodchuck. It was serologically confirmed in humans in 1967.[2] In this time period it has mutated from HBV A to H subtype.[5] Osiowy et al.[5] and others calculated that the hepatitis B virus mutates at a rate of one mutation per nucleotide per year. This slow rate of mutation enables it to fester and persist in a community [6-9] until pressured by the evolutionary forces of selection via vaccination or immune surveillance. Transmissions are vertical (mother to child) or horizontal (sexual, blood-borne).[10,11]

The two index patients (acute/reactivated) identified by the State with similar sub-genotypes had a 0.4% variance in the tested genome. This amount of variance occurs over a 12-year span based on the mutation rates of the HBV. These two patients had been in my practice for only 9 and 10 months, respectively. A third patient had a 1.1% variance. Again, based on the mutation rate of the HBV, this variance would need a 34-year span, which is longer than the duration of my oncology practice.

The PHIT used an artificial "case definition" derived from its own assumptions and internal analysis to decide whether a patient fit the definition of an acute case, chronic case, or "not a case" that could be purportedly attributed to my office. For example, in the PHIT report one patient with a 2.5 billion/cc viral load allegedly was not genotyped. Of the remaining eleven, six were HBV e-antigen negative while five were e-antigen positive. Note that e-antigenemia is directly related to a dual-single nucleotide mutation at T1762 and A1764 sites, which are not determined in their genetic assay.[12,13] Furthermore, the genotyping was done only on 1,900 of the 3,400 base pairs, the gold standard being HBV Whole Genome Assay! Additionally, the HBV can also remain dormant as an occult hepatitis in the liver tissues without peripheral surface antigen expression[14,15] for many years. Both occult and a persistent chronic infection can be reactivated in up to 70% of patients following chemotherapy, transplantation, or monoclonal antibody therapy targeted against immunity. This reactivation is a consequence of immune surveillance resurgence.[16,17] The BME was dismissive of HBV reactivation.

Table 1. HBV Prevalence Rates[18]

Comparative Office/ Institution Data	Prevalence Rate of HBV
Dara Office	2% of 1,405 patients
Memorial Sloan Kettering (MSKCC)	9.2% of 1,720 patients
M.D. Anderson (Revised data)[18]	10% of 11,212 patients

Data in Table 1 suggest a high prevalence of HBV in an oncology patient population. Therefore, to establish an outbreak of HBV, a control group is paramount. In fact, in a disclosed e-mail one of the epidemiologists on the PHIT expressed her extreme concern with the lack of a control group in the investigation of my practice. In contrast, the Belgian study referenced below conducted a comparative epidemiological study with a control group in an equivalent practice and in the surrounding community, thus providing an "odds ratio," in order to establish a correlative link for an outbreak.[19-22] Furthermore, additional errors were cited by the consultant from the Centers for Disease Control and Prevention (CDC) via e-mail, expressing her dissatisfaction with the rampant errors and discrepancies found both in the serological testing and results of my patients.

Allegations Concerning Unsafe Practices

The NJDHSS investigation alleged breaches of infection control as a source of HBV transmission. These included:

1. Alleged blood spot on the floor. (It was never determined whether this was blood or rust from the underside of IV pole.)
2. Tums wrapper.
3. A fragment of a pretzel under a chair.
4. A thermometer in the chemotherapy hood.
5. Syringes with saline in them.

(Observations 1-5 were from snapshots of the chemotherapy room. The nurse testified that she failed to clean the room because she had to leave early owing to a family emergency. She had planned to clean before the office reopened upon my return. No work was supposed to be done during my vacation.)

6. A pen used to mark the Vacutainer tubes.
7. A bag containing saline for intravenous administration, used for pre-filling the syringes. (The State alleged that the nurse was going back into the saline bag for flushes in between patients. Her testimony and practice was to pre-fill the syringes in the morning and keep them stacked in the chemotherapy hood.)
8. Multi-dose vial re-use.
9. Syringes prepped with covered needles.

10. Use of butterfly needles instead of Huber needles for accessing Porta-Caths. The State alleged this practice was a non-standard practice. However, at the hearing, I testified that the Huber needle had caused two patient ports to core and bleed, causing hematomas over the Porta-Cath site. After these two occurrences, 25-gauge butterfly needles were used to access ports. In 2010, all Huber needles were recalled due to "coring" issues.
11. Not allowing the alcohol to dry on "patient skin" before accessing vein. (This was done in a mock exercise without patients before the 10-member investigation team's raid.)
12. The CELL-DYN (CBC Auto-analyzer) efflux into the "sink-trap" would be infective via a "splashback."

Evidence

The BME Hearing started in September 2010 with testimony from scores of witnesses. With volumes of transcript data and hundreds of evidentiary proofs, the hearing ended after 6 months in February 2011.

The Medical Board previously had totally dismissed scientific information about hepatitis B reactivation, a phenomenon known to occur in cancer patients receiving chemotherapy, describing reactivation as an improbable theory. In its Order of Temporary Suspension, dated April 7, 2009, the Board wrote:

> In the face of highly credible and persuasive testimony from Dr. Montana regarding the epidemiological evidence that links the five cases of hepatitis B in his office, Dr. Dara proposes that these patients are latent carriers of the virus or that they contracted the disease through other venues at other times. As medical professionals who bring our own expertise to these proceedings, we reject his proffered explanation for the putative transmission as lacking any reasonable medical basis. Footnote: The articles referenced in respondent's brief were not provided at the hearing, but a review of the abstracts on line demonstrates that they do not support Dr. Dara's claim…. Instead, he rejects the scientific, epidemiological analysis and asserts his improbable theory for five patients simultaneously presenting with a latent hepatitis B infection, and seeks to have his practice continue stating that deficiencies have been remedied and he will comply with the Board's directives.[23]

By the time of OAL hearings, which took place in 2010 and 2011, the phenomenon of reactivation was no longer in dispute. In his decision, Judge Jeff S. Masin wrote:

> In addition to this undisputed information, it is also not in dispute that there is a phenomenon known as reactivation, whereby a person, who at some time in the past has acquired the HBV virus and either never knew that he or she had the disease, or did know it but assumes that he/she has become free of the virus, actually retains the virus and through some mechanism the virus is again activated such that the person may then present as if he/she has an acute case of HBV. As will be discussed, the extent of this reactivation amongst cancer patients, especially those undergoing chemotherapy, is a matter of significant testimony in this case, and its significance in respect to the findings and conclusions reached by the State Investigators regarding Dr. Dara's practice is highly contested.[24]

The record reflects that the State's principal epidemiology expert witness, Dr. Barbara Montana, infectious disease expert employed by the NJDHHS, acknowledged that hepatitis B reactivation can occur. The Judge noted in his decision:

> As noted earlier, in his response to the charges, Dr. Dara has asserted the possible role of reactivation of previously acquired HBV in the occurrence of twenty-nine cases of HBV among his cancer stricken, chemotherapy-treated patients. Dr. Montana agreed that reactivation of HBV can occur, and this is more likely with persons who have certain cancers than other [*sic*], but there are other factors besides cancer itself that can cause reactivation, such as immunosuppression from certain chemotherapy drugs and even latent and chronic cases that can spontaneously reactivate in 30% of the times without overt cause. Dr. Montana, after being presented with the facts, did finally acknowledge that it is possible that included in the group of nineteen patients with positive IgM, a classic sign of acute infection (exposure within six months), are persons who did not actually have such a recent acute exposure, but are instead reactivating, in which case they too would display a positive IgM. Also, a certain percentage of persons who have chronic HBV can have a level of IgM which is detectable even though they do not have acute HBV, but Montana did not know the exact percentage of such cases.[24]

In his decision the Judge noted the opinion of Dr. Larry Mark Weisenthal, a well-credentialed expert from California, concerning the epidemiologic study and conclusions offered by the State:

> Weisenthal concluded that the people that were doing this epidemiology were "utterly incompetent," and should be "sued for malpractice." "They don't know anything about biostatistics at all." He [Weisenthal] was especially struck by the lack of any control group…. The analysis is "farcical, it's laughable, it's a joke is what it is." Added to this is the fact that hepatitis, in the context of a medical oncology practice, has a significantly higher rate of occurrence than in the community at large, due both to the nature of the disease and the treatment. The only appropriate comparison control group to Dara's practice would therefore be another or a set of other oncology practices, and an analysis of similar number of those practices' patients…. Weisenthal concluded that, at least on this basis, there was no ground upon which to claim that his [Dara's] practice was the cause of most of the HBV cases in Ocean County during the time period in question. A conclusion that it is the source is "absolutely false" involving an "incompetent use of data…." Weisenthal noted that the increase in the percentage of patients with HBV over the percentage of the general population so infected is explainable due to the immunosuppressive effect of cancer, and the "profoundly immunosuppressive" effect of chemotherapy. In addition, the reactivation of previously acquired HBV will occur due to the immune-compromised status of these patients. Weisenthal commented on Dr. Montana's testimony before the Board of Medical Examiners, in which she was asked to comment on the presence of reactive IgM. At that time, she stated that the only explanation for this was

Table 2. Allegations Compared with Judge's Conclusion

ALLEGATIONS	OAL JUDGE'S CONCLUSIONS OF LAW
1."Failed to implement adequate infection control practices in his offices, resulting in a risk of harm, and actual harm, to his patients…."	"I CONCLUDE that there is no evidence to support a charge that Dara failed to properly maintain equipment."
2. "Failed to maintain sanitary conditions."	"The evidence credibly establishes that there was a cleaning routine and schedule for the office and separately for the chemo room. That it was left in an unclean state on this one day."
3. "Failed to develop infection control policies and practices and ensure proper staff training."	"I FIND that training was not lacking."
4. Claims a "failure to provide appropriate environmental controls and/or job assignments to eliminate potential for blood contamination during medication preparation and administration procedures." Subparagraph d) charges failures to properly handle medications and solutions. Subparagraph f) alleges failure "to adhere to aseptic technique….."	"I FIND that there is no direct proof that this ever happened." "I FIND that there is also no evidence that anyone failed to properly cleanse the stopper. And most importantly, despite what may have been misunderstandings about this practice regarding the draw-down of saline, I FIND that the evidence credibly establishes that the practice in the office was to pre-fill syringes from the single source at the beginning of the day and, as necessary, later on, by drawing saline into the syringes and storing them, rather than by going between the vial and the patient and then back to the vial." "I FIND that there is nothing except speculation to support that the practice as performed in the office either presented a reasonable likelihood of or that it actually did cause contamination and/or transmission."
5. "It is alleged that there was a failure to provide access to appropriate personnel protective equipment and a failure of the staff to properly use and dispose of this equipment."	"I FIND that her (DAG) concern cannot be elevated to a sufficiently credible breach of standards without more evidence that the gloves used did not meet the standards of oncologists and also that they were not of an adequate grade to use with chemotherapy drugs. That proof is lacking."
6. "Another criticism involves the alleged improper use of antiseptics prior to the performance of invasive procedures."	"There is certainly no evidence in this record that Dr. Dara either himself improperly cleansed a site or failed to allow alcohol to dry or was aware of any deviations from accepted procedures." "I FIND that it is possible to eliminate any realistic question as to likelihood that the virus was spread by the effluent from the CELL-DYN 1700. The effluent is treated by FDA approved methods, including internal cleansing procedures that did not rely upon staff to treat the effluent before it proceeds down the tubing to the bottom of the drain at the trap."
7. Charge that Dara "failed to update written policies and procedures regularly" and "failed to standardize procedures for peripheral and Portacath access, care and flushes."	"I FIND that there is no effective evidence that establishes that the use of butterfly needles in the manner utilized in Dara's office violated any applicable standard of care."
8. "The complainant contends that Dara was untruthful in his testimony before the Board when he denied that LPN 'administered' chemotherapy."	"I CONCLUDE that if the meaning of this portion of the Complaint is that her mere involvement in the administration/provision of chemotherapy to patients constituted a violation of applicable standards, then that charge must fail."
9. "Charges that Dara failed to adhere to the regulated waste management regulations in both his Toms River and Whiting offices. 41 The Comprehensive Regulated Medical Waste Management Act, N.J.S.A. 13:1E-48.1. to -25 and N.J.A.C. 7:26-3A-1 to -49 regulate medical waste."	"I FIND that in this case, ... these matters, essentially involving paperwork and without any allegation that Dara actually mis-handled such waste, do not support conclusions that the doctor committed gross malpractice and/or repeated incidents of malpractice."
10. "Complaint, which incorporates the allegations of Count I, charges that Dr. Dara failed to adhere to requirements of the Occupational Safety and Health Standards for Toxic and Hazardous Substances, 29 C.F.R. 1910 et seq., and related statutes. It points to a 'history of multiple violations of OSHA's rules and regulations dating back to 2002 and continuing until the present.'"	"I FIND that he did not either willfully or deliberately engage in any malpractice or gross malpractice in regard to these OSHA violations."

an acute or recent exposure. Indeed, the Medical Board's own summary included this concept. However, Weisenthal concluded that Montana "naïvely" believed this answer to be correct because she had absolutely no understanding of the medical literature, noting that "if you just bothered to spend five minutes on Google Scholar she would never have made such an absurdly naïve statement…." There are other reasons for an elevated IgM, such as reactivation. This phenomenon is reported in the literature, and in addition, there are persons whose IgM, which should go down to zero, who instead continue to have an elevated IgM and are chronically infected.[24]

The Decision

The OAL judge rendered his 169-page decision on Jun 5, 2011.[24]

The OAL judge drew the following conclusions:

> I FIND that the complainant has failed to demonstrate by a preponderance of the credible evidence that any of the allegedly improper procedures and techniques were more probably than not the actual means by which HBV was passed from actual patients to actual patients, rather than theoretically so, and as such I CONCLUDE that the complainant has failed to prove that Dr. Dara actually harmed his patients. I CONCLUDE that the complainant

has failed to prove that Dara engaged in any violation of standards that resulted in any of his patients acquiring HBV. Therefore, I am UNABLE TO CONCLUDE that the HBV that affected the several patients "stemmed" from or was "probably linked" to his practice, other than possibly due to the very fact of the patients' medical conditions and the chemotherapy treatments that they received from the doctor.

The judge went on to state:

I am of course very cognizant that as a result of the Board's decision that his license and his practice had to be suspended while this lengthy administrative matter proceeded, a period now over two years in length and likely to last for some significant time while the Board reviews this initial decision, he has already suffered greatly and lost much…. There is simply no reason whatsoever for any additional period of active suspension of his license. Any further active suspension would be nothing more than punitive in nature.

Board Rejects Judge's Decision

In the State of New Jersey, the BME can reject the OAL judge's decision. The BME did that in my case, summarily rejecting the judge's findings. It did this without providing any analysis of its own.

Additionally, the Board expressed its disapproval of my contesting the proceedings against me and my unwillingness to admit that my office was responsible for the transmission of HBV to my patients. The Board claimed that it was applying a "preponderance of the evidence" standard, but redefined it to be a medical/epidemiological standard. The Board also based its findings on unreliable summaries of interviews, not on the evidence introduced at the hearing—these are double-hearsay, prejudicial, and improperly relied upon.

The Board determined that the ultimate sanction of revocation was warranted. Based on the BME decision, which ignored the judge's 169-page ruling, I had no choice but to file an appeal in November 2011 before the Appellate Division of the Superior Court of New Jersey.

Conclusion

It appears that the purpose of government regulatory authorities is to scapegoat, vilify, and demonize physicians, and to protect their own unchallengeable authority.

Despite my previous excellent record—I served as chief of medicine and then chief of staff at Community Medical Center and held chairmanships of several committees at the hospital, including the Medical Education Committee, the Cancer Committee, and the Quality Assurance Committee. I have been forced out of the practice of medical oncology now for 39 months. The enormous stress placed on my family and me is incalculable. The larger harm caused to thousands of patients overwhelms the unproven (correlative) allegations of four initial patients with HBV. My patients were severely hurt by the lack of coordinated medical care as stipulated by the BME. Some of the patients could not find physicians to care for them. Others could not receive chemotherapy on schedule, reducing their chances of survival. The effects of their orders on the lives of thousands of compromised cancer patients did not matter to the DAG or the BME. The State expert claimed they had "found the source and moved on" and "the public welfare had been protected."

Was it?

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