

## FOR IMMEDIATE RELEASE

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### **Balancing Scientific Freedom and National Security**

*Two Georgetown professors explore a process needed to avoid the current dilemma faced by two scientific journals recently asked by the U.S. government to redact parts of scientific publications deemed to be a biosecurity threat.*

**WASHINGTON, DC** -- The U.S. government's request that the journals *Science* and *Nature* withhold scientific information related to the genetically modified H5N1 virus because of biosecurity concerns does not violate the First Amendment, say two Georgetown University professors. They caution, however, that a fair, transparent process undertaken by research organizations is preferable to governmental constraints on disseminating scientific information.

Writing in *Science*, John D. Kraemer, JD, MPH, assistant professor of health systems administration at Georgetown University School of Nursing & Health Studies, and Lawrence O. Gostin, the Linda D. and Timothy J. O'Neill Professor of Global Health Law and faculty director of the O'Neill Institute for National and Global Health Law at Georgetown University Law Center, explore the balance of scientific freedom and national security in their opinion piece published online today entitled, "The Limits of Government Regulation of Science."

In 2011, two research teams genetically modified the H5N1 avian influenza virus. The work, funded by the National Institutes of Health (NIH), demonstrates the ability to alter a virus in such way that it could possibly spread rapidly among humans – killing more than half who contract it (the research was conducted in an animal model believed to represent human behavior of the virus). The research prompted the National Science Advisory Board for Biosecurity, which advises the Department of Health and Human Services (HHS), to recommend that *Science* and *Nature* redact key information prior to publication. The NSABB and HHS expressed concerns that published details about the papers' methodology and results could become a blueprint for bioterrorism.

"The NSABB process seems to have worked well in this instance," says Kraemer. "It raised legitimate security concerns while avoiding censorship of the scientific press. But there remains a need to strengthen precautions around this type of research before it occurs."

To date, *Science* and *Nature* have not yet made their intentions known regarding the government's request.

In their commentary, Kraemer and Gostin write "HHS' request reveals a troubled relationship between security and science." However, the authors point out, "Given the absence of legal force or undue inducements or penalties, the government's request to withhold information does not violate the First Amendment."

Kraemer and Gostin say the First Amendment, "affords considerable protection to political artistic and scientific expression, triggering 'strict scrutiny' by the Supreme Court." They point out that had the government compelled either the researchers or the journals to withhold publication, that act would have violated the First Amendment.

In their opinion piece, the authors explore various court cases that challenge and support the government's rights to go further with such an issue. They say the federal government has the power to prevent dissemination of sensitive life science research, but warn, "...there are good reasons to exercise that power sparingly."

Looking beyond the current dilemma, Kraemer and Gostin ask: "Can the review process for high-risk biologic research be improved further?"

The National Science Advisory Board for Biosecurity origins can be traced to the Fink Report issued in 2004 by the National Research Council. However, Kraemer and Gostin point out that vital aspects of the Fink Report have not yet been implemented, including the need to employ an institutional review process for biological "experiments of concern" patterned on the NIH's Institutional Biosafety Committees (IBC).

Kraemer and Gostin make the following recommendations:

HHS, in partnership with institutions, will have to ensure that the IBC model works effectively: (1) institutions must develop the requisite expertise to review dual use research; (2) HHS must specify the categories of research requiring institutional review—minimally including the 7 types of high-risk experiments; and (3) HHS must set clear and consistent standards for institutional 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.

Kraemer and Gostin suggest that such a 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."

### **About Georgetown University Law Center**

Georgetown University Law Center is one of the world's premier law schools. It is pre-eminent in several areas, including constitutional, international, tax and clinical law, and the faculty is among the largest in the nation. Drawing on its Jesuit heritage, it has a strong tradition of public service and is dedicated to the principle that law is but a means, justice is the end. With this principle in mind, Georgetown Law has built an environment that cultivates an exchange of ideas and the pursuit of academic excellence. It brings together an extraordinarily varied group of teachers, scholars and practitioners, as well as an outstanding student body representing more than 60 countries.

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Georgetown University Medical Center is an internationally recognized academic medical center with a three-part mission of research, teaching and patient care (through MedStar Health). GUMC's mission is carried out with a strong emphasis on public service and a dedication to the Catholic, Jesuit principle of *cura personalis* -- or "care of the whole person." The Medical Center includes the School of Medicine and the School of Nursing & Health Studies, both nationally ranked; Georgetown Lombardi Comprehensive Cancer Center, designated as a comprehensive cancer center by the National Cancer Institute; and the Biomedical Graduate Research Organization (BGRO), which accounts for the majority of externally funded research at GUMC including a Clinical Translation and Science Award from the National Institutes of Health. In fiscal year 2010-11, GUMC accounted for 85 percent of the university's sponsored research funding.

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