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CHAPTER 1

Commentary on Ethics and Community-Based Research: Responsibility, Precaution, and Transparency

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The narratives about the "downwinders" at the Hanford nuclear site describe communities stricken with grief from their experiences of elevated thyroid cancer and other diseases, which they attribute to radiation exposures from plutonium and uranium processing facilities [1]. Closure has not come after 50 years of uncertainty about the nature and causes of the disease patterns.

The Manhattan Project, a national priority effort to develop the atomic bomb, was supported by a culture of secrecy, which was deemed necessary to prevent the Germans from winning the race with the allies to unleash the power of nuclear fission. Ironically, the first use of the atomic bomb on civilians was not on Germany but on Japan, which did not have an active program for developing an atomic weapon of mass destruction.

The secrecy surrounding the development of the A-bomb extended to every aspect of its production and the hastily created communities that were formed around research and production facilities to support its development. It is even reported that Vice President Truman was not aware of the A-bomb project when it was initiated [2]. Similar examples of secrecy can be found with testing of atomic weapons in Nevada and more recently with the exposures American

soldiers received from drugs and environmental chemicals during the first Gulf War period in the early 1990s [3].

A veil of secrecy hung over the radiation exposure soldiers received in the 1940s and 1950s as they observed atmospheric atomic testing. For decades government agencies (Atomic Energy Commission and the Department of Energy) refused to follow up on the illnesses of the atomic vets, who in later life felt they were treated like guinea pigs and abandoned after they participated in the early tests [4]. After the first Iraq Gulf War, returning veterans complained of a variety of neurological symptoms [5]. Initially, there was little or no transparency about the chemicals and vaccines soldiers might have been exposed to. The complex and diverse set of symptoms they reported during and after their military service did not comprise an easily recognizable pattern of disease. Their symptoms were like those of people who have been diagnosed with "multiple chemical sensitivity," a syndrome few medical practitioners believe is the result of environmental exposure.

In each of these cases (atomic testing, Gulf War exposures, and emissions from nuclear production facilities), the affected parties sought redress or validation from their government of the health claims of citizens and the need for continued health monitoring, and compensation to the families who had to deal with a close relative's protracted health problems.

SECRECY AT FEDERAL NUCLEAR SITES

At the Hanford nuclear weapons facility, the U.S. Government's initial secrecy conditions can be understood because of the strict national security requirements in effect during World War II. After the war, the global leadership in nuclear energy of the United States was no longer in question. New secrecy considerations were imposed in response to the arms race between the United States and the USSR, but there were no longer any secrets about the *function* of Hanford and its plutonium processing facilities. And there was no longer an overriding state interest in keeping people who worked at Hanford and who lived in Richland, Kennewick, Pasco, and other communities from understanding their exposures to radionuclides as well as to the importance of monitoring their risks from radiation disease.

The reason for continued secrecy and for the repression of any inquiry into health effects from radiation exposure is more likely the result of the government's effort to maintain weapon's production, minimize the expense or personnel effort needed to prevent exposures, and to avoid having to compensate workers or private citizens for radiation illness.

Yocum's report describes how government secrecy played itself out in the Fernald, Ohio communities where state and federal agencies continued to stay in the background and not communicate with the affected community [6]. As a consequence, the agencies lost their credibility with the community.

The atomic vets who were exposed to fallout radiation in the Nevada desert from the early atomic testing in the late 1940s and early 1950s wore exposure badges. When they retired from the military they were supposed to submit their badges to the military command. By the 1970s and 1980s, when the growing concern about the radiation disease of atomic vets influenced Congress to request health effects studies, it was learned that many of the radiation badges were lost or consumed by fires [7]. Thus, health-effects studies based on dosimetry measurements were constrained by missing information describing the exposure received by those serving in the military during the 1940s and 1950s.

Ms. Pritikin's account of the Hanford communities' thyroid disease explains the functionality of "compartmentalization" (restricting each person's knowledge to their own specific tasks) in the culture of atomic secrecy [8]. The concept of compartmentalization applied to the public health effects of radiation also functioned to protect the production system from being questioned. By treating each health effect as an isolated "monad" without tying it to the whole system, government bodies would not have to face the problem that the risks of the post-war production facility, which manufactured weapons grade uranium and plutonium, might outweigh the benefits, or that people were treated not as ends-in-themselves but as a means to an end, violating an important ethical principle that is essential for human dignity. The secrecy and compartmentalization that was emblematic of the post-war production at Hanford reduced the possibility of learning what the health risks could be.

COMMUNITY-INFORMED CONSENT

During the 1950s and 1960s the ethics of informed consent in human experiments had not yet been developed. It wasn't until the publication in 1979 of the Belmont Report on the ethical principles for the protection of human subjects that informed consent was codified for federally-sponsored experiments with human subjects. After reports appeared in the national press on the abuse of human research subjects, especially in poor communities, in prisons, and in state mental health facilities, Congress passed legislation that established our current regulations on the protection of human subjects. The Hanford experience speaks out for another form of informed consent; we can call it "community-informed consent." This form of informed consent has not been institutionalized in the United States with one exception. The courts have recognized the concept of community-informed consent for addressing issues of pornography. The term "community standards" is a legal concept that helps to resolve contested claims pitting free speech against offensive speech. Adult published materials and the sex trade must meet community standards. This is a new concept of informed consent at the community scale.

Informed consent applied to research and industrial facilities that carry risks involves both an "informed" component, namely, transparency about the risks

including uncertainties in measurement, and once the risks are communicated properly, a requirement of community consent. Both of these components were missing for communities in the vicinity of the Hanford site.

A contemporary example of the application of community-informed consent can be found in a controversy over the siting of a research laboratory in Cambridge, Massachusetts in the mid-1980s. The respected consulting firm Arthur D. Little signed a contract with the Department of Defense (DOD) to develop more effective military defenses against chemical warfare agents like VX and soman. Secrecy about the laboratory was part of the contract negotiations [9]. Elected officials were told nothing about the research and the purpose behind the construction of the new state-of-the-art laboratory, which was situated near a bowling alley and a daycare center. Local fire department officials were advised of the chemicals being stored in the facility so that they could be prepared in the case of a fire. One of the fire officials leaked the information to elected officials in an adjoining town whereupon the siting of the DOD-funded laboratory became a public issue [10]. The City of Cambridge convened a commission consisting of sixteen individuals including public health experts and community residents. The commission met for several months to determine the risks of a worst-case scenario and then reached a decision over whether the risks were acceptable on "community standards." It is important to note that the Cambridge citizens' commission did not base its decision on balancing the risks of the research on chemical warfare agents with national security interests. If any balancing took place it was between the risks and benefits of the research to the community.

In its report to the city, the commission's unanimous decision was that the risks of the chemical warfare research were not justified when measured against the benefits to the community [10]. The decision was supported by the city's chief health officer and in subsequent litigation upheld by the Supreme Judicial Court of Massachusetts. This is one of a growing number of cases where the concept of community standards is being applied to risk assessment [10].

RESPONSIBILITY TO INFORM AND INVESTIGATE

The courts have consistently recognized the responsibility of corporations to inform consumers about the dangers of their products. When corporations intentionally withhold information about the risks, dangers, or adverse effects of chemicals or consumer products, they are liable for fines or formidable product-liability settlements. DuPont agreed to pay $16.5 million in a settlement of an EPA lawsuit challenging the company for withholding information on the toxicological effects of Perfluorooctanoic Acid (PFOA), a chemical used in the manufacture of nonstick pans. The obligation to inform runs deeply in American jurisprudence. Because government agencies can be shielded from liability suits by individuals and organizations, one can argue that its responsibility to inform is missing a powerful incentive.

The Hanford nuclear weapons production facility provides a useful case for discussing the government's role and responsibility for informing communities of potential hazards from toxic substances that are the byproducts of federal weapons production facilities and its responsibility for investigating claims. Elevated risk levels of a disease related to by-products of a government facility is *prima facie* evidence, albeit circumstantial, of a connection between the emissions and the disease. If the evidence is corroborated (elevated thyroid disease), then the government's responsibility to inform and to investigate becomes clear. If the evidence remains circumstantial, there may still be government responsibility to continue investigating the claims until there is a semblance of closure in the minds of the communities at risk.

Closure is a key element in a community's social psychology of perceived health effects from toxic chemicals. Health experts may reach a conclusion that a locally desired health study is not a good use of public funds or that it is unlikely to yield results. But like a parent looking for a lost child, turning over every stone is part of the process of reaching closure and peace of mind. Community residents at Fernald, Ohio, wanted the Centers for Disease Control to investigate the groundwater pathway for radionuclide and toxic chemical release from the Nuclear Feed Material Production Center. But according to Yocum, their request was ignored by the CDC [6]. Yocum's account depicts a community that received no closure on the issues of concern. For example, the health report was issued four years late and failed to respond to many questions still being asked by the residents.

It is of course possible that some studies requested by the community might be methodologically difficult or impossible to carry out. In such cases, it would seem that an equitable approach is for government to explore possibilities with the community and work out alternative studies that might bring the community to closure.

In the case of Hanford, another ethical concern is conflicts of interest. Historically, the research and development and safety functions of the Atomic Energy Commission were eventually divided between the Department of Energy and the Nuclear Regulatory Commission. Eventually Congress acknowledged that one agency should not have the responsibility for both promoting the development and evaluating the safety of nuclear energy. The same standards should apply to investigations of the health effects of nuclear production facilities. When the federal government became apprised of the public concerns over elevated rates of thyroid diseases in towns surrounding the Hanford facility, the responsibility for investigating, evaluating, and monitoring the health effects should have been assigned to an agency or independent research center that was neither administratively nor financially connected to the DOE.

The decision to call upon the Centers for Disease Control and the Fred Hutchinson Cancer Research Center to conduct the Hanford Thyroid Disease Study, looks on the surface to be a good model. The CDC is not under the DOE.

The fact that the selection was congressionally mandated also distinguishes it from a DOE initiative. However, Pritikin's chapter discusses how the recommendations of the Agency for Toxic Substances Disease Registry (ATSDR), a subunit of the CDC, for medical monitoring were dependent on funding from the DOE [8]. This situation could be construed as a conflict of interest, as one might argue that the agency responsible for producing radioactive contamination should not be the same party sponsoring an investigation into the health risks associated with said contamination. Even the remote appearance of conflict of interest can weaken the community's confidence in the process.

Given that there was a special interest in the study by the community, by virtue of its unique relationship to the Hanford facility, an argument can be made that the CDC and Hutchinson had a responsibility to communicate with the community during the planning phase and upon release of the results of the thyroid study. Community residents who were experiencing thyroid abnormalities or diseases potentially had valuable information that could have informed the investigation. I have argued elsewhere that there are categories of technical problems where nontrivial contributions can be made by nonexperts in the investigations and solutions. The neglect of these types of contributions I call "folk wisdom" may result in inferior outcomes or lost opportunities [11]. The reason for this is that the socialization of experts and their restricted cognitive structures can neglect some important components of knowledge. The highly specialized and reductionist nature of scientific inquiry can be aided by more intuitive, personal, and holistic approaches to problem solving.

Members of the team investigating thyroid disease in communities exposed to radionuclides from the Hanford facility have a responsibility for doing dependable, independent, and disinterested science. But they also have a responsibility for reflecting on and reporting the limitations of their measurements including the sensitivity of the measuring instrument. Epidemiological studies are much more valuable when they show a correlation than when they do not show a correlation. The reason for this is in the nature of epistemology. Epidemiology is a blunt instrument for measuring the correlation between exposure and disease. Blunt instruments underreport health effects. Typically, epidemiological studies yield more false negatives than false positives. Therefore, a positive result is more significant in epistemic terms than a negative result. As an example, if a scientist is looking for a bacteriological agent as the cause of a disease but has a low-powered microscope, failure to see a bacterium under the microscope is not a good reason to discard the hypothesis that there is an infectious agent. Negative findings are not conclusive. But a positive finding may be. "No evidence of an effect is not the same as evidence of no effect." Moreover, the failure to demonstrate causality or a dose-response effect for humans does not relinquish responsibility for responding to community needs. This point is made in Seth Tuler's discussion of seeking justice in the face of radioactive iodine releases [12]. Tuler cites the community advisory board's advice to the DHHS:

"The difficulties in identifying individuals whose injuries are caused by fallout exposure does not absolve the federal government of its civil and moral responsibility to aid the injured."

Because of these epistemological conditions, authors of dose response studies have a responsibility to discuss the power of the study, to report error bars on measurements, and to explain how these factors affect the confidence level of the conclusions. An instrument of low power with high measurement errors will have low confidence. Applying error bars on measurements can be used to calculate different outcomes based on low, medium, and high values of a dose.

Those in the affected communities who have credible circumstantial evidence of an adverse environmental health effect will undoubtedly not find closure when a blunt instrument uses dose estimates that are subject to large errors. The Hanford Thyroid Disease Study (HTDS) reached the conclusion that for the communities surrounding Hanford, there was no dose-response relationship between exposure to radioactive iodine and thyroid disease. Based on studies of endocrine disruptors, we now know that chemicals can exhibit an inverted "U-shaped" dose-response curve. These chemicals can produce adverse biological effects on mammals despite their nonmonotonic dose-response characteristics. A mistake would be made if failure to find a monotonic dose-response function for these chemicals led one to the conclusion that the chemicals did not cause an adverse effect [13].

PLUTONIUM SLUDGE

It sounds like a bad joke: plutonium sludge used to fertilize people's vegetable gardens. What were people thinking at the time? Was this sludge considered a good source of plant nutrients? Did they assume that small amounts of radioactivity in the sludge was not unsafe and that adopting the sludge was a sign of being patriotic? Had the homeowners who brought the sludge into their vegetable gardens thought about the risks? Was it a time when people did not ask any questions about radiation?

Sutton and colleagues describe the efforts of communities to acquire information on the human effects of plutonium sludge used in community gardens [14]. How did people justify the use of plutonium sludge as a "soil conditioner in parks, landscaping around public buildings, and in home lawns and gardens?" Was this all an honest mistake or was this a devious way for the Livermore Water Reclamation Plant (LWRP) to save the expense of landfilling radioactive sludge?

Radiation hazards have been known since the 1940s, but extensive studies began in the 1950s and 1960s. Tolerance levels for radiation were reduced in the 1970s and 1980s as more knowledge of the health effects, especially effects from lower doses, became available. The levels of acceptable X-ray doses for dentistry, mammography, and CAT scans were reduced to conform to new health

information as the technology improved. The new X-ray technology made it possible to get good photos with better resolution and lower doses of radiation.

Once it became known that the health effects of radiation exposure were more hazardous than originally believed, what responsibility did government have to those who were given plutonium-laced sludge?

Under current environmental standards, there is support for the idea that the government's responsibility for plutonium risks should be covered "from cradle to grave." In other words, the government's oversight should include every aspect of production, distribution, storage, and disposal until the plutonium is out of sight and out of mind as a potential hazard to current or future populations. If science's understanding and knowledge of plutonium risks changes after the sludge is distributed to communities, a reasonable expectation would be for the government to reexamine the false negatives or its original policy and continue to track the exposed population for health effects.

PSYCHO-SOCIAL ASPECTS OF CLOSURE

Members of the public who were told the sludge was entirely safe may justifiably feel deceived by their government. They may ask, What did the government know and when did they know it? Or did government officials responsible for public safety initially ask the right questions before distributing the sludge? Did they take account of the uncertainties? What is the proper response of government when a community is seeking closure while at the same time trying to grasp its own vulnerability to plutonium hazards.

Loss of confidence by the community can only be regained if the community is brought into the process of assessing the risks. Government-community collaborations become important for several reasons. First, it sends a message to the residents that whatever mistakes might have been made in the past, the investigative agency intends to discover the truth about the health risks. Second, it acknowledges that members of the community who were exposed to higher levels of radiation have valuable knowledge about the historical events that can be useful to an investigative body. Including community members on advisory committees or health study teams can make the tacit and phenomenological knowledge more accessible.

It is unlikely that closure in this case could be attainable from a single study. More probable, however, is that closure (if it comes at all) will arise as the result of a continuing process of monitoring health effects and community-agency interactions. People have become dubious and inured to government claims that "the community is not at risk" or that "the plaintiff's sufferings have nothing to do with popular views about causation." This was said about Gulf War vets and the communities exposed to the contaminated air from the World Trade Center catastrophe. In both cases, initial claims of the health risks were premature and eventually proven false [15].

Concerns about risk from a serious exposure to toxic substances, especially but not only mixtures, must be taken through the life of those exposed and in some cases to the next generation. From epigenetic studies of mice, we have learned that imprinting from the exposure of a pregnant mouse (F_0) can be carried through two generations (F_1 and F_2), even as we fail to see any gross genetic abnormalities. This imposes a transgenerational responsibility on agencies investigating environmental contamination that may have been caused by governmental policies.

The Rocky Flats case study by Moore discusses the tireless efforts by Carl J. Johnson, who served as the chief public health office for Jefferson County, Colorado. Johnson brought to the public's attention the plutonium contamination from the government's nuclear bomb factory [16]. Moore's narrative describes the extent to which a government agency will go to protect its image or avoid taking responsibility for untoward events. Ironically, agencies of a government by the people exercise many of the tactics we have come to expect from corporations who seek to protect their image and power for the sake of their bottom line. Some would argue that an agency such as DOE, which took over some of the responsibilities of the Atomic Energy Commission, should not have been given the responsibility to oversee the safety of the facility or to set the standards for safe soil. Moore's example that DOE paid a contractor to refute Johnson's studies illustrates its interest in assuring the public that it had acted appropriately in the face of allegations that the public was endangered by plutonium contamination.

In Moore's account of Rocky Flats, one of the protagonists involved in the investigation into health hazards was quoted as saying: "For more than 40 years, assessment of health risks of radionuclides has been controlled by a vested interest establishment that has contrived to minimize or ignore adverse effects of all sources of human exposure to ionizing radiation." Why are government agencies so recalcitrant to engage in honest and open investigations of federal facilities, in particular, federal nuclear facilities? There are probably several reasons. First, government agencies do not like the negative publicity that arises from embarrassing congressional investigations and media spotlights on their practices. And while they might be called unresponsive or insensitive to community concerns by the local press, that might appear less worrisome to the agency than the disclosure of evidence of serious health hazards for which it has a role.

Second, while it might not be easy to sue a government agency, Congress can put pressure on agencies to pay compensation for health injury to the community. Alternatively, Congress can pass legislation to address compensation awards. In either case, agencies become defensive when they are faced with allegations of government-related activities that were responsible for illness. It took 30 years for a sitting president to apologize for the country to the people of Tuskegee, Alabama for the unethical experiments performed by government employees on black patients who had acquired sexually transmitted diseases [17].

People who take leadership roles in government agencies somehow become self-identified with the agency and are likely to take on a protective role defending the agency against any malfeasance rather than a role that is empathetic to community concerns. The third factor that could explain the behavior of federal agencies toward community health concerns (whether those agencies develop nuclear power or weapons or they evaluate the health risks of nuclear technology) has to do with the politics of that technology. Agency officials are hesitant to provide the grist in the form of health-effects data that will afford citizens greater reason to oppose further development of nuclear power. Federal health agencies typically set the bar high for demonstrating causality. While they do not make it impossible to accept cause and effect, the bar is much higher than "circumstantial evidence" from elevated disease rates or occupational illness.

Deception was a theme raised by community residents at the Rocky Flats, Hanford, and Livermore sites. When residents feel deceived about the safety of a facility, it is *prima facie* evidence that informed consent was not satisfactorily implemented. The community residents either felt that the high-level administrators knew things about the potential hazards that they did not communicate or they downgraded the importance of the uncertainties.

In clinical trials, if human subjects feel deceived then something is deficient about the informed-consent process. Perhaps the subjects were not adequately informed about the magnitude of the risks or their probability. In one highly publicized case at the University of Pennsylvania, the subject was not adequately informed about the conflicts of interest held by the institution and the clinical investigator [18]. Similarly, without a clear disclosure statement to the community, there can be no informed consent regarding a potentially hazardous facility.

Panikkar and colleagues have written an informative and stimulating chapter on uranium mining and the Navajo people [19]. The chapter documents the incidence of lung disease among Navajo miners, the beginnings of a government response to occupational and community illness from the uranium tailings and radon gas, the desecration of land from open-pit mining, and the growth of research on the health effects of uranium mining on the Navajo community. There is consistency between the findings of these authors and those who have written about Lawrence Livermore and Hanford on the fact that corporations involved in uranium mining, as well as the Atomic Energy Commission, the major federal agency responsible for uranium processing, turned a blind eye to the concerns of occupational sickness of uranium miners. They write ". . . from 1948–1969, no federal occupational standards kept miners safe from the harms of radiation and such intense mining" [19, p. 143]. This is another case in which a community of workers and their families have not felt that there has been satisfactory closure to their grievances which stem from the long period during which workers' health and safety were compromised. After many decades of filing

claims, Congress finally acted by passing the Radiation Exposure Compensation Act, which gave workers and their families 20 years to file claims after 1990.

When some scientists were prepared to speak out about the hazards, they were told by their superiors to limit their speech. What is the ethical responsibility of public health researchers, who in the process of studying miners learned of their endangerment in the mines? Do they have a responsibility to warn the workers immediately? Should they get permission from superiors before informing workers about their risks? Should they remain completely neutral and simply produce research results that others can use to inform workers? These issues remain no less resolved today than they were 50 years ago. There are recent cases of physicians involved in clinical trials who felt that they had a moral obligation to warn patients about the risks of a drug therapy before a clinical trial was completed, despite legal warnings from their private sponsor [18]. That is a responsibility they bear from the Hippocratic Oath in their role as a doctor. But they also have a legal responsibility, by virtue of a contract or grant, to the company or government agency sponsoring the trial [20]. Their legal responsibility may be in conflict with informing the patient—at least before the trial was completed. Physicians working within government agencies are also obligated to follow agency protocols on making public declarations. Usually important risk communications are made through the agency director and not through individual researchers. The Supreme Court has recently ruled on public versus private speech of agency personnel arguing that an employee of an agency must follow the agency rules and protocols when they are under the aegis of making "public speech" [21]. According to a 5-4 decision of the Supreme Court "public employees' free-speech rights are protected when they speak out as citizens on matters of public concern, but not when they speak out in the course of their official duties" [22] Thus, the current ruling is consistent with the head of the Public Health Service's statement in its 1952 study. "We did not want to rock the boat . . . We had to take the position that we were neutral scientists trying to find out what the factors were, that we were not going to make any public announcements until the results of the study were published" [19]. Of course the head of the agency, like the principal investigator of any clinical trial, can decide to inform the participants that they are at risk and can advise them to minimize or avoid that risk. Panikkar and colleagues ask "At what point is it ethically incumbent upon researchers to 'go public' or even commit civil disobedience by disobeying orders to protect the lives of affected workers" [19].

The responsibility to inform human subjects of their risks during the progress of a clinical trial is well established in the aftermath of the Tuskegee experiments. But suppose the research is an epidemiological study. Do the investigators bear the same responsibility? Social and public health scientists cannot hide behind the premise that they are passive observers and that because they are not testing a drug or medical device on a population they are excused from informing research subjects of risks that they are facing. Let us assume, for example, that an

epidemiological team is studying a group of workers who are exposed to vinyl chloride. If the team finds unambiguous evidence that there is an elevated risk of liver cancer in this occupational cohort compared with workers who are not exposed to the chemical, then it would seem irresponsible not to report this result and not to make recommendations for reducing or eliminating the risk. Similarly, under current standards, if miners are found to have higher risks of lung cancer, public health scientists bear a moral responsibility to inform them of the risks. Like the bystander who watches an assault and who is capable of informing the police to take action, the public health scientist cannot morally disengage from subjects when he or she has specialized knowledge that they are endangered from their workplace exposures. According to Panikkar and colleagues, at least one court concluded that physicians examining miners did not have a legal responsibility "to advise the miners voluntarily appearing for examinations of potential hazards in uranium mines . . ." [19]. Since that time ethical standards in research have changed. Institutional Review Boards (IRB) may set a high ethical bar on the fiduciary responsibility of researchers. A high moral standard for researchers is to (1) report; (2) inform; and (3) advise. This means that researchers should not hide valuable public health information because of political expedience. They should be responsible to inform the vulnerable populations of their risk. Beyond that, as knowledge bearers, they have a fiduciary responsibility to advise human subjects about reducing their risks. But the standards are not uniform and depend on the local conditions of the IRB.

COMMUNITY-BASED PARTICIPATORY RESEARCH

Community-Based Participatory Research (CBPR) can take several forms. At the minimum it can mean that researchers consult with and draw knowledge from members of the community in designing or executing the research protocol. It can also mean that researchers partner with members of the community by including them in the research team and as authors in a subsequent study. Luz Claudio, a public health scientist at the Mount Sinai School of Medicine, worked with community leaders in New York City to study the effect on residents of the air pollution from a power-generating plant. Her model of CBPR also included co-authorship of publications by Mt. Sinai scientists and community leaders involved in the study [18].

During the early 1980s, the Harvard School of Public Health conducted a study of the potential health effects of drinking water contamination from two town wells in Woburn, Massachusetts. Over three-hundred volunteers trained by Harvard scientists surveyed Woburn residents about abnormal pregnancies and childhood disorders. According to Brown and Mikkelsen,

> The most common objections to the study were directed against the very concept of public participation in science. All the critics charged that the

> study was biased because volunteers had conducted the health survey and because the study had a political goal [23, p. 26].

There are many other instances in which corporate-funded health studies and/or government-funded studies neglect the valuable perspective of community residents resulting in a biased outcome [24]. Research objectivity is an important ethical norm in science that must be protected whether or not the research is community-based, government-funded, or industry-funded.

ACCEPTABLE RISK

In the framework of risk management, the term "acceptable risk" is, on the surface, a normative idea. It means "What risk ought we (I) accept?" It is easy for people to conclude that "acceptable risk" is a subjective idea. Panikkar and colleagues state:

> There is always the problem of what level of risk is considered "acceptable." There is no scientific answer to the question of acceptable risk because it depends heavily on the personal values of each individual and communities and various moderating factors, such as income and employment that may be taken into consideration [19, p. 157].

For many normative or aesthetic judgments, there is certainly no scientific solution or empirical evidence to resolve the issue. But there is one thing to consider in the realm of public health. If a biological organism is under significant threat from an environmental exposure, then we can conclude that the risk is "unacceptable." Biological health is the bridge that crosses the normative and empirical realms. Biological health is the grounding for taking a moral position on deadly toxic exposures. It is still logically possible to say: "The exposure is killing the organism" and "The risk to the organism is acceptable." From a practical standpoint, rational beings would not accept these two statements unless your goal is to do harm or the organism is engaged in a higher good by being exposed. Of course there are circumstances where people expose themselves to deadly risks in time of war. But these are extraordinary times and people fighting in battle must set aside personal safety and rationality by following orders.

The case study by Robert Alvarez on the occupational health hazards of the nuclear weapons program shows us what happens to ethics during periods of national exigency [25]. But there are different time periods represented in the case. National exigency cannot be applied to all the periods. During the war, one can imagine the focus of the federal government toward one end and one end only, namely the production of the atomic bomb. The conventional explanation is that there was not time to both take a precautionary approach and get the job done—at least that's how most narratives of that period are written. This was,

after all, wartime. But there is, even in war, an effort to account for and document the wounded. Documenting wartime casualties and helping the wounded is an important part of the government's responsibility. Ironically, more data were collected about combat soldiers than there were about the civilian "soldiers" at home producing the weapons and invariably exposed to the dangers of atomic radiation.

How do we account for the government's effort to cover up the occupational illnesses from radiation that were occurring after the war and through the 1950s and 1960s? The most prevalent story is that federal agencies (primarily but not exclusively the U.S. Atomic Energy Commission) were still engaged in a war, we called the "cold war," and just as feverishly driven to produce weapons of mass destruction to compete with the Soviet threat. After World War II we weren't just producing one or two atomic bombs. The nuclear production system was in the business of producing thousands of nuclear warheads, expanding the number of workers exposed to radiation. Thus, the impulse to turn a blind eye to radiation hazards was part of the same tunnel vision that occupied the agencies during wartime. When individual radiation health experts began to leak out data, the agency saw itself as wanting to protect its mission; everything else was secondary. Thus, they asked what the impact of releasing risk information and health data would be to the radiation workers. The value system in which they operated was that all decisions must be viewed in terms of whether they will support or detract from the primary mission. It was a time when cancer was kept quiet in families. No one talked about cancer in the media. Alvarez encapsulates these ideas in this statement "Fears over liability and lack of public trust that might result from disclosure of workplace hazards was of dominant concern." It took many years for the government to finally adopt a position that any person in the street would have acknowledged from the outset. "An agency whose mission it is to promote the development of nuclear weapons should not be responsible for studying the risks to workers or the general population of its production facilities" [25]. The AEC had its blinders on when there were debates over atmospheric testing. Until independent scientists from other agencies and universities were able to assess the data of radiation hazards, the public only received public relations notices designed to keep the manufacturing process on course and to protect the budgets from paying out compensation to workers who were stricken with radiation disease and ancillary medical problems. Releasing health information that might affect the agency mission was heretical to those who had but one missionary zeal—to keep up the flow of weapons.

PUBLISHING PRELIMINARY FINDINGS

One of the ethical dilemmas raised by the Alvarez case relates to the publication of preliminary findings. Early release of preliminary results may either

exaggerate the risks (false positives) or understate the effects (false negatives). Complex public health assessments of environmental or occupational exposures often require iterative analyses, peer review, reanalysis of data, and additional or multiple data sources before consensus can be reached about the findings. There is no consensus among scientists or bioethicists on the ethics of publishing preliminary findings. The decision about whether to publish preliminary data or to wait for additional studies and more data can be made on scientific grounds, but is often guided by political or legal considerations. Journal editors may decide that the analysis is premature and not ready for publication. Investigators usually want to publish quickly so they will have standing in the scientific community on the subject matter. Or there may be competition among investigators over who will be first to publish on the subject matter. However, scientists must weigh the ethical consequences of publishing preliminary results. Will the release of the preliminary data bring anxiety and stress to a population at risk? Will the release create negative publicity for a public agency? Will the publication of preliminary data yield results that the investigator later will have to retract, potentially diminishing his or her stature in the field? However, I would make a distinction between withholding publication based on the quality of the science versus doing so out of concern for the political fallout of the results. Alvarez quotes Samuel Milham, an epidemiologist at the Department of Social and Health Services, Washington State who said "I felt that publication of my findings at this time might disturb the continuity of the study in progress and might cause undue concern in workers" [25].

There are some ethical considerations with regard to publishing preliminary data that *should* enter into decision making. If people can be helped, in a precautionary way, from the communication of preliminary results of a health study, then, it can be argued; there is an ethical responsibility to get the data out early. For example, if the preliminary data suggest a continuing health risk and one for which there is some action that can be taken to prevent further injury, then releasing preliminary data can be a duty. As a general norm, knowledge that can prevent harm should be communicated to the appropriate audience. The debate gets more complex if the data are released through the press rather than through a scientific journal. It is the responsibility of the individual investigator to balance the interests of science with the interests of public health. The scientist may decide that the preliminary data, while suggestive of health risks from an occupational exposure, is not sufficiently reliable to impel a "responsibility to inform." The scientist is not solely acting on his or her own. Journal editors make their own determination over whether the preliminary results should be reported in their journal. The journals may be hesitant to publish a paper based on preliminary and possibly incomplete data, yet the author may feel an obligation to warn people who, he or she believes, are currently at risk.

Public agencies are generally much more cautious about releasing preliminary findings than individuals or journals because if they misguide action by a

premature release, they will be severely criticized by stakeholder groups, the media, and politicians. On the other hand, if they remain quiet and do not release their findings, they are unlikely to get criticized, but will probably be viewed as being cautious. By acting conservatively on the release of early findings, the agency is protecting its image foremost but may also be responding to political winds that do not want to create public angst or foster litigation against the government or "responsible" corporate parties.

In one respect, independent scientists have autonomy over when and how they publish their results. Journals, as the gatekeepers of certifiable knowledge, act as a control agent against premature publications. On occasion, scientists have been known to report their data to the press prior to or in lieu of getting it published. There has been a serious ethical critique of such practices, known as "science by press conference." Some journals have adopted policies against publishing original articles if the data were released to the press prior to publication.

INSTITUTIONAL CONFLICTS OF INTEREST

Alvarez reports that former Secretary of Health, Education and Welfare Joseph Califano declared that "DOE had a potential conflict-of-interest between its missions of military and civilian nuclear energy development and assessing their health risks." The definition and standards for institutional conflict of interest have been slow to emerge even as Congress has acted legislatively on setting standards of conflict of interest for government employees and issued guidelines to universities on academic conflicts of interest. The USDA is often cited as an agency that regulates and promote agricultural products—an inherent conflict of interest in meeting the public interest. It is difficult for an agency to resolve these conflicts without separating the functions in different agencies. The Environmental Protection Agency was created so that one agency wouldn't be regulating pesticides while simultaneously promoting them for use in agriculture. Eventually, that is what happened to the Atomic Energy Commission and the Department of Energy. The safety assessment function of nuclear weapons and energy production was placed with an agency that was not promoting or funding its development, namely the Nuclear Regulatory Commission. But for agencies that still operate under competing or potentially conflicting missions, accountability for potential conflicts of interest comes only from the oversight by Congress, the General Accounting Office, or from the independent Inspector General, who will report on how effective the balance in these missions is carried out.

CONCLUSION

Community-based research, in contrast to "research on communities," is a process through which science and citizens are symbiotic to the research mission. Sometimes it means that the research protocols or hypotheses are driven by

community interests. Or it could mean that citizens and scientists are partners in the research process. The cases reported in this commentary describe how community values and ethical considerations enter into public and occupational health research from past negligence by federal and state agencies from lack of oversight, failure to respond to grievances, or neglect of compensation for illnesses. Many of the cases refer to events that took place around nuclear weapons production and testing. But the issues are not simply of historical interest. The ethical problems are recurring. In 2001 when fireman, forensic experts, police and cleanup crews were sent to the World Trade Center in the aftermath of its destruction by acts of terrorism, they were exposed to extremely unhealthy air that was filled with the fine granular remains of plastics, glass and concrete that pulverized during the collapse of two 100-story buildings. These individuals, known as first responders, were advised that the air in downtown Manhattan was safe—many therefore did not use safety masks. Five years later, medical and public health scientists were investigating the etiology of lung diseases and leukemia reported in this population. No clear accountability has been established for the incomplete and poor science that contributed to the misinformation about air quality post 9-11. Because precautionary action was not taken at the time, many more lives were shortened beyond those affected directly by the unconscionable acts of terrorism associated with a day that will live in infamy.

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TORTURED SCIENCE

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