Blowing the whistle: A pharmacist's vexing experience unraveled

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On February 6, 2005, the *New York Times* reported that Paul Kornak pled guilty to fraud and criminally negligent homicide a month earlier.[1] Kornak was a nonphysician employee at the Stratton Veterans Affairs Medical Center (SVAMC) in Albany, New York. On November 21, 2005, a federal judge sentenced Kornak to the maximum prison term of six years. According to a local report, "At least one veteran died and 64 others suffered unduly or were harmed by the forgeries, which involved manipulating their medical backgrounds so they would qualify to participate in lucrative drug studies . . .."[2] A decade earlier, two pharmacists had warned that patients were placed at risk or had died because of similar unethical experimentation.[2]

Currently, an elusive federal investigation purportedly continues to determine which Department of Veterans Affairs (VA) physicians and administrators were an integral part of the patient abuse conspiracy, the cover-ups, and the retaliation against the two pharmacists who dared to expose the truth for greater than a decade; I am one of those pharmacists. I will share some personal experiences and lessons learned and review the professional guidelines and moral responsibilities that are explicit in the pharmacists' code of ethics. I will also share the strategies that enabled me to persevere, should pharmacy colleagues face similar challenges to their professionalism and integrity.

In the beginning. It was in April 1993, after first following the usual chain of command, that I initially visited the chief of staff of SVAMC to orally report various cancer research violations. Some patients had been placed in research studies without informed consent, and some were coerced into study participation. Several patients did not meet study inclusion criteria for company-sponsored pivotal trials. Groups of patients received chemotherapy combinations of drugs with Food and Drug Administration-approved labeling to treat unsubstantiated tumor types while the study investigators secretly collected outcomes data. Certain data collection was subsequently sanctioned by the institutional review board (IRB). By November 12, 1994, I needed to document certain violations; within a month, I was the subject of an internal investigation questioning my professional conduct.

As I climbed the chain of command to report my observations, it became painfully obvious that institution officials were angered

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by my "protected" disclosures. I felt obligated to bring my concerns to an outside agency, the VA Office of Inspector General (VAOIG). According to documents filed with VAOIG, certain cancer patients were being placed on physically incompatible drug combinations. Outcomes data were selectively collected on patients without an IRB-approved protocol. Several patients' central-line catheters clotted, requiring surgery for line replacements. After putting these concerns in writing, I was threatened. The exact words still ring clearly in my ears, "Fudin, I will bury you." I reported many other research violations involving multiple studies; however, the extent and complexity preclude discussion herein.

In 1995, a new pattern of illicit research emerged using dangerous dosing patterns and combinations of drugs that were clearly unstudied for certain tumor types. In at least one case, there was an undisputable patient death, and in other cases, hastened deaths. As the Code of Ethics for Pharmacists enjoins us to tell the truth and to act with conviction of conscience, I wrote a report of my findings and sent copies to several administrative medical personnel in March 1996. It included my refusal to participate or comply with any physician orders to dispense these medications, at unstudied dosages in unstudied combinations, to patients. Within two days, I received a memorandum charging me with "patient abuse for failure to dispense medication as required by the oncologist." This prompted me to file complaints with VAOIG, the New York State Office of Professional Discipline (NYS-OPD), and the Office of Special Counsel (a federal agency supposedly in place to protect federal whistleblowers). NYS-OPD abrogated the complaint and sent it back to VAOIG, since it was deemed a federal matter. As the conspiracy unraveled, I learned that VAOIG had been working collaboratively with certain VA officials; this collaboration, in my opinion, served to avoid VA's accountability.

I disclosed several subsequent research violations to local, regional, and national VAOIGs. Although some cursory investigations commenced, it became clear that a conflict of interest existed, since VAOIG is a federal agency and working collaboratively with VA. As research funds continued to pour into SVAMC, pressures to squelch my disclosures at a very high administrative level seemed implausible but real. For instance, within two days of my reporting of another serious protocol violation that sent a patient to the medical intensive care unit resulting in the placement of a thorocostomy tube, I was investigated for "practicing outside [my] scope by requiring certain blood work prior to dispensing chemotherapy." Because of this conflict, I felt it necessary to report evidence to the Federal Bureau of Investigation (FBI). Unfortunately, FBI accepted VAOIG's request not to investigate, since I was the subject of an internal VAOIG investigation for practicing outside my approved scope. In essence, FBI did not investigate even after I produced documented evidence of patient harm, abuse, and deaths; this suggested to me an inappropriate collaboration between VAOIG officials, FBI, and VA administrators.

SVAMC was, however, obligated to convene an internal investigation to determine the legitimacy of my allegations. The investigation was assigned to a pulmonologist named Thomas Ferro. Many of his findings were consistent with my disclosures.[3] But the chief of staff changed the report and ordered Dr. Ferro to sign off on certain edits and to destroy any original documents and computer files. Dr. Ferro admitted this to investigative reporters for a local newspaper and the *New York Times*.[1,3]

By July 1995, the chiefs of staff and the department of medicine had approached Anthony Mariano, SVAMC's pharmacy manager at that time. Mariano was ordered to counsel and place me on probation regarding certain alleged "undesirable professional activities." A man of high integrity, Mariano refused to succumb to administrative pressures even though this made him vulnerable to retaliation. For supporting me and for making his own "protected disclosures," his desk was moved to an empty psychiatric ward where he had no computer, no phone, and no job assignments.[4] He was eventually terminated for allegedly allowing a clinical pharmacist to practice outside an approved clinical scope, a charge that, upon subsequent investigation by several agencies, was dismissed. This cluster of retaliations came from a newly assigned regional pharmacy manager, a pharmacist, who Mariano and I believe was sent to our region by Washington, D.C., officials to remove us from government service. Mariano was forced to resign with no opportunity for a hearing. Just two weeks after my own termination, the regional pharmacy manager was whisked off to a Washington-based job with a promotion, but in December 2001, I prevailed in court and was reinstated to SVAMC by a federal judge. The retaliation I experienced is too comprehensive for this commentary; however, a partial chronological summary can be viewed online.[5]

A balancing act. Why did you stay, how did you survive, and would you do it again are the questions most often posed to me. Yes, I would do it again but the chronology of my survival strategies would have changed on the basis of my experience. I believe some issues could have been resolved sooner. I could not walk away from a situation I felt was evil to health care workers and patients who would otherwise have been left behind. Had I left, it would have appeared that I did something awful that could have blemished my integrity and the pharmacy profession,

and the real perpetrators would have remained behind unscathed to torment more staff and to abuse more patients. A win for VA would be a huge loss for everything that seemed honorable.

This was a clear turning point in my career, because I needed to make a decision that would ultimately affect more than a decade of my life. Unbeknownst to me, it would be all encompassing, daunting, and expensive, and it would take a significant toll on my family. I needed to attempt to balance my integrity and responsibilities to patients, pharmacist colleagues and other medical peers, family, outside professional obligations, friends, and, perhaps most importantly, the maintenance of my own sanity. As time passed, I began to believe I was paranoid; however, I was often reminded by my VA colleagues that paranoia is an *unreasonable* fear; the fears that I endured were quite *real*.

By 2005, I had contacted local Congressman Michael McNulty (NY), U.S. Senator Hillary Rodham Clinton (NY), the Democratic and Republican staff directors of the Subcommittee on Oversight and Investigation for VA, four VAOIG offices, the U.S. Office of Special Counsel, two U.S. attorneys, New York State's Office of Professional Discipline, and FBI.

Survival strategies. Just before I was fired, a VA manager and long time friend said to me, "Jeff, I wish I didn't know some of the things I know. You should get out while you can, before they destroy your reputation."

Those days are long past. There comes a point when you need to run or fight back. I needed to create an environment where I was the predator instead of the prey, and I needed to make the message clear that anyone guilty could potentially be exposed. The paranoia needed to shift if I were to perservere. I learned that within the federal government, there is a protective shield for "insiders" known as bureaucracy. Since similar sociology likely occurs within nonfederal health care institutions, I suspect that this discussion has widespread applicability. I knew if the bureaucratic barrier were pierced, it would cause chaos among certain corrupt administrators.

Before taking such a bold plunge, I needed all the necessary documentation to support my allegations in order to preserve my credibility and not appear as a disgruntled federal employee. I was and remain disappointed, but I was not disgruntled and not yet disenchanted. Clear documentation was absolutely essential, for if it were not documented, it did not happen. I can offer this advice: If you are going to court, get an attorney who knows the system and specializes in employment law, not health care law. Allow your friends and colleagues to help. If you work for a large institution, you have the advantage. If you did the right thing, medical doctors, nurses, pharmacists, and other health care professionals will help you achieve your ultimate goal—protecting the patient. It is similar to the American colonists fighting the redcoats—the settlers were more familiar with the inner workings of the U.S. territory, and they could easily ambush their adversaries. Without realizing it, I was considered a modern-day Paul Revere, a whistleblower. And so, the struggle began.

It was clear that I could not count on any federal agency or politician to step up to the plate. As a cautious returning SVAMC employee, I watched the 2002 Kornak story unfold in my local newspaper.[2] I knew in my heart that although he deserved punishment for his crimes, he had been used by the government as a convenient scapegoat to avoid accountability for more than a decade of criminality predating his employment. I decided it was time to enjoy the first amendment right to freedom of speech. How appropriate it seemed that the very patients I cared for were the ones that have preserved that freedom. Several newspaper articles began slowly exposing the patient and staff abuses, first piecemeal, then chronologically. Mariano and I were asked by local veterans groups to be co-Grand Marshals for the 2003 Albany Memorial Day Parade, a rare honor bestowed to nonmilitary men. Shortly after, the media attention started to snowball locally, nationally, and in professional journals and meetings. In late 2004, I was contacted by the *New York Times;* it was interested in publishing an exposé of the unfolding story since it had national implications in time of war. This exposure, coupled with documents I began posting on my newest Web site,[6] made a lot of people nervous.

In April 2005, I contacted an FBI whistleblower, Sibel Edmonds, founder of the National Security Whistleblowers Coalition (NSWBC).[7] The comparisons between retaliation suffered by her coalition members were so similar to that of VA whistleblowers, one would think that there was a policy manual on how to harass federal whistleblowers. I learned that similar to VA whistleblowers, our NSWBC counterparts all attempted to address corruption from within their agencies before going public. All were honest employees who risked their careers to do the right thing; they were heroes, not troublemakers. We agreed that it would be beneficial to start a partner group, the VA Whistleblowers Coalition, to assist targeted VA practitioners.[8] Although it was a time-consuming task, I well understood that to go it alone is a stressful undertaking—my health care colleagues could benefit from the experiences and support of others. The power of the Internet came alive.

Reality, practicality, and morality. Investigations of unauthorized experimentation, malfeasance in health care provision, and medical corruption are difficult and expensive to investigate. FBI and other fed-

eral agencies tasked with investigative responsibilities seem unprepared for investigations of VA and remain reluctant to start investigations. These agencies may be reluctant to investigate, perhaps out of fear of what may be found, perhaps because of reticence to attack another government agency, or perhaps because the victims of these crimes are poor and sick and have few resources. I believe the government needs to be prompted to develop an investigative protocol using a nonfederal organization with no conflicts of interest or incentives. The government must remember that the people who are being harmed at VA are those who have risked their lives to keep this country free.

Administrators and licensed professionals who spent a decade retaliating against employees attempting to bring the abuses of Kornak and others to light should be held accountable for their actions. These people are far more dangerous than a dozen Kornaks, since they have taken up various posts across the country and threaten to undermine accountability at a number of VA institutions.

Finally, we all need to be reminded of our promises endorsed by the American Society of Health-System Pharmacists. "A pharmacist has a duty to tell the truth and act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients . . .. The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly."[9] This commentary provided a brief chronology of patient care violations. To report such violations is a duty *required* by the pharmacy profession's codes of conduct; the method by which one makes these disclosures is *optional.*

I treasure my job and feel honored and fortunate to serve veterans. Although some may judge this history as seditious, I wish to clarify that my allegiance to U.S. veterans and the pharmacy profession will always trump bureaucracy. Unlike my adversaries, I did not specifically set out to destroy any single person's reputation and certainly not the VA as a whole. But I made it very clear to the world that pharmacists are masters of documentation and are respectable professionals who take their oath of patient advocacy seriously.

References

1. Sontag D. In harms way. Abuses endangered veterans in cancer drug experiments. *N Y Times.* 2005; Feb 6:A1, B28.
2. Lyons B. Apologies and excuses at VA case sentencing. www.vawhistleblower.com/11-22-05%20Apologies%20and%20excuses.pdf (accessed 2006 Sep 14).
3. Lyons B. Cover-up charged in VA probe. www.vawhistleblower.com/2003-05-26-TU-Charged.pdf (accessed 2006 Sep 14).
4. Memorial Day media clip. www.vawhistleblower.com/memorialday%20media%20clip.avi (accessed 2006 Sep 14).
5. www.vawhistleblower.com/12-20-05%20Collective%20Retaliation.rtf. (accessed 2006 Sep 14).
6. VAWhistleblower.com. www.vawhistleblower.com (accessed 2006 Mar 21).
7. National Security Whistleblowers Coalition. www.nswbc.org (accessed 2006 Sep 14).
8. Veterans Affairs Whistleblowers Coalition. www.vawbc.com (accessed 2006 Mar 21).
9. Code of ethics for pharmacists. www.ashp.org/bestpractices/ethics/Ethics_End_Code.pdf (accessed 2006 Sep 14).