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PUBLIC HEALTH AND BIOSECURITY

The Limits of Government Regulation of Science

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Last summer, two research teams funded by the National Institutes of Health genetically modified H5N1 avian influenza viruses, making them capable of efficient respiratory transmission between ferrets. Ferrets are thought to be a good animal model for influenza in humans. A small number of genetic changes might be able to convert the presently zoonotic H5N1 virus into a pathogen with dangerous pandemic potential—transmissible

ology and results could become a blueprint for bioterrorism (1).

The U.S. government's request not to publish key scientific findings sparked considerable controversy. To many researchers, knowledge about what mutations enable respiratory transmission is essential to surveillance of and early action against variants of H5N1. They worry that government intrusion into scientific innovation would discourage vital research. However, security

A transparent institutional review process will balance scientific freedom and national security better than publication restrictions.

about building a hydrogen bomb, even though the information was in the public domain; the injunction was later vacated when the article was published elsewhere (2). In 2005, the *Proceedings of the National Academy of Sciences* refused to comply with an HHS request to decline publishing a mathematical model of botulism in the milk supply (3). The H5N1 case, however, is the first time government has sought to redact information after an institutionalized HHS review process.

The court ruled that federally funded scientific research, especially at universities, should be free from prior restraint—calling into question the validity of CUI conditions on research grants.

from human-to-human, with a >50% case-fatality rate. The National Science Advisory Board for Biosecurity (NSABB), which advises the U.S. Department of Health and Human Services (HHS), recommended that two journals, *Science* and *Nature*, redact key information before publication. The NSABB and HHS expressed concerns that published details about the papers' method-

advocates believe the greater risk is that the mutated virus could escape or that knowledge about these mutations could get into the wrong hands. They suggest that research of this kind should not be funded or undertaken in the first place. Where, as here, the research has already been conducted, they urge scientific journals not to publish any sensitive methods or results (1).

The HHS request reveals a troubled relationship between security and science. This is not the first time a government has requested that a journal not publish information. In 1979, the U.S. Department of Energy secured an injunction against the magazine *The Progressive* to prevent the publication of an article

Constitutional Limits on Government Restrictions of Scientific Publications

The First Amendment to the U.S. Constitution affords considerable protection to political, artistic, and scientific expression, that could trigger "strict scrutiny" by the Supreme Court (4). The court is most vigorous in reviewing government restraints on speech in advance of publication, which it calls "prior restraints." Prior restraints are uniquely threatening to First Amendment values because they prevent ideas from ever being heard (5).

Had the government compelled the H5N1 researchers to cease research or the journals to withhold publication—whether through the force of law or by creating adverse consequences such as loss of funding—it could have violated the First Amendment. Even informal systems of restraint can be unconstitutional, such as a government threat to prosecute publishers (5). In this case, however, HHS' request, by its own terms, was nonbinding, and the journals had discre-

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tion whether or not to comply (6). Given the absence of legal force or undue inducements or penalties, the government's request to withhold information does not violate the First Amendment.

There are situations in which a government has the authority to block scientific communications. The clearest case is when research has been properly classified under federal law and the person seeking to communicate findings obtained it under the terms of a security clearance—whether they are still working for the government or not, so long as procedural requirements are met (7). Although a researcher is obliged to keep classified information confidential, publishers who obtain that information lawfully have a right to publish. In the *Pentagon Papers* case, the Supreme Court held that President Nixon did not overcome the “heavy presump-

on research grants. The wider the scope of CUI conditions, the more likely that courts will invalidate them (4).

The Supreme Court's “unconstitutional conditions” doctrine holds that government may not place conditions on public funding that require the recipient to surrender First Amendment rights. Thus, government has no obligation to provide research funding, but if it chooses to, it cannot restrain the free expression of researchers without a compelling state interest. For example, a federal appellate court recently struck down HHS guidelines requiring recipients of AIDS prevention funding to pledge their opposition to prostitution, reasoning that it was an unconstitutional condition (10).

The unconstitutional conditions doctrine, however, is hard to decipher. For example, the Supreme Court upheld HHS prohibitions on

Could the public obtain sensitive data that have been redacted from publications through a FOIA request? If so, governmental requests to redact sensitive information would be fruitless.

tion” against prior restraint when he sought to prohibit publication of classified materials. The court found that an undefined concept of “security” did not “abrogate the fundamental law embodied in the First Amendment” (8).

It is far less clear whether government may suppress the publication of research conducted with government funding when the results are “controlled unclassified information” (CUI) [sometimes referred to as “sensitive but unclassified” (SBU)] under conditions set by government grants or contracts. Traditionally, the federal government restricted communication about basic science research only through classification. However, CUI restrictions have become more common, and no court has directly addressed their constitutionality. Although it is unclear how often CUI clauses include a prepublication review requirement, research suggests that they occur with some regularity (9).

Board of Trustees of Leland Stanford Jr. University v. Sullivan is the most pertinent case for evaluating CUI restrictions. Stanford University challenged an NIH confidentiality clause that required the university to seek prior approval before publishing preliminary findings about artificial heart research to protect the public from unvalidated research findings. The court ruled that federally funded scientific research, especially at universities, should be free from prior restraint—calling into question the validity of CUI conditions

the use of family planning funds to counsel women regarding abortion, reasoning that government is entitled to subsidize one protected right (family planning), while refusing to subsidize analogous rights (abortion counseling) (11). The court similarly upheld the government's right to withhold funding to any public university that denied access to military recruiters, even though the universities claimed it violated their freedom to disapprove of the military's “don't ask, don't tell” rule. The court said the law neither denied the institutions the right to speak nor required them to say anything (12).

Scientific Publication from Countries Subjected to U.S. Economic Sanctions

In the past, the federal government has impeded scientific publication processes, not because of articles' content but rather because the authors were from countries against which the United States had imposed economic sanctions. The Department of Treasury's Office of Foreign Assets Control (OFAC) enforces these economic sanctions. For a brief period in 2003, OFAC restricted the review process for scientific papers submitted from countries sanctioned by the United States (13). In particular, OFAC informed the Institute of Electrical and Electronics Engineers (IEEE) that, although its journals could subject papers from sanctioned countries to peer review, they could not make prepub-

lication edits without a specific license. In essence, OFAC argued that editing a paper was providing a service to foreign authors in violation of trade embargoes. In 2004, OFAC reversed that decision and allowed normal scientific editing to occur (14). Had OFAC not reversed itself, First Amendment challenges against the policy likely would have prevailed (15).

Access to Sensitive Data Under the Freedom of Information Act

A functioning democracy requires that citizens be able to access information in the government's possession, but not if access poses an unacceptable security risk. The Freedom of Information Act (FOIA) balances these concerns by affording access to federal agency records unless the records fall within a statutory exemption. Federal agencies support much of the research in the United States, including both of the recent H5N1 studies. Could the public obtain sensitive data that have been redacted from publications through a FOIA request? If so, governmental requests to redact sensitive information would be fruitless.

FOIA applies only to “agency records,” so a threshold issue is whether university research data acquired under a grant constitute an agency record. In 1980, the Supreme Court ruled that research data produced under an NIH grant and used in regulatory proceedings by the U.S. Food and Drug Administration did not constitute an agency record subject to FOIA because it was retained by the non-governmental grantee. The court found that FOIA required the agency to either produce or obtain permanent custody of the data (16).

The “Shelby amendment,” enacted in 1999, expanded public access to data produced at universities and other nonprofit research entities under federal grants. The public can request the data if they were produced under a federal grant and “cited publicly and officially by the Federal Government in support of an agency action that has the force and effect of law” (17). Federal agencies could take care not to officially cite highly sensitive data, thereby avoiding a successful FOIA request. However, it is not always simple or easy to refrain from referencing sensitive research. The NIH, for example, might reasonably refer to the H5N1 research as justification for revising biosecurity policies.

Even if sensitive data do become part of an agency record, FOIA provides the federal government with ample authority to refuse a request on security grounds. FOIA provides nine exemptions under which records that would otherwise have to be disclosed

may be withheld, one of which is for “matters that are specifically authorized under criteria established by an executive order to be kept secret in the interest of national defense or foreign policy and are in fact properly classified pursuant to such an executive order” (18). Through this exception, Congress has acknowledged broad executive authority to classify records so long as it is done lawfully pursuant to an executive order.

President Obama’s 2009 Executive Order 13526 revises existing classification standards (19). Although it was designed to reduce the amount of classified materials, the executive order affords agencies considerable discretion to classify on security grounds. Consistent with prior policy, the executive order mandates that “basic scientific research information not clearly related to the national interest shall not be classified.” However, the order permits the classification of “scientific, technical, or economic matters relating to the national security,” provided that disclosure is reasonably expected “to cause identifiable or describable damage to the national security.” Furthermore, agencies may classify data that meet the executive order’s standards even if the data were not classified at the time of the FOIA request (19). Thus, federal agencies have wide authority to prevent the release of research information through a FOIA request simply by classifying it, provided that there are legitimate national security justifications.

In 2010, President Obama issued a further executive order stating that CUI is not automatically exempt from FOIA (20). Thus, to ensure that sensitive biological research information is not disclosed, agencies would have to classify it. [Certain nonbiological research, such as nuclear energy, is automatically exempt from FOIA, as are the locations where select biological agents are held (21).] Some research data also might be protected under FOIA exemptions for trade secrets or predecisional deliberative memoranda within the government, but these options are limited (22).

The law, then, draws a distinction between classified and controlled unclassified information. However, from a constitutional perspective, it would be troubling if the result turned solely on the label the government placed on the data. If the result did turn on the label, the government could simply relabel research from CUI to classified and thus prohibit its dissemination. Although decisions to classify can be challenged, prevailing is difficult, and unnecessary classification is common (23). This appears to place too much discretion in the hands of public officials.

The problem of government discretion is compounded by highly inconsistent practices among federal agencies in the classification systems they use. There is inconsistency of structure (the labels attached, such as classified, CUI, SBU, or other terminology), as well as in the application of that structure to individual documents (no clear standard exists for deciding whether to classify particular information). In short, the line between classified and CUI remains unclear, as agencies struggle to apply President Obama’s executive orders (24).

Balancing Scientific Freedom, Constitutional Values, and Biosecurity

The federal government has the power to prevent the dissemination of sensitive life-sciences research, but there are good reasons to exercise that power sparingly. The current system of deliberation by a federal expert advisory board and HHS-issued voluntary recommendations is preferable to formal government mandates. Although we do not have all the data, the NSABB process in the H5N1 cases appears reasonable, given that unredacted publication could enable bad actors with scientific skill to replicate the studies, with profoundly harmful effects. The federal government has promised to share the researchers’ methods and conclusions with scientists with a need to know, which substantially advances scientific objectives.

Can the review process for high-risk biologic research be improved further? The NSABB’s origins can be traced to the so-called Fink report issued in 2004 by the National Research Council (21). However, vital aspects of the Fink report have not been implemented. In particular, the Fink report proposed an institutional review process for biological “experiments of concern”—those falling into seven research classes, making the pathogen considerably more attractive as a bioterrorism agent (e.g., by enhancing virulence or transmissibility or by rendering vaccines ineffective). This approach was patterned on the Institutional Biosafety Committees (IBCs) required by NIH for recombinant DNA research at institutions receiving federal funding, which generally have been considered to be successful (21).

HHS, in partnership with institutions, will have to ensure that the IBC model works effectively: (i) institutions must develop the requisite expertise to review dual-use research of concern; (ii) HHS must specify the categories of research requiring institutional review—minimally including the seven types of high-risk experiments; and (iii) HHS must set clear and consistent standards for institu-

tional review. If IBCs are formally designated to conduct the institutional review function, HHS will have to clarify whether NSABB will guide and oversee the process (21). In addition, because IBCs may recommend that researchers voluntarily restrict access to methods or results in some instances, it will be important for HHS to develop a system for managing access to sensitive data and for disseminating it to those with a need to know in a fair manner.

If HHS improves its functioning, the institutional review process can ensure a sound balance between scientific freedom and national security. A fair, transparent process undertaken by research institutions, with a balanced approach to scientific benefits and public safety, together with HHS guidance and oversight of high-risk research, is preferable to government constraints on scientific information by force of law.

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