

DrRich becomes radicalized

A vignette: Your author wakes up One afternoon in June of 1994, I was summoned to a meeting by a vice president of the hospital for which I worked at the time. Meetings, especially unannounced ones, are the bane of employed physicians; but this one, I was led to understand, was mandatory. I found the meeting room filled with high-ranking hospital administrators, hospital attorneys, and my clinical chairman. A gathering of luminaries such as these, especially on short notice, was decidedly rare. As I walked into the room all eyes were on me. I knew all these people; they've been my friends and colleagues for years. We've been fighting the healthcare wars side by side. But now they studied me as if seeing me for the first time. "Who died?" I asked, just to break the ice. "To be determined," responded one of the lawyers. They got right down to business. The chief hospital attorney explained: The federal government, in the guise of the Office of the Inspector General (OIG), had launched a major investigation of allegedly improper Medicare billing practices related to the use of investigational implantable cardioverter defibrillators (ICDs) in the late 1980s. This investigation, I was told, had begun as a whistleblower law suit out on the west coast, and the feds were now expanding their inquiry. The OIG had just subpoenaed records from approximately 120 of the largest hospitals in the country that implanted ICDs. We were one of the 120. Now I understood why I was here. As Chief of Cardiac Electrophysiology, research with the ICD was one of the major endeavors of my career. The ICD is a device that is designed to prevent sudden death in patients whose cardiac disease makes them susceptible to such an event. Once implanted, the ICD recognizes the sudden, lethal heart rhythm disturbances that cause nearly instant death, and automatically delivers a shock to the heart to restore it to a normal rhythm. It is a remarkably effective device, and was obviously so from the very beginning. Seldom, in fact, has a more dramatically effective life-saving therapy ever been devised for any illness or disease. For this reason, as long as I had access to these devices I (and most electrophysiologists), felt morally obligated to offer them to any eligible patients who were at high risk for sudden death.

So now I understood why I had been summoned to the meeting. What I didn't understand was why the feds thought we'd done anything wrong.

"We shouldn't have any problems there," I protested. "You'll recall that we looked into the legality of billing for ICDs back in '87 when I first started working here. And Medicare said it was okay." While I was an employed physician (and so the hospital handled all the billing for my services), I'd had enough concern about billing Medicare for investigational devices that I insisted the hospital get clarification from our Medicare Intermediary (the local agent and representative for Medicare) on the matter.

One of the attorneys answered. "That's right. The Medicare Intermediary indicated at the time that there was nothing illegal about billing for the ICDs, but couldn't guarantee they'd pay for them. As it turns out, they've paid for each one we've implanted, and never questioned our using them."

"Then what's the problem?" "Medicare now says we've been in violation by sending the bills," the lawyer replied. "There's apparently an obscure instruction in the Intermediary's guidebook that prohibits billing for some investigational devices."

"But we got clearance from the Intermediary," I protested.

"And that's the defense we'll take. The Intermediary itself didn't know about this rule. But unfortunately, Medicare operates a little like the IRS. If you call the IRS with a tax question and they give you bad advice, it's your fault if you follow that advice. The fact that the Medicare people were unaware of their own rules, and apparently told us the wrong thing, doesn't absolve us." "So what's the worst case scenario?" someone asked. "That we'll have to pay all the money back?"

"The monetary penalties are much worse than that," intoned the CFO. "We're looking at over 100 investigational ICDs that the good doctor here has implanted," he said, glaring at me. "And at about \$25,000 each, that's a pretty penny right there. But the Feds are also talking about a \$10,000 fine per incident, plus triple damages, so we're really looking at several million dollars we can't afford."

What's worse, the fact that the OIG joined the whistleblower's actions suggests that they're going to claim we intentionally violated Medicare regs — which could mean jail time. He was looking at me again when he said "jail."

"Don't worry," a vice-president said to me sympathetically. "We're all in this together. We'll help you as much as we can."

"What do you mean, you'll help me?" I shot back. "I just work here. You do all the billing, keep everything you collect, and pay me a paltry salary."

"Like I said, we're all in this together. But those bills do go out under your name, Dr. Fogoros. As far as Medicare is concerned, they're your bills." As I've since learned, when the feds begin pointing their fickle finger, it's customary for everybody to dive for cover.

For the next two years my life was plagued by a series of complex machinations — legal probes and parries — made in response to the feds' investigation of our supposed "fraudulent" submission of bills. I won't bore you with the details — I'll just hit a few highlights.

First, my hospital threw in with two dozen other large hospitals from all over the U.S. that were also affected by the OIG's subpoena, and together we hired a fancy inside-the-beltway law firm that specialized in healthcare law. These attorneys ultimately determined that the obscure regulation the OIG was invoking against us had itself been illegally promulgated, and therefore should not be enforceable. Accordingly, our hospitals sued Donna Shalala, Secretary of Health and Human Services (HHS) in federal court to prevent her from enforcing this obscure, previously unknown, and (we held) illegal rule. "We have maybe a 50-50 chance of winning this suit," I was told by one of our

attorneys, “but it won’t be settled for years.”

While all this was going on, the subpoenaed hospitals also lobbied Congress to act on the essential unfairness of it all. “Look,” the hospitals said, “we’ve got one agency of the federal government (Medicare) coming after us for doing research that had been duly approved by another agency of the federal government, the Food and Drug Administration (FDA). We need laws to make the feds behave consistently. When the FDA approves clinical research, Medicare should allow patients to avail themselves of that approved research.” Finally, in November of 1995, Congress passed just such a law. “So we’ve won!” I exulted when the hospital attorney called me with the good news. “Not exactly,” was the reply, “The OIG prevailed on Congress not to make the law retroactive. So the OIG is still coming after us for what they say we did in the 1980s.”

Then, in January of 1996, the Feds launched a new attack. Senator Roth, Chair of the Senate Finance Committee, decided it would be in somebody’s best interest to have a showcase hearing, highlighting the grievous crimes against Medicare that are being promulgated by avaricious physicians and institutions like me and mine. So the Permanent Subcommittee on Investigations sent subpoenas to the CEOs of several hospitals from the OIG’s list of 120, mandating that they appear before that committee on Valentines Day (i.e., heart day) to answer questions regarding the allegations that we’d committed Medicare fraud in our use of the ICD. It was to be a real circus – it was to be covered on C-SPAN, with major networks in attendance and lots of national publicity. The works. Immediately, there was a mad rush to have the subpoenas quashed. All the hospitals from states whose Senators were members of the Finance Committee managed to be excused from appearing. At the end of the day, only four hospitals remained. Mine was one. I was sure my career had ended. My family, friends, patients and colleagues were about to see the CEO of my hospital appearing before a hostile Senate Investigational Committee answering questions on the Medicare fraud that I supposedly had committed. I knew it didn’t matter that I hadn’t done anything wrong. Truth is only a compilation of some facts, whereas perception is everything. I spent two days in Washington helping the fancy beltway lawyers prepare our CEO for his testimony. I failed miserably in my emotional pitch to be allowed to testify in his stead (the CEO had been subpoenaed, not me; and besides, anyone who seemed eager to testify before Congress must be crazy enough to get us in trouble). But at least I managed to convince the CEO that we should take a hard line with the subcommittee. After all, we had truth, righteousness, ethics, and possibly even the law on our side. We shouldn’t allow ourselves to be intimidated.

Each witness was to be permitted to read a statement into the record before the questioning began. Our attorneys had prepared a 10-page statement that was vague, wishy-washy, filled with legalese, and as nearly as I could tell, didn’t deny wrongdoing as much as it promised we’d be more careful next time.

So I prevailed on the CEO to tear up this lawyered-up document and instead use a one page statement that I wrote for him, saying, in essence: 1) We implanted investigational ICDs in Medicare patients because they were at high risk of dying without them, and to withhold such life-saving devices when they were available to us would have been unethical and would have constituted malpractice. 2) Before implanting the investigational ICDs, approval for their use was obtained through the FDA. 3) Before billing for the investigational ICDs we asked for and received clearance to do so from our Medicare Intermediary. 4) The records and documents we sent Medicare in support of our billing for these ICDs clearly indicated that the devices were investigational, and yet Medicare reimbursed us each time, over a period of several years and without questioning our actions or our bills. 5) The regulation Medicare is now invoking was unknown to us during this period of time, and also, apparently, to the Medicare Intermediary. 6) In any case, as we have asserted in federal court, that regulation was illegally promulgated, and is therefore not a legal rule. 7) Congress has agreed that regulation to have been at least an ill-advised one, as evidenced by the fact that Congress recently passed legislation that now renders that regulation illegal, whatever its previous legality. 8) If they now assert that our actions constitute fraud, then the message the OIG, Medicare and the Senate subcommittee is sending to the public is that doctors and hospitals are expected to discriminate against the elderly, and will be called to task by the federal government if they refuse to do so. 9) Thank you for your attention.

The hearing was indeed quite a show. The whistleblower himself was the first witness, and he entered the chamber wearing a hood to hide his face, sat behind a screen, and spoke with his voice electronically distorted. This was the first time in history, I was told, that a witness had appeared before Congress disguised in this way, except in hearings featuring Mafia turncoats, drug lords, and the like. The implication, I presume, was that I and my fellow cardiac electrophysiologists were no less evil or potentially violent than other, more famous sorts of felons; and that if we learned this guy’s identity his life wouldn’t be worth a nickel.

Then it was us perpetrators’ turn to testify. The CEOs of the other three subpoenaed hospitals, after reading their lengthy, lawyerly and seemingly contrite statements into the record, were grilled mercilessly by the Senators of the subcommittee. Our CEO was the last witness. Once he read our brief but much more aggressive statement, the Senators seemed not to have any substantial questions for him. His testimony was over almost before it had started. Our hard line had paid off.

One more blessing occurred on that day. Somebody apparently found some Whitewater documents that weren’t supposed to have existed, so ten minutes before the hearing, C-SPAN pulled out and went running down the hall to televise the Whitewater doings. All the other news media went with them. Our hearing, despite the big build-up, the dramatically disguised whistleblower, and the fact that it was Valentine’s Day, barely made the news. The lack of national news exposure (and as a result, the lack of local news coverage) spared my reputation and that of my hospital.

Then finally, later in 1996, a federal judge ruled in our favor in our suit against HHS – the regulation Medicare was invoking, the judge ruled, had indeed been illegally promulgated. The OIG still didn’t give up, but in the end offered a settlement deal to the hospital for a mere million or two (which, by this time, was less than we had already

spend defending ourselves), and nobody would have to admit to wrongdoing or go to jail or have a criminal record.

So, thanks to a few smart people and a few lucky breaks the whole episode seems to have had a happy ending. Right?

I'm not complaining. It could have turned out a lot worse. And the whole ordeal provided me with enough amusing anecdotes to last a lifetime. But having the feds coming after me for more than two years was truly an eye-opening experience. As I saw it, the rightness of my actions seemed completely obvious. I had used those ICDs because my high-risk patients needed them, and from every indication their usage was legal and proper. But, in the service of my patients I (through my representative and billing agent, the hospital) had failed to discover a vague, obscure and difficult-to-interpret regulation – one that also had escaped the notice of the Medicare Intermediary in whose guidebook the rule appeared. As a result I had been caught up in the great Wonkonian anti-fraud initiative. For over two years I could never be sure of what was going to happen to me. There were periods of days at a time, usually just after another round of legal punches and counter-punches, when there was little else I could think of. (Would I lose my job, my career, my reputation, all my worldly possessions – would I go to jail?) During those times I was of little use to anybody – colleagues, family or patients. Of course, in the end it all turned out just fine – but the reason for the favorable outcome wasn't that the feds finally agreed that my actions had been appropriate and non-fraudulent. It was because our lawyers had found a legal technicality in the fed's own actions. Had it not been for this entirely fortuitous discovery, who knows what might have happened? So I've seen a side of the anti-fraud imperative that most doctors have not, and I'm willing to admit to a more robust paranoia on the subject than most would have at this moment. The way it looks from here, Wonkonians – at least sometimes – are willing to go to great lengths to prove just how rife with fraud is our healthcare system, and, once they set their sights on an alleged perpetrator, are pleased go to equally great lengths to bring that supposed perpetrator down. At least sometimes they're willing to base their prosecution on bad rules that are poorly written, illegally promulgated, and hidden away in obscure manuals; they're willing to ignore the fact that the alleged perp had relied on advice from the feds' own agents before proceeding; they're willing to summon that perp before a televised, circus-like inquisition to be publicly humiliated for actions that, just a few months earlier, they themselves had passed explicit laws to endorse; and they're willing, when all legal justifications for their persecutions have at last been taken away, to make a final demand, that some might consider extortionate, for a cash payment before they'll go away. At least, that's how it looks from here. It is not my position that the Wonkonians have been engaging in an unmitigated orgy of illegitimate anti-fraud activities over the past dozen years or more. I am sure they have not. Indeed, most of the anti-fraud activities the feds have undertaken have undoubtedly been legitimate and useful. Furthermore, I fully understand that any get-tough government initiative – whether it be anti-fraud or anti-terror – has got to have teeth, and that it is natural if regrettable that occasionally, a few innocents will be ensnared in such efforts. I admit the possibility that my frightening experience may represent nothing more than the collateral damage that will naturally happen whenever the sovereign power finds it necessary to wield its great hammer in the overriding interest of the public good. But forgive me if I believe it is more likely that the experience I have just related represents instead an early glimpse into the Wonkonians' methods of intimidating and controlling doctors who, without these kinds of necessary checks, will, in caring for their patients, simply keep doing whatever they'd like with the government's money. If I am correct, then the utter unpredictability, arbitrariness, doggedness and seeming absurdity of the government's actions in my own case are not accidents, but are essential to the Wonkonians' goal of keeping their prey completely off balance and in their thrall. If I am correct, then we should be able to find evidence that this example is not isolated, but is instead part of a recurring pattern of behavior.