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COMMENT

Smarter Regulations

Commentary on "Responsible Conduct by Life Scientists in an Age of Terrorism"

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Abstract In the United States a rapidly increasing regulatory burden for life scientists has led to questions of whether the increased burden resulting from the Select Agent Program has had adverse effects on scientific advances. Attention has focussed on the regulatory "fit" of the Program and ways in which its design could be improved. An international framework convention to address common concerns about biosecurity and biosafety is a logical next step.

Keywords Biosafety · Biosecurity law · Biosecurity regulations · Scientist · Laboratories · Research · Bioterrorism · Terrorism

As an outgrowth of the issues and concerns associated with dual use of life science technology described by Ronald Atlas (2009), a rapidly increasing regulatory burden has accumulated for life scientists in the United States. As a result, recently introduced legislation asks for an inquiry by the U.S. National Academies to determine whether the regulatory requirements of the Select Agent Program has had adverse effects on scientific advances, and if so, whether the program could be better designed.[1] Additional regulatory burdens on life scientists, will likely not reap

[1] S.B. 3127, *Select Agent Program and Biosafety Improvement Act of 2008,* introduced by Senators Richard Burr and Ted Kennedy, Committee on Health, Education, Labor and Pensions, U.S. Senate, June 12, 2008; reintroduced as H.B. 1225, and S.B. 485, *Select Agent Program and Biosafety Improvement Act of 2009,* February 26, 2009. It was referred to the Subcommittee on Crime, Terrorism, and Homeland Security and no further action has been taken as this article goes to press.

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proportionate benefits, and perhaps more of the burden of ensuring biosafety and biosecurity should be placed elsewhere.

The Regulatory Framework for Life Scientists

After the anthrax attacks of the fall of 2001 in the United States, the U.S. responded by passing legislation that created the Select Agent Program, which regulates the possession, transportation and use of "listed" select agents,[2] some of which could be potential bioweapons. This law was implemented as 42 CFR §73, adding to already existing regulations for the transport of select agents. Prior to the promulgation of 42 CFR §73, if a scientist did not ship or receive through transport, regulated select agents, a scientist could avoid what existed as the regulatory framework. The promulgation of 42 CFR §73, however increased the scope of the framework to include scientists who merely possessed these regulated select agents, subjecting them to civil and criminal penalties for violations of these rules. It is important to note that the effort to close the regulatory gap for select agents made researchers more exposed to potential civil and criminal liability as the scope of the regulation expanded to include activities of scientists and researchers not only in the transport of select agents, but in every aspect of the acquisition, storage, inventorying, and work with them.

This gap-closing effort continued with the signing into law of the USA PATRIOT Act of 2001, which expanded the criminal section to include possession of certain quantities of select agents for no "reasonably justified" purpose. This crime became punishable by a maximum term of incarceration of ten years and a fine of as much as $250,000. This added to existing law passed in 1989 in response to the Biological Weapons Convention, the Biological Weapons Act of 1989,[3] which made it a crime to use or intend to use biological weapons. A graduate student was the first charged under this law in November 2001 (U.S. Dept. of Justice 2002), and the case was settled by a plea bargain without going to trial. Additional regulations in this regulatory framework arise from the requirement that all recombinant DNA studies receiving funding from the National Institutes of Health (NIH) must be approved by the NIH.

The response to the anthrax attacks came from the strongly held belief that the anthrax used must have come from biological laboratories, probably in the United States. A biodefense researcher in a regulated laboratory, emerged as the FBI's sole suspect in August 2008 bringing further scrutiny on the biodefense research community, but this could prove to be a mistake. This is reminiscent of the old story where one man asks another who is intently looking on the ground under a streetlight, "What are you looking for?" The man replies, "I am looking for my keys," to which the first man asks, "Is this where you think you lost them?" The answer from the second man is, "No, but this is where the light is." It highlights the

[2] "Select agent" is the regulatory term for a listed biological agent subject to biosafety and biosecurity regulations.

[3] 18 U.S.C. 175b (2008).

need to resist the temptation to regulate "where the light is," that is, to focus only on the easy targets.

Scientists who are working with potential bioweapons in almost all cases, are subject to the Select Agent rules, a relatively new program with a heavy administrative component: individual researchers are made responsible for record-keeping and reporting, must submit to background investigations, and must ensure that their laboratories are secure from entry by unpermitted individuals. Both civil and criminal penalties are possible for violations of the law. Texas A&M University was suspended from the Select Agent Program when it failed to file a report of a release of a listed substance within the seven-day time constraint required by the program. This culminated in a one million dollar civil penalty against the institution.

Shipping and transportation regulations further restrict the ability for life scientists to share biological samples with colleagues both domestically and internationally. Internationally, both import and export regulations control the transport of some biological agents. The importation of biological agents is regulated by the Center for Disease Control (CDC); export of certain biological agents is regulated by the Department of Commerce, and requires a permit for export to certain countries. One instance of the criminal violation of this law—the exportation of plague bacteria to Tanzania, and a guilty determination by a jury, earned the plague researcher, Thomas Butler, a sentence of two years in federal prison. Thomas Butler turned the streetlight on himself, when he reported that plague bacteria had been stolen from his laboratory.

Designing Smarter Regulations

Associate Justice of the U.S. Supreme Court, Stephen Breyer, wrote in 1982 that regulatory mismatch occurs where the target of the regulation does not match the goals of the statute (Breyer 1982). In the U.S. regulatory framework for ensuring biosafety and biosecurity, the focus on life scientists has left a number of gaps in the framework, causing regulators to perhaps not look beyond the light of the streetlamp. In fact, the goals of biosafety and biosecurity may not be sufficiently met because researchers are the target of the regulation almost exclusively. The first modern bioterrorism attack in the United States occurred in Dalles, Oregon: the Rajneesh organization developed a salmonella bioweapon in their state-permitted laboratory which they then used to sicken restaurant patrons. The important fact however, is that this laboratory was regulated under the Clinical Laboratory Improvement Amendments (CLIA), and all such CLIA-permitted laboratories are explicitly excluded from the Select Agent Regulatory Program!

Biodefense Laboratory Regulations Would Not Have Prevented the Anthrax Attacks

The FBI suspect in the anthrax attacks would not have been detected under the current Select Agent Program. Moreover, the CDC regulation of biodefense work, which has

been criticized for the onerous burden it places on individual researchers and institutions and its unworkable requirements, would not have prevented these attacks if the individual responsible had worked in a civilian biodefense laboratory. These CDC regulations cover a range of possible threats to safety, involving transport, possession and use of "select agents". The rules apply to civilians in civilian laboratories, and the military laboratories have agreed to be regulated by them as well. This led to the discovery of the sole suspect in the Amerithrax[4] investigation who worked at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). However, a DOD regulation temporarily issued (in interim) around the same time as the civilian regulations, adopted the CDC requirements for FBI background investigations before the researcher can have "access" to biological agents. In addition, the Department of Defense which is responsible for USAMRIID, adopted its own, more extensive background investigation requirements.

The CDC background investigation regulation allows the denial or revocation of access "to any select agent or toxin to an entity or individual identified by the Attorney General as a 'restricted person' under 18 U.S.C. 175b." In particular, a "restricted person" is someone who could not meet the requirements to obtain a gun permit: they cannot be under indictment for, or convicted of a felony; be a fugitive from justice; be an unlawful user of a controlled substance; be unlawfully in the United States; be found mentally defective by a court; or have been dishonorably discharged.

However, for biodefense researchers in military laboratories, the DOD background investigation requirement is much more extensive, has much higher threshold standards and also adds the CDC FBI background investigation requirement. Specifically, USAMRIID researchers must be "mentally and emotionally stable, trustworthy, and physically competent." Mandatory disqualifying factors include "attempting or threatening suicide while currently enrolled" as a researcher, or "individuals who have attempted or threatened suicide before entry into" the program. The certifying official is required to revoke access to the researcher who meets any of those criteria. Even "inappropriate attitude or behavior" including "aberrant behavior such as impulsiveness, suicide threat, or threats toward other individuals," are mandatory factors for disqualification and barring an individual from work. It is worth noting that, since high school, the individual suspected in the Amerithrax investigation was alleged to have had a history of homicidal threats.[5] Despite the many requirements cited above, the suspect obtained and maintained the required clearances to work in the world's most sophisticated and well-equipped biodefense laboratory.

A civilian institution researcher has only to meet the requirements of an FBI background investigation that comprises nothing more than meeting the requirements for a gun permit. However, DOD has significantly greater additional military regulations for access as outlined above. One must ask if the right regulatory

[4] "Amerithrax" is the code name of the investigation of the anthrax letter mailings of fall 2001, assigned to it by the FBI. See http://www.fbi.gov/anthrax/amerithraxlinks.htm (Accessed 22 June 2009).

[5] Allegations made in the testimony of the suspect's therapist in the restraining order filed in Montgomery County.

mechanisms have been selected to protect public health and national security. It may be time to rethink the regulatory framework for the nation's biodefense research, focusing more effort on fully implementing the background investigation requirements and better perimeter security, and placing less emphasis on filling out forms, filing reports and counting units of self-replicating organisms. A regulation that is filled with requirements that are time-consuming and unworkable, may well prove to be a significant distraction from attention to the background investigation regulations that truly may be key to protecting against the misuse of biological agents.

Regulatory Misfit

The requirement to keep inventory records of naturally propagating organisms, modeled after programs which regulate inventories of radioactive materials in research laboratories, was a regulatory mismatch because the regulating agency attempted to use a regulatory model that fit neither the target nor the outcome. In their comments on the regulation, the American Society for Microbiology (ASM) made an elegant argument about the unworkability of this part of the Select Agent Program, though to no avail. More than five years after promulgation of the inventory regulation, in 2008 at least one piece of legislation introduced in the U.S. Senate required an "effectiveness" to "burden... on laboratory personnel" test for evaluating the inventory-keeping regulation of "biological agents that can propagate," be conducted. (See footnote 1 (*Act of 2008, Sec. 105 (b) (1)*)).

At the same time, while some regulations are overly burdensome, in many respects current regulations are inadequate. Certain potential biological weapons which are found naturally in the U.S., such as *hanta* virus from the southwestern United States, are not on the select agent list, making it not illegal to possess or store them, unless an individual accumulates so much of the biological agent, that it exceeds the "reasonably justified" quantity standard of the criminal statute. While biosafety is reasonably focused on biological laboratories, it should also be focused on new technologies, such as those nanotechnologies that might be potentially used in bioweaponry. At present, the safety regulation of nanotechnology is focused on the introduction of products into the market place and applies existing regulations to the rapidly emerging areas of nanotechnology where its safety is still poorly understood. Synthetic biology is also poorly regulated except for NIH-funded recombinant DNA research which is regulated by the NIH. For investigators whose research is regulated and who fail to follow the NIH recombinant DNA guidelines, the penalty is suspension of NIH funds. The burden for compliance again, falls squarely on the researcher. It is not enough to continue looking only under the streetlight.

The Dual-Use Dilemma and Codes of Conduct

The dual-use dilemma arises at various stages during the process of research and the target is again researchers. While voluntary codes of conduct are important, and

arguably even essential, it is important that these codes do not continue to put disproportionate burdens on the individual researcher.

Some codes of conduct which include provisions for self-regulation are desireable and useful for defining practices which engender biosafety and biosecurity among the research community. However, efforts to force the community into self-policing will ultimately fail because there is only a disincentive to report unethical research. Codes that encourage reporting to the public open the individual researcher to charges of libel and slander against the accuser and his or her institution. Even if the accusations are true, the informant will potentially spend years in mediation or in litigation since the burden of proof is on the informant and not the targeted individual. Expecting an individual informant to define "unethical research" or research "likely to contribute to bioterrorism or biowarfare," a task which has proven elusive even to the most austere and distinguished scientific bodies, is an unreasonable burden for the individual researcher. Conversely, while whistleblowing (in this article defined as reporting misconduct on the part of the employee's institution) is made possible because there are statutory protections for federal government workers, at the state level it is more perilous because each state is left to determine whether to provide protection and in what manner for individual whistleblowers. This does not provide an attractive option for codes of conduct that require self-policing of the profession.

While codes of conduct are continuing to develop, focus should not be solely under the streetlight on the researchers' street. Rather, an international dialogue on national efforts to support a biodefense ethic is critical, and should be a route considered by the delegates to the Biological Weapons Convention.

A Call for an International Framework Convention

Biosafety and biosecurity is a burden that cannot be shouldered by research scientists alone. Just as the Biological Weapons Convention signaled a world consensus that all countries could agree that these weapons should be totally banned and criminalized, an international framework convention can provide a different path for global consensus for the Biological Weapons Convention. For example, the experience with United Nations Inspection teams in Iraq and the final report they produced were considered anything but definitive. This suggests that the expectations of an inspection protocol may simply be too high and that other approaches may result in progress from which later formal protocols may benefit.

In an article published in 2005, I called for an international framework convention to consider an international biodefense ethic among nations (Sutton 2005). This proposal comes from my experience in the process of the development of international agreements. In 1990, I was a member of the White House staff who worked to prepare for the first Global Climate Change Convention, hosted by the United States, which was the first step of the international process that ultimately led to drafting of the Kyoto Protocol. The dialogue began, much like a dialogue might begin with an ethic of biodefense—by identifying the core concepts on which all can agree.

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