

19 The Regulatory Environment for Science: Does Democracy Trump Science?

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Issues of integrity and responsibility in science generate headlines, but rarely are they connected with questions of democracy in science. This paper offers some first steps toward a more democratically integrated vision of the regulation of scientific integrity and responsibility. It contrasts an old, contractual model of the relationship between science and society, which addressed only a narrow scope of issues in integrity and responsibility in but a constrained way, with a new model that manages a wider scope of issues through more democratic processes. These issues include research misconduct, data availability, conflicts of interest, human subjects of research, and cultural limits to knowledge.

This chapter presents six points. The first point is, very simply, “that was then, this is now”—meaning that the political context for research and the relationship between the federal government and the scientific community have fundamentally changed, and that members of both communities have to come to terms with it.

The old division of the relationship between science and society was something of a contractual one, as if two autonomous groups had agreed on certain principles of exchange to achieve independent but mutually beneficial aims. In the new vision, however, society views science as a little less like a simple input-output device and a little more like a complex social realm where the full range of human motivations and the attendant opportunities to influence them are at play.

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We can quibble about the time of this transition between “then” and “now.” The year I favor as pivotal is 1980, when Congress passed the Bayh-Dole Act and some important changes in the administration of scientific misconduct cases took place (Guston 2000).

The second point is that in the old vision of the relationship between politics and science, there were fewer rationales and opportunities for the regulation of science, broadly speaking. There was financial accountability (to be sure), the beginnings of formal protection for human and animal research subjects, and some questions about what were called the limits of scientific inquiry, with, for example, the creation of the Recombinant DNA Advisory Committee (RAC) (Holton and Morison 1979).

These arrangements were not entirely without controversy when they occurred, but now they seem almost like second nature. Certainly research should be held to the same principles of financial accountability as all other recipients of public funds. Research must respect the autonomy of human subjects, and must ensure that animal subjects (especially primates, dogs, and cats) are not treated cruelly. As long as scientists themselves were doing the regulation, institutions like the RAC were acceptable.

Regulatory issues in the new vision of the relationship between science and government are more varied and more complicated. Some issues extend earlier concerns. They include: the extension of financial accountability with the Government Performance and Results Act; research misconduct, which in some of its aspects is another extension of financial accountability; the variety of questions about human subjects (see Koski, Chapter 20 of this volume); and the extension of the protection of animal subjects, potentially from the large and easily anthropomorphized animals covered in the original Animal Welfare Act to more frequently used birds and rodents.

New issues have arisen in this new, more complex relationship. They include: financial conflicts of interest that exacerbate issues concerning human subjects and research misconduct, not to mention more traditional regulatory issues; rules about the accountability and availability of data under the Freedom of Information Act, and the publicity of science advice under the Federal Advisory Committee Act; and what might be called “the cultural limits to knowledge” in such laws as the Native American Graves Protection and Repatriation Act. In summary, there were fewer opportunities in the past for the regulation of science, but we now have a much more complex environment.

The third point is about the stake of these regulations for scientific inquiry. I will elaborate on a couple of these issues in order to develop what I mean by “stake.” In essence, the discussion of the regulation of science as I have framed it, and I believe as others have framed it too, is about values. It is about what values get to compete seriously with scientific inquiry, and, in some cases, what values get to trump the value of pursuing scientific inquiry. In other words, what values get to supersede the value of scientific inquiry, if any, and under what circumstances? In regulating the use of human subjects, for example, most people have concluded that the value of human autonomy, at least in some circumstances, trumps, or supersedes, the pursuit of scientific knowledge. That is, we as a society and the scientific community itself so value the ability of a single human being to conceive of and pursue his or her own path, that we have preemptively agreed that experiments will not be conducted, or may be halted, should a human subject not provide informed consent. That is a rather extreme way of saying it. An analogy for that extremity is saying that this is the scientific equivalent of that individual civilian standing in front of a tank and halting its progress.

I certainly do not want to cast researchers in the same position as that of corrupt Communist dictators. Informed consent rarely gets to that stage of confrontation. But by accepting the principle of informed consent, we also accept the principle that a lone individual, at least at some point in time, can halt scientific inquiry. I think we accept informed consent at that level of commitment because we understand the brutality of a system that does not accept it, because the concepts of information and consent are so central to our broader conception of what good government is, and because actual harm, to the extent that criminal law recognizes some failures of informed consent as assault, can come in not accepting it.

These factors are not as much at issue in a new category that I have labeled “the cultural limits to inquiry.” For example, under the Native American Graves Protection and Repatriation Act, native tribes can lay claim to what are known as “culturally affiliated artifacts and human remains,” whether or not they have been studied scientifically. The Act became rose to prominence in the controversy over what became known as Kennewick Man, which was a set of well-preserved human remains found on the banks of the Columbia River in Washington State in 1996. Five tribes claimed the remains and desired them repatriated without scientific study. Some research ended up occurring on the remains, which were dated to about 7,000 B.C.E., and questions about their biological

and genealogical connections to the tribes that claimed them were raised in these early scientific inquiries. An article in *The New Yorker* displayed a computer-reconstructed face that researchers put on the skull of Kennewick Man. According to some of the researchers Kennewick Man was possibly not affiliated with the groups that we traditionally think of as genealogically associated with Native Americans. At one point, a researcher claimed that Kennewick Man looked more like Patrick Stewart, the actor who played Jean Luc Picard on one of the *Star Trek* series. He did not have the sort of features typical of the ancestors of Native Americans.

It is possible that further scientific scrutiny could have settled the matter, at least as far as scientists were concerned. But Native Americans thought otherwise, and then-Secretary of the Interior Bruce Babbitt concluded that the remains had been studied thoroughly enough, and that geographic and oral history provided enough evidence to repatriate them. A federal court ordered the Interior Department to reconsider, and the case now sits in the courts.

The story of Kennewick Man shows the difference between the Graves Protection and Repatriation Act and human subjects protection. In the Act, scientific inquiry is trumped, not by issues of individual autonomy and safety, but by a set of values ranging from the distribution questions about who benefits from culturally and economically important artifacts to religious questions about the sacredness of human remains.

Native Americans and researchers have had more productive interactions over this Act. Museum curators will often tell you that these interactions have been very helpful. But Congress has essentially granted a community the ability to halt a small number of scientific inquiries because of values situated in that community. The same kind of problem appears in conflicts in stem cell research and human cloning.

The fourth point elaborates on the comparison between human subjects and the cultural limits to inquiry. It is essentially this: Whereas informed consent gives an individual the right to trump an experiment, the Graves Act gives a group the right to trump a whole line of inquiry. Does democratic society more broadly and appropriately possess this trump card? Over what scale or level of organization of science might democratic society possess this trump card?

Consider, for example, that we ask social scientists to follow the requirements for informed consent because of possible emotional and mental risks to their subjects. And consider that federal requirements protect the families of human research subjects. In a recent case, re-

searchers in Virginia were sanctioned because they failed to gain informed consent from family members of survey participants who were asked sensitive questions about those family members. And yet we do not protect non-subjects in the general population from similar or even more profound risks from research. Instead of extending informed consent requirements to those who are affected but are not subjects of scientific research, we labor under two assumptions: 1) there is broad consensus in society for scientific research, regardless of the risks to safety or culture; and 2) the extant mechanisms for funding, priority setting, and conducting research are themselves sufficiently consensual. Yes, there is great public support for research in most or all of its manifestations. And yes, research and development (R&D) policy is part of a generalized democratic system. But I believe that neither of these are truly sufficient to support these assumptions.

The fifth point is that we need to talk more about how to make democratic decisions about R&D policy and the regulation of science, particularly because the word “democratic” means so many different things to so many different people. Meanings range from participatory town meetings to the application of high constitutional principles.

In a 2001 editorial in *Science*, Irving Weissman and David Baltimore argue against limits on stem cell research. They write, “Scientists alone should not make the decisions about the ethical conduct of their work or about its social implications.” That is a clear and valuable statement. They continue, “It is appropriate that governments, with appropriate public input, define the societal interest, in particular, lines of research.” This statement is also valuable, but notice how much work that word “appropriate” modifying “public input” is doing. We need to have a lot of discussion about what that word “appropriate” means in this context.

Weissman and Baltimore conclude, “But in making those policies, the state should minimize purely political considerations and be mindful of the separation of church and state.” Here, I think, is a major difficulty. “Purely political considerations” could mean the disparate values that motivate politics, and the concerns of elected officials for outcomes like reelection and power, rather than outcomes that are simply good public policy. I will be very explicit here: In my view of democracy, minimizing these considerations eviscerates democracy itself.

Weissman and Baltimore also ask us to be mindful of the separation of church and state, and here there is some critical common ground. We have in the United States an agreement that when the daily politics of legislative and executive institutions fail, we return to constitutional

principles. I take Weissman and Baltimore here to mean that they believe arguments with an explicit religious basis—for example, whether a conceptus has a soul or not—should not be considered relevant to public decision making, at least apart from the ability of individuals who might hold that belief to act on that belief.

But we can also take their point more generally and agree, at the very least, that questions about the regulation of science should be made under these same constitutional principles. This agreement would mean, for example, that there is no right to research as such, but that there is a right to speech, a right to association, a right to due process, and so forth, and that even these constitutional rights have defined (but flexibly defined) limits under the law.

The sixth and final point is this: The regulation of science, particularly the democratic regulation of science that is constitutionally grounded, does not need to be conceived of only as a threat to science. The study of regulation indicates that it often provides a service to the regulated industry or community. For example, it can secure a wider market, as in the case of the requirement that prescription drugs be found safe and effective. It can also provide barriers to entry against potential competitors, as in the case of the licensing of professionals or regulating polluting enterprises.

So in an age of worries over the commercialization of research at universities and the proliferation of pseudo-knowledge on the World Wide Web, democratically produced regulations for the responsible conduct of research can provide a service to the scientific community, as well as, in some cases, restrict it.

References

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