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LEGAL ISSUES IN MEDICINE

Bioterror and “Bioart” — A Plague o’ Both Your Houses

George J. Annas, J.D., M.P.H.

Since September 11, 2001, the threat of bioterrorism has caused Congress and the President to dramatically increase research funding for countermeasures, including funding for new biosecurity laboratories. The new kind of war against non-state actors who use terror to intimidate populations has also made the creation of new ethical and legal rules for researchers seem critical. New laws have been passed, and there have been proposals for new codes of ethics for bioterrorism-related research. Almost five years after September 11, however, the outcome of the development of new research rules remains uncertain.

Ethical guidelines for life sciences research that could be related to bioterrorism are critical, and the scientific community should be actively engaged in setting the standards for such research.^{1,2} As the National Research Council of the National Academy of Sciences has stated, “biological scientists have an affirmative moral duty to avoid contributing to the advancement of bio-warfare or bioterrorism.”¹ It is reasonable for society to expect that scientists will adopt the equivalent of the physician’s “do no harm” principle.¹ Arguing for such an oath well before September 11, literary scholar Roger Shattuck noted that it could “help scientists scrutinize the proliferation of research in dubious areas” as well as “renew the confidence of ordinary citizens” in what is a potentially revolutionary endeavor.³

As the debate about the role of ethical standards proceeds, some legal standards have already been adopted. Even with their new legal powers, the Federal Bureau of Investigation (FBI) and Central Intelligence Agency (CIA) have been unable to discover the source of the anthrax attacks. The FBI investigations have, however, focused on two other biosafety cases that have become infamous. Neither of these cases involves bioterrorism, but both illustrate how — in a post-September 11 world — the federal government and the public can be expected to react and even

overreact if new biosafety rules are broken in ways that may create a biohazard or public health problem.

THE CASE OF THOMAS BUTLER

Dr. Thomas Butler was the first and so far the only physician-scientist to stand trial in the United States on a bioterrorism-related charge after September 11. On January 2, 2006, Butler completed a two-year sentence that was imposed after a jury trial and upheld by a U.S. Circuit Court of Appeals.⁴ The bioterrorism-related facts no longer seem to be in serious dispute.

According to his colleagues in the field of infectious disease, Butler has had a long and successful career dating from completion of medical school and residency at Johns Hopkins University at the end of the 1960s and his service in Vietnam in the Naval Medical Research Unit. He was a faculty member at Johns Hopkins University Medical Center and Case Western Reserve University before becoming chief of infectious diseases at Texas Tech University Health Sciences Center in 1987, a post he held until his trial. His work on plague (*Yersinia pestis*) dates from his experiences treating civilians in the Vietnam War. Most recently, this work involved research in Tanzania, where he and a colleague there compared the efficacy of gentamicin with that of doxycycline in treating patients with plague infection.⁵ The results of this research were published soon after Butler was released from prison.⁶

Butler traveled to Tanzania to help set up the study in 2001, and he returned in 2002 to collect samples of *Y. pestis* taken from the subjects. He returned to the United States with these samples without the required transport permits. In June, he drove to the laboratory of the Centers for Disease Control and Prevention (CDC) in Fort Collins, Colorado, to have the samples tested, again without the required government transport permits.

In September 2002, he sent a set of plague isolates back to Tanzania in a Federal Express box labeled “laboratory materials” without the required export permits, and in October, he flew from Lubbock, Texas, to Washington, D.C. (to the Army Medical Research Institute of Infectious Diseases), with plague samples without the required permit.

In November 2002, after a series of confrontations over timely documentation of complications and death among subjects in a study of antibiotics for the biotechnology company Chiron, Butler’s local institutional review board prohibited him from performing research on human subjects. On January 9, 2003, the board, dissatisfied by his lack of cooperation, reiterated the suspension in an e-mail.⁷ On January 10, he was notified by letter of a formal inquiry into his activities. On January 11, a Saturday morning, Butler noticed that a set of 30 tubes of *Y. pestis* cultures was missing, and he noted in his journal, “Set 5 missing!” The next day, he wrote, “Can’t explain other than intentional removal, suspect theft.”⁸ On Monday, January 13, 2003, he reported to the biosafety officer at the health center that 30 vials of *Y. pestis* were missing from his laboratory. The next day, senior officials at the health center met and decided to notify the local police and the health department. The police notified the FBI, and more than 60 FBI agents and local police officers conducted an immediate investigation.

Butler was questioned by the FBI, and he waived his right to counsel (this waiver is almost always a mistake). He first insisted that he did not know what happened to the samples. However, after failing a lie-detector test (the failure was not admitted in court) and, he says, being told by an FBI agent that if he signed a statement that he had accidentally destroyed the samples (to reassure the public that there was no danger), that would be the end of the matter, he signed a statement to this effect.^{4,9} However, this statement was not the end of the matter. Butler was arrested, spent six days in jail, and then was placed under house arrest. In April 2003, a grand jury returned a 15-count indictment charging him with various crimes relating to his transport of *Y. pestis*, making false statements to the FBI, and tax evasion. Texas Tech also turned against Butler and helped the prosecution reframe the university’s contract disputes with him as crimes. In August 2003,

after Butler refused to plead guilty in exchange for a six-month sentence, he was charged with 54 additional criminal counts; these included mail fraud, wire fraud, and embezzlement arising from Butler’s research for two companies (Chiron and Pharmacia-Upjohn — now Pfizer) and concealment of two contracts with the Food and Drug Administration (FDA) from the university.⁴

As part of Butler’s pay structure, a percentage of his income was provided by the state of Texas and the remainder came from the university’s Medical Practice Income Plan, which included money earned from seeing patients, research grants, and clinical trials. All monies from these sources, with the exception of consulting contracts, were to be remitted to the Health Sciences Center. Butler entered into contracts with both Pharmacia and Chiron in which his fee per subject would be split between the Health Sciences Center and himself. These contracts, the first of which commenced in 1998, continued until August 2001, and they did not come to the attention of the Health Sciences Center until July 2002.⁴

Butler voluntarily gave up his medical license before the trial. After the three-week trial, which included testimony from 40 witnesses, a jury found Butler not guilty on almost all the plague-related charges (which included lying to the FBI) and not guilty of tax evasion. It did, however, find him guilty on most of the charges related to his split-fee contract arrangements (44 of the 54 fraud counts) and on 3 of the 18 charges relating to the transport of plague samples.⁴ He was sentenced to 24 months in prison and 3 years of supervised release and was charged \$15,000 in fines and \$38,675 restitution to the university. He appealed.

Five issues were raised on appeal. The two most important of these issues dealt with the possibly prejudicial effect of combining the “plague counts” with the contract counts and whether there was sufficient evidence of criminal intent relative to the failure to file the required shipping forms for plague samples. Regarding the first issue, the appeals court ruled without much discussion (and arguably without much understanding of how medical research is conducted) that all these counts could be combined because they all had to do with Butler’s “research efforts”: “Butler’s handling of plague bacteria as part of his research efforts was ultimately related to his scheme to defraud HSC [Health Sciences Center] by concealing both his contracts with the FDA

and the split contracts Butler maintained with the two pharmaceutical companies.”⁴ If the Supreme Court agrees to hear his appeal, the possibly prejudicial effect of combining these counts is Butler’s strongest argument.

The appeals court also had little sympathy for Butler’s contention that the evidence was insufficient to show that he acted willfully in regard to the only 3 plague-related charges (of 18 charges) he was convicted of: first, exporting plague to Tanzania without a license; second, describing plague as “laboratory materials” on a Federal Express waybill; and third, violating federal hazardous materials regulations in shipping plague to Tanzania.⁴ Regarding the first and third plague-related charges, the court was persuaded that because Butler “had successfully and legally shipped hazardous materials [during the 1990s] at least 30 times before making this particular shipment” there was sufficient evidence that he knew how to ship it properly and that “his infraction could not have been due to a good faith mistake or a misunderstanding of the law.” As for Butler’s contention that he did not intend to deceive anyone by labeling plague “laboratory materials,” the court accepted the government’s argument that he had also certified on the same label that he was “not shipping dangerous goods” and that the jury could reasonably conclude that he knew “that plague was a dangerous good requiring the proper identification.”⁴

“BIOART” AND BIOTERRORISM

Shortly after Butler’s trial, in another part of the country — Buffalo, New York — FBI agents were called in to investigate a suspected act of bioterrorism in the home of Steve Kurtz, a professor and artist at the State University of New York at Buffalo. Kurtz awoke on May 11, 2004, to find his wife dead beside him. Kurtz and his wife previously had cofounded the Critical Art Ensemble, an artists’ collective “dedicated to exploring the intersections between art, technology, radical politics and critical theory.”¹⁰ Kurtz liked to distinguish what he did from the emerging field of “bioart,” which is perhaps best known to the public because of the notoriety of Alba, a rabbit that glowed green because of the insertion of a jellyfish gene. Kurtz thinks of bioart as consisting of stunts and his own art as an exploration of “the political economy of biotechnology.”¹⁰ He had

previously argued against the introduction of genetically modified food, and he had encouraged activists to oppose it by means of “fuzzy biological sabotage” — for instance, by releasing genetically mutated and deformed flies at restaurants to stir up paranoia.¹⁰

The day after his wife’s death, the FBI raided his home in full biohazard gear. Kurtz had been studying the history of germ warfare for a new project. In connection with this project, he was growing bacterial cultures that he was planning to use to simulate attacks with anthrax and plague. He had obtained the bacteria samples (*Serratia marcescens* and *Bacillus atrophaeus*) from a colleague, Professor Robert Ferrell, a geneticist at the University of Pittsburgh Medical Center, who had ordered them for him from the American Type Culture Collection. Kurtz and Ferrell were suspected almost immediately of being involved in a bioterror ring and were thoroughly investigated. Once the New York Department of Health determined that the bacteria were harmless and that Kurtz’s wife had died of natural causes, the bioterrorism investigation was dropped. The Justice Department nonetheless charged both Ferrell and Kurtz with four counts of wire fraud and mail fraud. The allegation was that Ferrell, at Kurtz’s request, defrauded the University of Pittsburgh and the American Type Culture Collection by representing that the bacteria samples he ordered would be used in his University of Pittsburgh laboratory.¹¹ Neither case has yet gone to trial.

Exactly what Kurtz was planning to do with the bacteria is unclear, but *Serratia*, which is known for its ability to form bright red colonies, has been used in biowarfare simulations in the past. Perhaps its most well-known use was a 1950 simulation in which an offshore naval vessel blanketed a 50-square-mile section of San Francisco with an aerosol spray containing *Serratia* to determine what dose could be delivered effectively to the population.¹² Whether using a similar technique as an art exhibit would constitute bioart, biotechnology, or biohazard (or even bioterrorism) may be in the eye of the beholder even more than in the eye of the artist or scientist.

Bioart is not bioterrorism, but the two are related politically. As bioart curator and commentator Jens Hauser has said, bioart aims “at the heart of our fears” and is meant to “disturb.” He notes, “these artists expose the gulf between the apologetic official discourse about technosci-

ence on the one hand, and paranoia on the other.”¹³ Like defensive and offensive bioweapons research, bioart and biotechnology may be impossible to distinguish by anything other than the researcher’s or creator’s intent. Thus, Alba, the bunny with the inserted jellyfish gene, is considered to be and is accepted as a creation of bioart, at least in the contemporary art community; whereas ANDi, the monkey with the inserted jellyfish gene, is considered to be a creation of science, at least in the biotechnology community. Hauser was referring to paranoia in the face of the “rapid acceleration of technical prowess.”¹³ On the basis of the reaction of federal law enforcement to the actions of Thomas Butler and Steve Kurtz, however, although the advances of biotechnology that have potential applications to bioterrorism and biowarfare are scary, even scarier are the responses — in the name of preventing bioterrorism — of law-enforcement agencies to legitimate scientists and artists whose actions pose no threat to the public.

Butler’s arrest came about one year after a simulated bioterrorism event in Lubbock, Texas; this simulation involved the use of aerosolized plague at a civic center.⁵ Simulations have been a centerpiece of efforts to prepare for acts of bioterrorism. As we should have learned from our obsession with building bomb shelters during the Cold War, however, simulations promote fear of worst-case scenarios and make them look much more likely. Bioterrorism simulations such as Dark Winter (smallpox) and Top Officials (TOPOFF) (plague) involve more art than science and are likely to provoke a response based more on fear than logic. They should probably be classified as bioart in the sense of performance art, and they should have their most socially useful outlet not in federal law-enforcement agencies or biosafety laboratories but in television dramas like 24.

BIOTERRORISM AND SCIENCE

The case of physician-researcher Thomas Butler has been the subject of many commentaries — most arguing that his prosecution represents a gross overreaction on the part of federal authorities. Nonetheless, in an article in *Science*, Margaret A. Somerville and Ronald M. Atlas argued that Butler’s prosecution “sent a clear signal to the research community, especially scientists and uni-

versity researchers, that all ethical and legal requirements must be respected when undertaking research.”¹⁴ They continued, “Biosafety regulations are not merely legal technicalities. They constitute some of the terms of the pact between science and the public that establishes public trust.”¹⁴

Somerville and Atlas are correct to argue that researchers must take law and ethics seriously, and their call for a new code of ethics is reasonable. It would be too broad, however, to suggest either that there are no such things as “legal technicalities” or that all such technicalities are reasonable. Jennifer Gaudioso and Reynolds M. Salerno of the Sandia National Laboratories, for example, have argued persuasively that not all pathogens and toxins pose the same risks and that risk in the laboratory should “be a function of an agent’s weaponization potential and consequences of its use” (rather than the current assessment of biosafety risk, which focuses on “infectious disease dangers and the risk of accidental exposure in the laboratory”).¹⁵ They also note that under the regulations of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act and the Public Health Security and Bioterrorism and Response Act that require entities with certain agents to register with the CDC, only 323 of the 817 facilities that the CDC expected to register actually did.¹⁵ Other facilities may register, but many research entities decided to discontinue their research projects, rather than conform to the new federal administrative and security rules for such research.¹⁵ A 2006 National Academy of Sciences report rejects the use of an agent-specific threat list and instead recommends adoption of a “broader perspective on the ‘threat spectrum’ . . . to ensure regular and deliberate reassessments of advances in science and technology and identification of those advances with the greatest potential for changing the nature of the threat spectrum.”²

Ethics and law are related, but they are not the same. Law draws the line we cannot cross without becoming “outlaws.” Even if we do not like it, we must nonetheless follow it (while working to change it) or risk, as Butler did, being prosecuted for being an outlaw. All Americans, including physicians, should recognize that when the FBI wants to talk to them about their role in a possible bioterrorist event, they should not talk

to the FBI without first speaking with a lawyer. Americans can go to jail for violating the law, but not for violating codes of ethics. We aspire to uphold ethics — we deserve praise (at least some) for behaving “ethically”; whereas we deserve none for simply following the law, some of which is in fact made up of “legal technicalities.”

Because the differences between research on offensive biologic weapons and research on defensive biologic weapons are a matter of degree, not kind, and because biotechnology research is an international activity, any evidence that such research is doing more to put the public at risk than to protect the public will (and should) be especially damaging to the entire enterprise. This is one reason why Butler’s report of missing plague bacteria (still unaccounted for) could not be tolerated by federal officials who support the expansion of research on countermeasures. It is also what makes Kurtz’s bioart so disturbing — the public is confronted with the dark side of bioterrorism-related research, and it provokes a response. The inherent dual nature of biodefense research has been dubbed “the Persephone effect,” which refers to Demeter’s daughter who was forced to spend six months every year with Pluto in Hell so she could live the other half of the year on Earth.¹⁶

One reasonable response to the dispute between Butler and the Justice Department and the dispute between Kurtz and the Justice Department could be Mercutio’s retort in *Romeo and Juliet*: “A plague o’ both your houses.”¹⁷ This is because the public is currently more victim and bystander than participant and seems much more likely to be harmed than helped by much of the research. Members of the public recognize this probability, and their skepticism of federal authorities, of the effectiveness of countermeasures, of the existence of weapons of mass destruction in Iraq, and of the entire bioterrorism scare is well illustrated by the few people who took drugs to treat anthrax that were offered after the anthrax attacks.¹⁸ This same skepticism, combined with the lack of evidence of stockpiles of smallpox in Iraq and the certainty of side effects from the drugs, also explains the small number of health professionals who volunteered to take the smallpox vaccine immediately before and shortly after the commencement of the war in Iraq.¹⁸

Table 1. Seven Classes of Microbial Experiments That Should Require Review.*

The experiments would:

- Demonstrate how to render a vaccine ineffective
- Confer resistance to therapeutically useful antibiotics or antiviral agents
- Enhance the virulence of a pathogen or render a nonpathogen virulent
- Increase transmissibility of a pathogen
- Alter the host range of a pathogen
- Enable the evasion of diagnostic and detection methods
- Enable the weaponization of a biologic agent or toxin

* Data are from the National Research Council.¹

ETHICS, BIOTERRORISM, AND LIFE SCIENCES RESEARCH

Research directed at creating new pathogens or toxins that have direct bioterror or biowarfare applications deserves condemnation. The National Research Council, for example, has identified seven classes of microbial experiments (Table 1) that should “require review and discussion by informed members of the scientific and medical community before they are undertaken.”¹ If such experiments are undertaken at all, I believe there also should be a requirement for publication of the protocol and public input into the decision. Research directed at individual pathogens and their weaponization potential also risks the diversion of scientific resources from more important public health concerns,¹⁹ just as it has seemed to divert the FBI’s attention from real terrorists.

There appears to be a consensus in the scientific community that the free and open exchange of information is ultimately the best defense to both naturally occurring pandemics and deliberate biologic attacks.^{2,20} There is also a growing recognition of the importance of developing an international code of ethics for scientists as well as a recognition that such a code must “become part of the lived culture” of scientists.^{2,20} Like bioart, the development of this code remains a work in progress.

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