Redaction of Sensitive Data in the Publication of Dual Use Research of Concern

ABSTRACT The publication of scientific information that derives from dual use research of concern (DURC) poses major problems for journals because it brings into conflict the benefits of free access to data and the need to prevent misuse of that information by others. Recently, a group of authors and a major scientific journal addressed the issue of publishing information on a newly discovered, highly lethal toxin that can be delivered to large populations and for which there are no available countermeasures. The journal addressed this conflict by permitting the redaction of information that is normally considered essential for publication. This action establishes a precedent for redaction of sensitive data that also provides an example of responsible scientific publishing. However, this precedent leaves many questions unanswered and suggests a need for a discussion by all stakeholders of scientific information so as to derive normative standards for the publication of DURC.

In recent years, submission of scientific information for publication when the information results from "dual use research of concern" (DURC) has led to a vexing problem for journal editors. DURC was defined by the National Science Advisory Board on Biosecurity (NSABB) as "research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel" (http://oba.od.nih.gov/biosecurity). When considering DURC for publication, journals have struggled to balance the principle that scientific information be published in its entirety so that it can be reproduced and gainfully exploited with the concern that such information could also be used for nefarious purposes.

Perhaps the best-known case for the issues and difficulties involved in publishing DURC arose from the submission of two papers from independent groups in 2011 describing the ability of H5N1 avian influenza viruses to acquire the capacity for mammalian transmission as a result of several well-defined amino acid changes that were created in the laboratory (1). In that case, the NSABB considered the research presented in these papers and determined that it represented DURC and that sharing of the data in its entire detail also posed a real risk for either intentional or unintentional misuse of this information. The NSABB concluded that the genetic descriptions of the laboratory-engineered mutations could be misapplied with grave consequences and, at the same time, did not provide a commensurate immediate benefit to public health or society; therefore, NSABB recommended in 2011 that the mutation sequences be redacted from the papers. After several months, the NSABB was informed that redaction was not feasible because a number of factors, including export control requirements, required that all or none of the research methods and results be published. NSABB subsequently in 2012 voted unanimously for the publication of a revised manuscript with all genetic data from the Kawaoka group and 12 to 6 for the publication of a revised manuscript with all genetic data from the Fouchier group. Both papers were published in 2012, and since that time, at least two other papers reporting laboratory-engineered mutations that confer gain-of-function in avian flu viruses have been published (2, 3), with accompanying editorials explaining the editors' decisions to proceed with full publication of scientific details (4, 5).

One of the issues left unresolved from the H5N1 influenza virus publication controversy was whether there is a practical mechanism and process for redaction of critical data by journals. Redaction refers to the results of an action, "to select or adapt (as by obscuring or removing sensitive information) for publication or release" (http://www.merriam-webster.com/dictionary). Although one might argue that redaction is routinely practiced by journals in the process of scientific publishing when reviewers and editors ask for the removal of certain data or text in order to improve a manuscript, the type of redaction that we are discussing here is the deliberate removal of data that under normal circumstances would be considered important for furtherance of the scientific enterprise but that constitute a serious potential risk to the public welfare. Three scientific arguments are generally made against redacting information: (i) that redaction of data precludes reproduction of the study, (ii) that the data must be published because they are essential for supporting the conclusions of the paper, and (iii) that based on principle and tradition, scientific data born in the free pursuit of knowledge shall remain openly available. Implicit in the last argument is the notion that such information may find usefulness in future studies even when such benefit may not be discernible in the present. A fourth legal and policy issue concerns compliance with export control and International Traffic in Arms Regulations (ITAR) requirements. These arguments and issue have created a high standard and barrier against the use of redaction. Consequently, most if not all papers that describe DURC have resulted in full publication. In fact, we are not aware of any prior examples of redactions in life science publications over security concerns.

Recently, the *Journal of Infectious Diseases* (JID) published two papers reporting a new type of *Clostridium botulinum* toxin that is not neutralized by existing antitoxins (6, 7). After the authors of the study voiced concern about the DURC implications of this discovery and the risks associated with open dissemination of the toxin sequence, JID took the unusual step of waiving its requirement that sequence information described in the manuscript be

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deposited in public databases, and none of the critical genomic sequence information was published (8, 9). The need for limited distribution of these data is only temporary, since the development of specific antisera to the new toxin is likely to be feasible in the near-to-midterm future. Hence, JID decided to transmit the important new information that there is a new botulinum toxin in nature but not the detailed information that could be used by a skilled person to produce this toxin. We are not aware of a formal review of this decision by the respective federal agencies responsible for export control (Department of Commerce) or ITAR (Department of State). The latter issue remains a concern.

We consider this action to be an example of responsible scientific journalism and commend JID and the authors for exercising prudence and responsibility. Furthermore, we believe that this action may establish an important precedent if it indeed complies with export control and ITAR requirements, or inspires a revision of these requirements so as to comply. JID has shown that it is willing to follow through with the mechanism that the NSABB originally recommended in regard to the H5N1 gain-of-function work. This redaction provides an example of responsible authors and editors working together to diminish the negative externalities associated with DURC.

We note that the redaction of critical data by this journal leaves many unanswered questions and opens new conundrums. For example, how will the data be shared with responsible scientists so that the work can be independently confirmed and antidotes generated? What is meant by a responsible scientist? Who can have access to the sequence information? How will the data be preserved so that they are available to future generations? Are there sunset provisions on the withholding of scientific data for publication? Answers to these questions cannot be expected from one journal alone, let alone a group of interested scientists. The government of the Netherlands has required an export control license for the publication of an H5N1 paper (10), and the requirements for similar licenses in other countries for the publication of DURC, if any, need to be clarified. We call for a discussion by all stakeholders of scientific information, including the broader scientific community, representatives from the publishing world, funding agencies, the pharmaceutical industry, the general media, and the rest of the public, in order to forge a consensus on how the results from future studies involving DURC are to be handled. We note that NSABB was not involved in discussions about the recent botulinum toxin papers. Although members of the U.S. government were consulted, this is an example in which an investigator(s) takes the initiative in identifying dual use research of special concern (11). Over the past decade or so, much progress has been made in identifying issues involving DURC, including the issuance of guidelines and reports by the NSABB and others worldwide. Furthermore, there is now considerable awareness of the potential for life sciences research to generate information that can be used for both good and harm. Although there may be some lessons from experiences in the physical sciences with nuclear weapons technology, research in the life sciences is easily undertaken with modest infrastructure by individuals and small groups. The action taken by JID and the authors in publishing redacted forms of the botulinum toxin work suggests that redaction is a feasible option for some in the world of scientific publishing who are willing to take the lead in pushing forward important issues for discussion.

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