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Gail-of-Function Virus Research: An Uneven Regulatory Environment

Several years of turbulence around the legitimacy and value of research that alters the genetics of highly dangerous pathogens in order to determine the relationship between DNA and function were the backdrop to the 2014 announcement of a temporary moratorium on federal funding for new gain-of-function research involving influenza, MERS, and SARS, as well as a call to pause any current research in progress. "Gain-of-function" (GOF) studies include experiments that can introduce genetic changes into the genomes of dangerous pathogens in order to study both transmissibility and pathogenicity; such genetic alterations, however, may confer new or enhanced functions on a pathogen that makes it more dangerous than in its native (wild-type) state. As a result, this kind of research could produce what have been called potential pandemic pathogens (PPP). These experiments also exemplify dual-use research of concern (DURC), owing to their potential for both productive and malicious uses. When scientists reported the creation of GOF highly pathogenic avian influenza H5N1 viruses in 2011 that exhibited potential aerosol transmissibility in animal models, concerns emerged as to how such scientific detail should be publicly shared (if at all). Most of the controversy focused on the publication of genetic details regarding GOF viruses with enhanced transmissibility, evidencing concerns that the pathogens could be reconstructed for malicious intent. Although these controversial experiments were published, a voluntary and temporary moratorium on such research was agreed to by scientists in early 2012.

The controversy over GOF virus experiments can also be attributed to a serious concern over the integrity of biocontainment for these viruses; recent reports in 2014 of widespread biosafety lapses at high-profile federal laboratories only heightened alarm over the possibility of an inadvertent release of a PPP. As it announced the funding moratorium on GOF virus research in late 2014, the Obama administration called on the National Science Advisory Board for Biosecurity and the National Research Council to undertake more formal evaluative reviews of the pros and cons of these experiments. This can be interpreted as an official acknowledgement that the funding of GOF virus research requires a more formal deliberative process which needs to precede, not follow, federal decisions to fund such research. This presentation will review the uneven regulatory climate in which GOF virus research has been conducted to date, and examine how federal funding decisions will operate to structure research possibilities in this field and therefore shape its future environment. The presentation will also contrast the voluntary moratorium on GOF research instituted by scientists in 2012 with the 1974 moratorium on recombinant DNA research initiated by molecular biologists in conjunction with the landmark Asilomar Conference on Recombinant DNA. Lastly, the presentation will consider how federal funding decisions have operated to structure other life science research climates, including the Bush-era funding ban on embryonic stem cell research.