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COMMENTARY

"It is easier to denature plutonium than to denature the evil spirit of man" – Albert Einstein

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As we debate issues in health care and the role of government in our lives, I would like to believe that I retain a passion for the pediatric perspective of being something of a medical socialist and human rights advocate. Occasionally, a book comes along that grabs both my intellect and passion in that debate. *The Plutonium Files*[1] by Eileen Welsome is such a book. I wish to make the case that it be required reading for all toxicologists.

After returning from the 2011 North American Congress of Clinical Toxicology in Washington, D.C., I had two general opinions: first, I had suffered through the paperwork required to do a simple case report as required by the institutional review board at my hospital. A simple statement that I was not going to put any names on this case report, in my mind, should have been sufficient. Instead I had to lumber through an NIH required training course on the rights of patients to privacy and informed consent. "Yet another example of overregulation by the federal government intruding into my personal existence", or so I thought.

Second, while attending the meeting, my wife and I took an afternoon to visit the United States Memorial Holocaust Museum. It is, of course, a disturbing place. Within this disturbing place, a special warning is placed on the exhibit involving medical research. The exhibit is considered even more distressful. I, of course, was well insulated by the fact that these were after all, Nazis'. The moral compass of these physicians was driven by hatred with the full recognition and consent of an equally evil government. These physicians, in my mind, could never exist in the United States and the presence of this evil in another place and time does not justify the hysterical behavior we display for human rights and dignity. Right?

After returning home, I was browsing for some history to read and came across *The Plutonium Files*.[1] My first impression was that this would be a histrionic accounting of a few small events in some distant past. Case in point: the book opens with a discussion of Mr. Elmer Allen. Mr. Allen was an African-American working as a Pullman Porter for the railroad. It was several months before the first nuclear weapon was to be tested in New Mexico. A misdiagnosis of osteogenic sarcoma led his physician in San Francisco to recommend amputation of his leg. Sensing an opportunity and an "obviously" fatal diagnosis, this physician, who worked part-time at the University of California Berkeley as a part of the Manhattan Project, decided to inject a syringe loaded with plutonium into Mr. Allen's calf 3 days prior to the amputation. The pathology report showed that he had osteomyelitis. A small miracle for Elmer, but a shock for his physicians. Elmer was never able to return to full-time employment. He lived a long and sad life in Italy, Texas where he was known as the "town drunk" who spouted strange conspiratorial stories of doctors injecting him and then studying his urine and stools for many years. That the book would start with such a bizarre story is not surprising. The fact that the author has found 18 patients so treated makes this an amazing account. I am sure anyone would say "this was wartime, they were part of the Manhattan Project, secrecy was critical," and it was a "different" time. This is, however, the first chapter of a startling discussion of the evolution of radiation biology and a failure of our government and physicians collaborating across a broad spectrum of the United States to meet their aggregate and individual responsibility to protect human rights.

Following the discoveries of the Nazi medical experiments and the resolutions evolving from the Nuremberg trials, one would have expected the behavior of physicians and institutions in the United States to undergo a radical change. It did; they got more secretive. That they did not change their approach to protecting patients is the more disturbing part of the book. Disturbing the already disturbed reader.

The Plutonium Files[1] follows the history of our understanding of nuclear physics as a part of medicine from the late 1930s well into the 1970s. Institutions and universities that we know and respect for their research in the new millennium were promoted through funding from the Manhattan Project and its successor the Atomic Energy Commission, now the Department of Energy. Thousands of individuals were exposed to high levels of radiation without their knowledge or consent. Testicular radiation experiments on prisoners,

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total body irradiation of sick adults, soldiers marched into known hot areas, or asked to stare in the direction of nuclear explosions all demonstrate the dereliction of responsibility. The indigent prenatal clinic at a major university administering a radioisotope during pregnancy shows the complete lack of limits to the thinking of these people and institutions. The cover-up of these abuses remained in place until the 1990s when reparations were difficult to impossible. That is a sad tragedy.

I found myself wondering whether I was sitting in my mother's womb when she was asked to drink an unknown liquid as a "health elixir" that contained radioactive iron 55/59. Before my tonsillectomy, did someone give me a beverage with a radioisotope that was later studied in the pathology specimens? This extremely well-documented tome will shake your pre-existing notions of the higher moral ground of the United States to the core.

The book is also an excellent history of the evolution of our medical understanding of radiation and its harmful effects: a science that exploded on the scene as quickly as the "bomb" itself. For that reason alone, it should be required reading for all of us in clinical toxicology. For its impact on our understanding of the role of research funding, the federal government, higher education, and the medical profession, in allowing the criminal abuses of these patients, it should be required reading for anyone in healthcare.

We are at a time in history when the role of government in our lives is under great debate and this has spilled over into science. Who should regulate research? Can the government simultaneously regulate and pay for research? Should the government sponsor research when they have a vested political interest in the outcome? Good investigators have been known to suppress results that are not consistent with the worldview of regulatory/funding agencies or the political party in power in order to maintain federal funding. On the other side of the debate, is corporate research inherently biased? Ethical investigators with results that are not politically consonant with some radical elements will by their nature attract the financial support of industry. We have all heard the tag "an industry supported study" as a euphemism for tainted. No research can truly be viewed as scientifically unbiased and independent in the current climate.

Even when not politically motivated, regulation by government can have unanticipated negative effects. The goals of IRB regulation (that I am now well versed in) speak to protecting special populations and not placing a burden on one group over another for advancing science. A recent publication[2] has pointed out that the burden of these regulations forces bias into research on neonates. Individuals from lower socioeconomic groups are practically limited from both participation and benefit. Costs associated with this research are also being pushed higher at a time when funding is diminishing and the studies are prolonged, thus delaying the implementation of promising improvements. The editorial description[3] of a python gradually tightening its grip is a good one. When government funds research and regulates the process, the grip of the python is exaggerated. There is an implied sense that to suggest relaxing regulation speaks to a laxity of moral fiber. Sub rosa to the discussion is an implied threat to further funding for researchers who question a poorly conceived federal snake.

Thus, we have two sides to the story. How can we loosen the regulatory process if something as described in *The Plutonium Files*[1] may occur? The collective failure of government and individual practitioners allowed the Nazi party to do unspeakable research on human beings. That a similar collective failure could occur in the United States should serve as a reminder that no culture is above reproach. In the case of the Nazi's, ideology seems to have driven evil. In the case of nuclear research in the United States, money was a major driver. Federal funding should be disclosed with the same scrutiny and skepticism as to bias as industry funding. In the end, if the individual researcher fails those that have trusted them, no amount of regulation can make it safe or unbiased. If the government fails, then it is the scientific community that must step forward. We all must watch the watchers. We must all participate in the conversations about these controversies.

I strongly encourage reading *The Plutonium Files*[1] as a not-so-subtle reminder of our recent failures. I hope you will consider all the aspects of this as you read. For my part, I will not complain about having to fill out the paper work for the IRB the next time I want to do a research project.

Declaration of interest

The author report no conflicts of interest. The author alone is responsible for the content and writing of the paper.

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