

THINKPIECE

BALANCING NATIONAL SECURITY AND OPEN
SCIENCE: A PROPOSAL FOR DUE PROCESS
VETTING

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BRIAN J. GORMAN

Since 9/11 and the anthrax attacks of the same year, the national security and scientific communities have been grappling with a dilemma over the danger posed by the publication of "dual use" science that may advance basic science and aid bioterrorists at the same time. A spate of life science articles recognized as having the ability to aid bioterrorists or enemy combatants have been published amid much consternation. The national security community turned to experts in the life sciences to develop options to address this dilemma, but the scientific community has responded defiantly at times with surprising recommendations to expose and distribute sensitive articles even more widely despite the obvious risks to national security. After succumbing to pressure from the government, the scientific community ultimately adopted a censorship policy for sensitive research. Thus the censorship policy begs questions as to whether it is sincere and whether it will dissuade researchers from pursuing biodefense research. This paper attempts to move the debate away from emotions and politics to specific methodologies to address this dilemma. A Due Process Vetting System is presented along with a Risk Assessment Scale and a Least Restrictive Classification System for the communication, assessment and disposition of sensitive life science research in a manner consistent with national security interests.

I. INTRODUCTION

The open science dilemma has been recognized as a top priority in the scientific and national security communities since the terrorist attacks of 2001. It is undisputed that the fruits of scientific advancements may also be subject to harmful "dual use" by enemy combatants, terrorists, and any number of other malefactors with the necessary skills and resources. The dilemma over open science arises from the incompatibility of restricting access to scientific findings in the interests of public welfare with a notion of public welfare that is itself reliant upon the open exchange of findings and scientific data. Therefore,

great care is needed to avoid remedies that unnecessarily impede the exchange of information between researchers and deter important lines of inquiry. Thus, a carefully crafted remedy is needed to cease free-ride opportunities available to malefactors interested in misusing scientific advancements without impeding much needed advancements in science.

Surprisingly, the most draconian and potentially deleterious remedies to the open science dilemma, to date, come from the scientific community. As of January 2003, over twenty scientific journals adopted a policy calling for the censorship of articles that present unjustifiable risks.¹ However, many recognize that censorship is not a guarantee of protection. In October 2002, the former President of the American Society for Microbiology warned that, “censorship of scientific communication would provide a false sense of protection.”² Severe measures are of concern because, if carried, out they may discourage research in areas critical to biodefense efforts. Moreover, even if applied sparingly, censorship policies are destined to undermine academic freedom and compromise national security interests.

Unfortunately, there has been little discourse in the literature on specific methods to effectively remedy the problem. While the dilemma clearly calls for “an articulated and uniform practice” to identify and assess sensitive research, efforts to create formal procedures have been abandoned.³ For example, the journal *Proceedings of the National Academy of Sciences* (PNAS), which published a sensitive article on the variola virus,⁴

1 Journal Editors and Authors Group, *Statement on the Consideration of Biodefense and Biosecurity*, 421 NATURE 771 (2003) (“FOURTH: We recognize that on occasions an editor may conclude that the potential harm of publication outweighs the potential social benefits. Under such circumstances, the paper should be modified, or not be published.”) *see also infra* Part III.

2 Daniel S. Greenberg, *Self-Restraint by Scientists Can Avert Federal Intrusion*, CHRON. OF HIGHER EDUC., Oct. 11, 2002, at 20.

3 Nicholas R. Cozzarelli, *PNAS Policy on publication of sensitive material in the life sciences*, 100 PROC. OF THE NAT'L ACAD. OF SCI. 1463 (2003).

4 See Ariella M. Rosengard et al, *Variola Virus Immune Evasion Design: Expression of a Highly Efficient*

abandoned its pursuit for uniform procedures after a self-congratulatory assessment of its ad hoc handling of the article.⁵ Despite satisfaction with the “natural” manner in which the article was vetted, flaws remain in the allegedly successful approach. For instance, the national security community was not consulted during a review of the article. Moreover, such unorganized approaches invite second guessing by participants in the process, an example of which can be found in the curious post-publication change in perspective of one of the authors of the widely discussed mousepox article.⁶ Author Ian Ramshaw subsequently presented some regret by “lean[ing] towards not publishing” after the article was released.⁷

Ramshaw’s situation and subsequent reaction is not unique. In 1975 a young Stanford University engineer, Martin Hellman, fought and won a righteous fight against the National Security Agency (NSA) in the name of academic freedom. The subject of the battle was a powerful new computer cryptology technology the NSA identified as a potential asset for U.S. adversaries. Hellman ultimately regretted his actions several

Inhibitor of Human Complement, 99 PROC. OF THE NAT’L ACAD. OF SCI. 8808 (2002).

⁵ See *supra* note 3 at 1463.

⁶ Ronald J. Jackson, et al, *Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox* 75 J. OF VIROLOGY 1205 (2001). See Brian Vastag, *Openness in Biomedical Research Collides With Heightened Security Concerns*, 289 J. OF THE AM. MED. ASS’N 686 (2003) (“The unexpected outcome...While trying to sterilize mice using genetically modified mousepox virus...a team from the Pest Animal Control Cooperative Research Centre, Canberra, Australia, discovered instead that their virus defeated the rodents’ immune systems.”); COZZARELLI, *supra* note 3 at 1463; Deborah Mackenzie, *U.S. Develops Lethal New Viruses*, NEW SCIENTIST.COM, Oct. 29, 2003, available at <http://www.newscientist.com/article.ns?id=dn4318> (last visited Apr. 12, 2005).

⁷ Philip Cohen, *Recipes for Bioterror: Censoring Science*, NEW SCIENTIST.COM, Jan. 18, 2003, available at <http://www.newscientist.com/article.ns?id=dn3266> (last visited Apr. 12, 2005).

years later when he realized that his quixotic views were “ridiculous.”⁸

It would not be surprising to find participants on either side of the open science debate change perspective down the road as emotions, ideals, patriotism, and the impact of policies are considered over time. Given the grave consequences this debate may have, some participants may yet find themselves on profound journeys of introspection similar in scope to those undertaken by atomic scientists from the Manhattan project. Sudden and profound advancements in sensitive research may trigger such introspection. For example, an unexpected advancement in DNA synthesis caused a proponent of self-governing science⁹ to depart somewhat from her alignment with the self-policing position to acknowledge a need for additional oversight of research at some point in the future.¹⁰ Regardless of position taken in the present debate, there is little disagreement over the possible remedies.

A few remedies for the dual use dilemma were discussed in the National Academies report, entitled “Biotechnology Research in an Age of Terrorism,” (hereinafter the NAS Terrorism Committee). Remedies ranged from implementing gossamer filters of “awareness” to endorsement of the draconian censorship policy and screening of research projects.¹¹ The proposals, however, lacked meaningful inclusion of the national security community in the evaluation and disposition of sensitive articles. One proposal did include the National

⁸ Gina Kolata, *Scientists Debate What to do When Findings Aid an Enemy*, N.Y. TIMES, Sept. 25, 2001, at F1.

⁹ Randolph E. Schmid, *Panel Urges Sharing of Data on Germs, available at* <http://www.sunherald.com/mld/sunherald/news/9629330.htm> (last visited Apr. 12, 2005). Claire M. Fraser said, “[n]ational security needs are best served by facilitating downstream work...we just didn’t see any way to do that other than continuing with the current open access.” *Id.*

¹⁰ Nicholas Wade, *A DNA Success Raises Bioterror Concern*, N.Y. TIMES, Jan. 12, 2005, at A17.

¹¹ See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM* 110 (2004).

Institutes of Health in vetting sensitive research, but only at the discretion of nonplussed self-governing bodies.¹² Another National Academies report entitled, "Seeking Security: Pathogens, Open Access, and Genome Databases," (hereinafter the NAS Genomic Committee) likewise discussed some safeguards for science raised by the security experts in attendance at their workshop.¹³ The security measures mentioned included the use of U.S. security classifications, partial withholding of data, and a registration prerequisite to access sensitive data. But consideration of these security proposals were summarily dismissed for being beyond their purview and ultimately unnecessary since they concluded "current policies are effective."¹⁴ Proposals from the scientific community to date invariably appear to shun meaningful partnerships with the national security community in favor of self-governance within the scientific community.¹⁵ Despite the popularity of self-governance in scientific circles, there clearly needs to be further discussion of more reliable security measures.

Therefore, this article suggests that the scientific community unleash the greatest resource at its disposal, via its system of open science, to host a vigorous exchange of specific methods and ideas to remedy the crisis facing the international community of science. In this effort, a new cooperative vetting system that incorporates a Least Restrictive Classification (LRC) system for sensitive research findings is presented.

II. THE DILEMMA

The convergence of a new age of science and a new age of terrorism threatens to compromise the delicate yet powerful engine of open science. Once-dramatic advancements in genomics, virology, and bacteriology have become de rigueur and more affordable than ever. In like manner, what was formerly unthinkable in terrorist activity has become a new reality. The

12 *Id.* at 116.

13 COMMITTEE ON GENOMICS DATABASES FOR BIOTERRORISM THREAT AGENTS, NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, SEEKING SECURITY: PATHOGENS, OPEN ACCESS, AND GENOME DATABASES, (2004) at 36.

14 *Id.* at 40.

15 *See supra* note 11 at 116; *see supra* note 13 at 40.

spirit of Sir Liam Donaldson's admonition is apt. We underestimate the warnings raised by recently published articles on the synthesis of polio and mousepox among others "at our own peril."¹⁶ Fortunately, awareness of the growing threat of bioterrorism from the misuse of life science research is widely acknowledged within scientific circles.¹⁷ Moreover, the general threat of bioterror is receiving increased attention in the national and global security communities as well.¹⁸ But the polarizing positions taken by leaders in the life sciences raise concern over the ability to find workable solutions to the dilemma.

In an apparent attempt to address the dilemma as an in-house matter, a faction of scientific editors and authors met

¹⁶ Sarah Boseley, *Agency to Fight Bioterrorism and Diseases: Government Scientists Join Forces as Growth of World Travel Spreads Infections and Boosts Risk of Attacks From Dissidents*, THE GUARDIAN, Jan. 11, 2002, at 7. *see also* Jeronimo Cello, et al., *Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template*, 297 SCIENCE, 1016 (2002); Ronald J. Jackson, et al., *Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox*, 75 J. OF VIROLOGY 1205 (2001).

¹⁷ The Royal Society and Wellcome Trust Report, *Do No Harm: Reducing the Potential for the Misuse of Life Science Research*, Oct. 7, 2004, available at <http://www.wellcome.ac.uk/assets/wtx023408.pdf> (last visited Apr. 12, 2005). "The threat of advances in the life sciences being used for harmful purposes is a real one." *Id.* at 1.

¹⁸ Eric Lipton, *U.S. Lists Possible Terror Attacks and Likely Toll*. N.Y. TIMES March 16, 2005, at A1 (The Department of Homeland Security identified and estimated the effect of a number of terror threats. The biological attacks included anthrax, pneumonic plague, food contamination, and the intentional spread of foot-and-mouth disease); Ronald K. Noble, Opening Ceremony Address at Preventing Bioterrorism: 1st Interpol Global Conference (Mar. 1, 2005) ("Today, we are all making history. This is the largest meeting of police ever in terms of country participation. Not just in Interpol's history, but ever...The reason, simply stated: there is no criminal threat with greater potential danger to all countries, regions and people in the world than the threat of bio-terrorism.").

privately to discuss options before adopting a hastily drawn censorship policy.¹⁹ Ironically, this private gathering occurred after the meeting on “Scientific Openness and National Security,” convened by the National Academies of Science and the Center for Strategic and International Studies in Washington D.C.²⁰ The editors of the journals adopting the censorship policy, however, inadvertently assumed conflicting duties in an attempt to protect the public from bioterrorism. The self-policing guidelines designed to regulate the release of “harmful” data to the scientific community was adopted by over twenty journals. The ad hoc agreement formulated by the Journal Editors and Authors Group, (hereinafter the Editors Group) sets broad guidelines for the modification or rejection of articles based upon the potential danger an article poses to society. Thus, journal editors are in the awkward, if not incompatible, position of advocating for the ideals of open science on one hand while manning the censor’s gate to the scientific community with the other.

Since it is not possible to prune a branch of science without cutting into academic freedom, society at large will be denied the benefit of an untold number of scientific studies. Under a censorship scenario, scientists interested in fighting bioterror will not be able to obtain access to other scientists’ sensitive research findings unless they become affiliated with some new underground network for the exchange of sensitive data. Furthermore, this agreement will also have an unjustifiable chilling effect on the field by discouraging researchers from undertaking research that may get blocked at the gate.²¹

19 David Malakoff, *Researchers Urged to Self-Censor Sensitive Data*, 299 SCIENCE 321 (2003); see also Journal Editors & Authors Group, *Statement on the Consideration of Biodefense and Biosecurity*, 421 NATURE 771 (2003) (“FOURTH: We recognize that on occasions an editor may conclude that the potential harm of publication outweighs the potential social benefits. Under such circumstances, the paper should be modified, or not be published.”).

20 Amy Harmon, *Threats and Responses: The Scientists; Journal Editors to Consider U.S. Security in Publishing*, N.Y. TIMES, Feb. 16, 2003, at 15.

21 Erika Check, *U.S. Officials Urge Biologists to Vet Publications for Bioterror Risk*, 421 NATURE 197 (2003)

A. THE ROAD TO CENSORSHIP

Unfortunately, the relationship between the scientific community and the U.S. government has deteriorated steadily since the terrorist attacks of 2001. An example can be found in the transformation in the joint positions held by the leaders of the National Academy of Sciences, National Academy of Engineering and Institute of Medicine, which began as a patriotic call to action when legions of scientists were aligned in a “war footing” on terror.²² It then shifted to a unified protest against the Bush Administration out of fear the “sensitive but unclassified” label would be used to restrict the publication of federally funded research.²³

The protest of the scientific presidents is emblematic of the pervasive discontent of scientists over attempts to fashion security measures for the scientific community. Further

(Immunologist Ariella Rosengard said, “I’m worried that if we eliminate our ability to freely express our research results, we will end up saying it’s just not worth it.”); Vastag, *supra* note 6, at 686-690 (Donald Kennedy, editor of *Science*, said, “I’m worried about the papers that I don’t get from scientists who have been dissuaded”); *supra* note 20 at 15 (Michael B. Eisen from Lawrence Berkeley national laboratory said, “This could stifle exactly the kind of research and ideas that are most likely to yield new defenses.”).

²² John Donnelly, *Fighting Terror The Scientific Approach; Panel of Scientists to Tackle Terrorism*, THE BOSTON GLOBE, Oct. 13, 2001, at A1; Ceci Connolly, *Public Health System is on War Footing; Officials Call Mobilization and Realignment of Resources ‘Unprecedented’*, WASH. POST, Oct. 27, 2001, at A14.

²³ William J. Broad, *Threats and Responses: Security Measures; Researchers Say Science is Hurt by Secrecy Policy Set Up By The White House*, N.Y. TIMES, Oct. 19, 2002, at A8; Megan Twohey, *Security Restrictions from Government Put Researchers in a Bind*, SAN DIEGO UNION TRIB., Dec. 10, 2003, at F1 (“More than 50 troublesome [federal research] contracts [with universities] have been identified so far.”); William Matthews, *Sensitive Label Strikes a Nerve*, Federal Computer Week, Oct. 31, 2002, available at <http://www.fcw.com/article78010..htm> (last visited Apr. 12, 2005).

evidence of this poor relationship can be found in MIT's snubbing of a government research award in protest to federal restrictions on personnel involved in the project, Cornell's outright stance against research funds with prior restraint provisions, fears generated by the prosecution of Thomas Butler for mishandling vials of plague germs, and protests by prominent scientists against White House policies on science.²⁴ Thus, the negative atmosphere of late may actually help account for the surprising adoption and continued support for the censorship agreement created within the scientific community.

In addition to the aforementioned, there are arguably at least two cases of institutional defiance exhibited by the National Academies of Science. In the first instance, the NAS refused to suppress a report on vulnerabilities to terrorism discovered in the U.S. food supply as per a request from the U.S. Department of Agriculture. The NAS felt justified in releasing the report over government objections after removing specific details on the foreign pests and pathogens that could pose a threat to U.S. agriculture.²⁵ This instance likewise invited a prior restraint challenge. But the government did not pursue that loathsome option in this instance. The use of a cooperative due process vetting approach such as the one discussed *infra* could have fostered a meaningful dialogue and helped the parties reach a mutually agreeable result.

Another high-profile act of defiance was exhibited by the NAS Genomic Committee which was commissioned by the National Science Foundation, the National Institutes of Health, the Central Intelligence Agency, and the Department of

²⁴ Office of the Vice President for Research, Stony Brook University, *Monday Memo* January 21, 2003, at www.research.sunysb.edu/monmemo/archivesmonmemo030121.html (last visited Apr. 12, 2005); Philip Lane, Cornell Daily Sun., via DAILY ILLINOIS, Feb. 10, 2003, available at <http://www.dailyillini.com/feb03/feb10/news/stories/campus02.shtml> (last visited Apr. 12, 2005); David Malakoff, *Plague of Lies Lands Texas Scientist in Jail*, 299 SCIENCE 489 (2003); John Mangels, *Scientists Ask Bush to End What They Call Ant-Science Policies*, PLAIN DEALER, Oct. 16, 2004, at A11.

²⁵ Matthews, *supra* note 23.

Homeland Security.²⁶ This Committee tapped the expertise of 36 leaders in the field for a workshop on October 1, 2003.²⁷ After weighing costs and benefits for nearly a year, the NAS Genomic Committee's recommendation staunchly argued that genomic data should be off-limits to governmental classification and be even more accessible to the public despite the obvious risks.²⁸ When it came to dealing with dual use research, the committee side-stepped in-depth treatment of security measures and merely cited approvingly the call for self-governance in the NAS Terrorism Report.²⁹ The oft cited argument holds that open availability of sensitive research outweighs the added security risks since open availability will enable a broader and faster response from legions of well meaning scientists able to produce biological counter measures such as vaccines against new threats.³⁰ The report and other proponents of self-regulation, however, have yet to refute Nobel Laureate Joshua Lederberg's 1970 comment that, "[t]he potential undoubtedly exists for the design and development of infective agents against which no credible defense is possible, through the genetic and chemical

26 See COMMITTEE ON GENOMICS DATABASES FOR BIOTERRORISM THREAT AGENTS, NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, *supra* note 13.

27 *Id.* at 73. (Appendix C)

28 *Id.* at 52. "Recommendation 1: Policies with regard to release of genome data on microbial pathogens should not change. Rapid, unrestricted public access to primary genome sequence data, annotations of genomic data, genome databases, and Internet-based tools for genome analysis should be encouraged." *Id.*

29 *Id.* at 2. "A reliance 'on self-governance by scientists and scientific journals to review publications for their potential national security risks' was recommended, and a number of major journals that publish life-science research have already committed to implementing such a review process (Atlas, 2003a, b,c)." *Id.*

30 *Id.* at 53. "Open access allows life scientists everywhere to evaluate, interpret, adapt, and extend results from many fields of inquiry for use in their own work and thereby accelerates research and speeds the delivery of life-saving benefits that biological and medical research are so rapidly creating." *Id.*

manipulation of these agents.”³¹ Thus, the public dissemination of sensitive research not only diminishes the nation’s strategic advantage in time and knowledge, it may actually provide an adversary with the ability to create a pathogen we will be unable to control.

The NAS Genomic Committee report was met with disappointment by one of its sponsors, Homeland Security Secretary Tom Ridge, and with warnings of government intervention by a former White House national security aide, which echoed a previous warning from a White House staffer.³²

Although the poor relationship plays a major role in the adoption of the censorship policy it appears that indelicate lobbying from Washington may have tipped the scales in producing the counterproductive policy. Scientists also reported that they were warned that the government would put the screws on, if the scientific community did not provide a remedy for the open science dilemma.³³ In addition, concern over “overly restrictive” legislative action may have contributed to their fears.³⁴ The NAS Terrorism Committee also made note of a failed Congressional resolution on the open science dilemma authored by Representative Weldon.³⁵ The poor relationship between the scientific and national security communities, however, leaves the door open for unilateral and piecemeal legislation on bioterrorism such as the little known law that

31 Mark Wheelis & Malcom Dando, *New Technology and Future Developments in Biological Warfare*, DISARMAMENT FORUM 4 (2000), pp. 43-50.

32 Schmid, *supra* note 9; Jeff Nesmith, *Panel Supports Flow of Gene Data; Bioterror Concerns Outweighed*, THE ATLANTA J.-CONST., Sep. 10, 2004, at 7A; Vastag, *supra* note 6, at 686-690. Parney Albright of the Office of Homeland Security and the White House Office of Science and Technology Policy said, “The basic message here is that the [scientific] community has got to get its act together or someone will get it together for you Congress abhors a vacuum.” *Id.* at 689 (internal quotations omitted).

33 Harmon, *supra* note 21, at 15.

34 *See supra* note 11, at 68.

35 *See supra* note 11, at 28.

criminalizes the synthesis of variola passed last December.³⁶ Unless relations improve between the national security and scientific communities the new variola law, which was a last minute amendment drafted without open debate, may portend future legislation on bioterrorism and scientific research.³⁷

Before gatekeeping policies went into effect at the Editors Group journals, some authors of scientific articles, concerned with the risks of exposing their articles to the public, asked journal publishers to delete the methods sections of their articles.³⁸ This approach, however, was rejected by the ASM.³⁹ The grounds cited for this position are based on the understanding that all published research must be replicable. There is much sound reasoning in support of this principle. Fear of opening the door to such “opaque” articles will cripple the ease of replication necessary for the open verification process which assures integrity of individual articles and the field as a whole. In addition, opaque articles will stifle the cumulative effect of the expanding knowledge base by thwarting the ability to apply extant techniques and findings to future research. Regardless of the devotion to that principle, the editorial boards of over twenty bioscience journals acknowledge that exceptions have to be made for certain dangerous research findings. But the bioscience community has yet to fashion an approach to

³⁶ See *Unnoticed Amendment Bans Synthesis of Smallpox Virus*, SCIENCE, March 11, 2005, at 1540. “By adding a last-minute amendment to a massive intelligence reform bill in October, Representative Pete Sessions (R-TX) has made it illegal for most U.S. researchers to synthesize the smallpox virus, variola, from scratch.”

³⁷ *Id.* at 1540-41.

³⁸ Lila Guterman & Jennifer K. Ruark, *Bioterrorism Threat Raises a New Question for Journals; Trinity U. Restarts Its Press*, THE CHRON. OF HIGHER EDUC., Aug. 9, 2002, at 14.

³⁹ Andrew Moesel, *Scientists Call for Withholding Sensitive Data*. CHI MAROON, August 12, 2002, at http://maroon.uchicago.edu/news/articles/2002/08/09/scientists_c_all_for_.php. Atlas said, “Our [the ASM’s] current position is that we will not publish any material that cannot be repeated.” See also Lila Guterman & Jennifer K. Ruark, *Bioterrorism Threat Raises a New Question for Journals; Trinity U. Restarts Its Press*, THE CHRON. OF HIGHER EDUC., Aug. 9, 2002, at 14 (“Methods sections [of papers] are going to remain.”).

handle sensitive research other than cauterizing the complete line of work.

As a result, however, the exception may swallow the rule due to the inconsistent approach journals are taking toward dual use research articles. Despite the stated goal of unfettered open science underlying these ad hoc policies, there is a critical failure in reaching this objective in a fair and systematic way. Unfortunately, these failures are likely to repeat until the national security and scientific communities work together in creating a fair and effective remedy to the problem.

An outright battle against the government--or hastily drawn solutions to avoid government intrusion--is contraindicated. An adversarial approach is premature and may lead to greater division. Moreover, a hastily drawn solution merely provides a false sense of security and delays the implementation of reliable remedies to the dilemma. Instead, the scientific community should seize the opportunity to put forth as many alternatives and options for treating sensitive research as possible.

In *U.S. v. Progressive*, the U.S. government successfully argued for prior restraint on an article threatening to reveal H-bomb secrets.⁴⁰ Publication of the article was delayed for 6 months⁴¹ until the government abandoned its effort and withdrew the case.⁴² Dr. Jeremy Stone's sage admonition that classification disputes are ill-served by the adversarial system was noted in the *Progressive* opinion,⁴³ and stands true today. Unfortunately, costly debacles similar to the *Progressive* case are more likely than ever in the biosciences, unless new cooperative vetting systems between the scientific and the national security communities are put into place.

This process will require the development of a reliable system for identifying and evaluating dual use research articles. Although the recently released NAS Genomic Committee failed

40 486 F. Supp. 5 (1979).

41 Editorial Comment, *The "Secret" Revealed*, THE PROGRESSIVE, November 1979.

42 Charles R. Babcock, *U.S. Will Review Data in H-Bomb Article Case*, WASHINGTON POST, October 2, 1979, at A2.

43 467 F. Supp. 990 (1979), at 996.

to “bridge the chasm,”⁴⁴ between openness and security concerns, it did make a contribution to the debate over open science by helping to bring some important principles in this debate to the foreground. For instance, it is clear that any remedy to this issue must: (1) not inhibit the progress of scientific research,⁴⁵ (2) deal with articles on a case by case basis,⁴⁶ and above all, (3) safeguard the public by reducing the potential misuse of scientific research.⁴⁷ In addition, it is clear that the mechanism used to reach these goals must be transparent, consistent, compatible with the global community, and easy to use.

Review of the current stalemate between the Editors Group and the government reveals shortcomings in both camps. The Editors Group could be criticized for proffering an ineffectual vetting system at the expense of national security and the government could be admonished for strong-arming the implementation of a specious self-censorship policy. The failures, however, are mutual because the government should provide leadership and the scientific community should provide the greatest resources at its disposal to develop effective remedies to this dilemma. Regardless of blame, these mutual failings leave stakeholders with an untenable compromise between the solipsistic extremes of the scientific community and the U.S. government. The dangers of boundless science and heavy handed infringements of academic freedoms are equally

44 Vastag, *supra* note 6, at 686-690.

45 See COMMITTEE ON GENOMICS DATABASES FOR BIOTERRORISM THREAT AGENTS, NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, *supra* note 13 at 58 (“Research exploiting the revolution in genomics has an important role to play in increasing our ability to defend against infectious agents of importance to biodefense and global infectious disease.”). See also COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11, at vii (“The charge to our Committee was to consider ways to minimize threats from biological warfare and bioterrorism without hindering the progress of biotechnology..”).

46 Erika Check, *Biologists Apprehensive Over U.S. Moves to Censor Information Flow*, NATURE, Feb. 21, 2002, at 821. Dr. Anthony Fauci said, “As we move into more research on counter-terrorism, we should examine this issue on a case by case basis.”

47 Schmid, *supra* note 9.

untenable. Unlike typical disputes, the bitter pill of compromise will not suffice. Nothing short of a consensus among all stakeholders will prove effective in this dilemma of first impression. The first step in rectifying the situation should include a review of the history of classified science.

B. HISTORY OF CLASSIFIED SCIENCE

While the current dual use problem is unique, a review of the historical relationship between the scientific and national security communities provides valuable insight. For instance, the twenty-five year-old agreement between the American Council of Education and the NSA to submit academic cryptography research for pre-publication review⁴⁸ bodes well for the prospect joint vetting. The NAS Terrorism Committee dismissed the notion of a similar joint enterprise with life sciences due to the greater volume of biological papers published each year.⁴⁹ Regardless of the NAS Terrorism Committee's view further investigation of this agreement and others like it should prove helpful in fashioning new remedies.

Comparisons have been made between the World War II era Manhattan Project and the current open science dilemma. But, that analogy has been considered inapposite by President Bush's Science Advisor Dr. John Marburger⁵⁰ and Dr. Tara O'Toole who distinguished the analogy due to the small community of scientists involved in the Manhattan Project.⁵¹

⁴⁸ Genevieve J. Knezo, CRS Report for Congress, *"Sensitive But Unclassified" and Other Federal Security Controls on Scientific and Technical Information: History and Current Controversy*, July 2, 2003, at <http://www.fas.org/irp/crs/RL31845.pdf> (last visited April 12, 2005).

⁴⁹ See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11, at 85.

⁵⁰ Thomas Hayden, *The Big Brains are Searching for Solutions. But There are No Easy Fixes*. U.S. NEWS & WORLD REPORT, Dec. 31, 2001, at 60.

⁵¹ Tara O'Toole, *Bio-terrorism: The Threat of the 21st Century*, Preventing Bioterrorism: 1st Interpol Global Conference, Address, Lyon, France (March 1, 2005).

While there are limits to the Manhattan Project analogy, it does have some value in that it demonstrates that a field of science can advance in a closed community, contrary to the fears⁵² of some scientists.

Although Dr. Marburger believes that life sciences may present a special problem, he did acknowledge that nuclear physicists and mathematicians have a long history of keeping secrets with the government.⁵³ Thus, participants in this debate would be well served by reviewing the many years of classified science conducted during the cold war years. Lessons learned from the era illustrate that despite some challenges, compartmentalization of scientific projects did not appear to hamper the exchange of information between scientists.⁵⁴ This finding was made in regard to the vast number of classified studies conducted at national laboratories such as Los Alamos, Brookhaven, Argonne, Berkeley, and Oak Ridge. It may actually come as a surprise to some participants in this debate to learn that biological research was also classified as far back as the 1940s. For instance, out of a total of 86 “health and biology” research reports emanating from national laboratories between 1947 and 1948, 66 were classified.⁵⁵

Much like today, some scientists were opposed to the classification of science during the cold war, while others became emotional over requirements such as loyalty oaths.⁵⁶ Although an analogy between the current dilemma over open science and the cold war era is more relevant than one drawn from the Manhattan Project, there will undoubtedly be a number of distinguishing factors. Any distinctions, however, do not obviate the lessons that can be learned from the cooperation between the national security and scientific communities during that era.

The Editors Group agreement reflects an unprecedented and unsustainable change in the scientific community. The agreement, notwithstanding its heavy cost, falls woefully short of attaining its goal of resolving the open science dilemma.

52 Check, *supra* note 46.

53 Malakoff, *supra* note 19.

54 Peter J. Westwick, *Secret Science: A Classified Community in the National Laboratories*. 38 MINERVA 363 (2000).

55 See Westwick, *supra* note 54, at 369.

56 See Westwick, *supra* note 54, at 373.

Rather, the agreement merely forestalls the creation of more carefully drawn remedies capable of balancing open science and public safety. It will not take long before the shortcomings of current policies are widely known and momentum builds again for scientific reform. Thus, it is fair to say that further changes in the scientific community will be made to address the open science dilemma. The question begged by this situation is whether or not future remedies to the open science dilemma will be made by consensus or fiat.

C. NEW INITIATIVES

Despite some critical failures to date, progress is being made. For instance, the department of Health and Human Services (HHS), following a recommendation from the NAS Terrorism Committee, is in the process of forming another group, which is heralded as a government-wide effort, to address aspects of the open science dilemma.⁵⁷ The HHS group will be known as the National Science Advisory Board for Biosecurity, also known as the NSABB.⁵⁸ The NSABB is, however, different from previous expert groups on the open science dilemma in that it appears to be well poised to make recommendations that will be the basis for administrative laws governing dual use research in the scientific community. The NSABB will be charged with creating strategies to oversee biological research, in addition to training guidelines and codes of conduct for scientists and lab workers.⁵⁹

Unfortunately, however, the creation of the NSABB represents a missed opportunity to establish the first review body with legal authority to address the dual use dilemma.⁶⁰

⁵⁷ Editors Choice, *Biosecurity: HHS Will Lead Effort to Enhance Bioterror Research in "Dual Use" Funding*. BIOTERRORISM WEEK, Mar. 29, 2004.

⁵⁸ See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11, at 9.

⁵⁹ The NSABB Charter is available at <http://www.biosecurityboard.gov/SIGNED%20NSABB%20Charter.pdf> (last visited April 12, 2005).

⁶⁰ See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF

Regardless of the likelihood that future classification decisions will be reached by consensus, the government needs to prepare for the worst case scenario in prior restraint situations. The Secretary of the Department of Health and Human Services is a likely candidate to assume this authority of last resort if he can assemble a cooperative board of experts to help him make informed classification decisions. The HHS Secretary clearly has the authority to classify information related to bioterrorism.⁶¹ But the question remains whether the Secretary will reserve the authority for narrow uses only, such as those related to vaccine storage sites, laboratory floor plans and details on emergency medical stocks as originally envisioned by officials when the authority was conferred.⁶²

Although the NSABB has a limited charter, it has worthy goals and should prove helpful in bringing the government and scientists together over this divisive issue. It is self evident that the longer it takes to resolve the dual use dilemma the more likely sensitive research findings will be made available to potential malefactors. Yet, more than a year after the NSABB charter was signed by Tommy Thompson, its 25 membership positions have yet to be filled. The exact reason for this extended exposure is not known, but the lack of cooperation of the scientific community may be a contributing factor. If the fervor in the scientific literature against classification is truly indicative of the sentiments of the field, finding cooperative experts to fill the life science positions on the board could be a considerable challenge.

The government needs to examine present and future needs to regulate and otherwise oversee the life sciences. The NAS Terrorism Committee report opined over the numerous government agencies that regulate various aspects of the life sciences including: the Department of Agriculture, Environmental Protection Agency, the Nuclear Regulatory

BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11, at 107, for a discussion on the lack of a national or international review body with the legal authority to address to the dual use dilemma.

⁶¹ Federal Register, Dec. 12, 2001 vol. 66, number 239, presidential documents, p. 64345-64347.

⁶² Alison Mitchell, *A Nation Challenged: Classified Information; Bush Gives Secrecy Power to Public Health Secretary*, N.Y. TIMES, December 20, 2001, at B6.

Commission (NRC), the National Institutes of Health, Food and Drug Administration, and Centers for Disease Control, and Health and Human Services, the Organization for Economic Cooperation and Development, in addition to cooperative activities with other governmental agencies.⁶³ Given the number of regulatory agencies with overlapping authority over life sciences, it is no wonder that the scientific community cannot find a partner in government to sit down with to resolve the open science dilemma. Therefore, it may be advisable to remedy this problem by creating one comprehensive oversight agency for the life sciences. This new agency could be modeled after the Nuclear Regulatory Commission (NRC). In like manner, the life sciences agency may be called the “Biologic Regulatory Commission” (BRC). The general structure and goals of the NRC, when applied to the life sciences, fills a need that disjointed government oversight fails to address.⁶⁴ Or it may, in fact, be warranted for the NRC to expand its expertise and assume regulatory oversight over sensitive life science research. The proposal for a BRC warrants more discussion than this paper affords. Nevertheless, for the sake of clarity, “BRC” will hereinafter refer to the government entity with prior restraint or classification authority over sensitive research for the purposes of this proposal on joint due process vetting.

Clearly, any remedy to the open science dilemma should be forged by consensus and be compatible with the global community of science. Thus, this paper presents basic elements of a cooperative Due Process Vetting System (DPVS) between academia and governmental authorities that may work in concert with the existing model of open science at the national or international level.

The DPVS addresses three primary goals that have proved elusive thus far. First, high-risk articles can be

63 See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11, at 41.

64 U.S. Nuclear Regulatory Commission, *Who We Are*, last modified Aug. 17, 2004, at <http://www.nrc.gov/who-we-are.html> (“The NRC’s mission is to regulate the Nation’s civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, to promote the common defense and security, and to protect the environment.”).

safeguarded and be made available to a select academy of biodefense researchers after the authors, the publishing journal, and others, reach a consensus with the government through cooperative vetting of the article in question. Second, the DPVS will provide the government with a consistent and reliable mechanism for notice of potentially dangerous articles before they reach the presses.⁶⁵ Third, the DPVS promotes the advancement of science by avoiding the deleterious effects of censorship. To this end, a new Risk Assessment Scale (hereinafter RAS) is presented along with a mechanism for handling temporarily classified research that dovetails with the traditional model of open science.

III. THE ASM MODEL

Dr. Ronald Atlas addressed the open science dilemma while presenting the American Society for Microbiology's (ASM) testimony before the U.S. House of Representatives Committee on Science in October of 2002.⁶⁶ Dr. Atlas detailed the ASM's approach toward dual use research for some eleven journals under its control. The ASM model has been the subject of much discussion and has been accorded deference in a National Academies report as the "formal procedures" added to the peer review process.⁶⁷ ASM's linear approach consists of a hierarchical system that relies on graduated gatekeepers with

⁶⁵ See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11, at 119. The NAS Terrorism Committee likewise cited the importance of giving the government prepublication notice of scientific articles, but deferred to the anticipated NSABB to create the methods to meet this challenge.

⁶⁶ Ronald Atlas, Testimony of the American Society for Microbiology before the House of Representatives Committee on Science, Conducting Research During the War on Terrorism: *Balancing Openness and Security*, Oct. 10, 2002, at <http://www.house.gov/science/hearings/full02/oct10/charter.htm> (last visited Apr. 12, 2005).

⁶⁷ See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11, at 97.

sole discretion to divert an article for further review or pass it through to complete the usual review process for non-security issues. It appears that the original peer reviewer has sole discretion to flag an article for additional review by the editor or let it pass through to complete the review process. Next, if the journal editor personally believes the flagged article to be safe enough to publish, then he or she returns the article to the reviewer to continue through the review process. But if the editor also believes the article presents a risk, then it is passed on to the editor-in-chief and chair of the publications board, who again have the discretion to return the article back to the review process if they both agree the article is safe enough. If, however, the editor-in-chief and chair of the publications board likewise agree that the article poses a sufficient risk, then it is passed on to the publications board for final consideration.

The primary problem with the ASM's approach is that it may be tainted by a spirit of resistance against government interference in a manner that errs on the side of publishing sensitive research. The ASM's testimony, which places responsibility for measuring the risk of an article in the sole discretion of one individual at a time in the first and second steps, conflicts with its own press release of the same day. An ASM press release on the same day as its aforementioned testimony before the House of Representatives said, "[n]o individual is empowered to decide what is potentially dangerous knowledge."⁶⁸ However, consistency can be found between the ASM's prone-to-err approach and an earlier pledge by editors from leading journals who likewise vowed to err on the side of openness.⁶⁹ In this connection, the ASM appears to leave itself open to criticism when it apparently releases different sets of statistics to different audiences. When an ASM representative spoke to the New York Times in February 2003 about how the organization speculates that it will only need to use the censorship pact in "extremely rare circumstances," the Times attributed the following quote to the ASM, "[The ASM] said only

⁶⁸ American Society for Microbiology, American Society for Microbiology Cautions that Scientific Publication Restraints May Have Negative Impact on Public Health and Safety, Oct. 10, 2002, at <http://www.asm.org/Media/index.asp?bid=2813> (last visited Apr. 12, 2005).

⁶⁹ Vastag, *supra* note 6, at 686-90.

2 papers out of 14,000 had been flagged since December 2001.”⁷⁰ If a reader is accustomed to the meaning of flagged as a mere “marking device” or “tab,”⁷¹ than one might question the difference in the statistics found in the NAS Terrorism Committee Report. While discussing the ASM’s “formal” review procedures and its concern over publishing sensitive research the NAS Terrorism quoted the following ASM statistics, “In 2002, of 13,929 manuscripts submitted to ASM journals, 313 select agent manuscripts received special screening, and of these two manuscripts received additional screening by the full ASM publications board.”⁷² Of course, the ASM is using the term flagged to refer to articles on select agents submitted for full review. Apparently the select agent articles are routinely screened. Regardless, the opportunity for confusion remains.

The ASM’s linear approach toward reviewing papers relies on a succession of solitary decisions and mutual agreements before the article has the benefit of review before a committee. The system contains other structural flaws as well. For instance, the ASM’s approach fails to use objective measures, fails to solicit or use input from the author, places too much discretion in the hands of individuals in a hierarchical process, and uses joint conferral of a potentially sensitive article as a last resort. Unfortunately, the ASM is not alone in relying on the “I know it when I see it” measure. Rather, it appears to be the accepted standard among many leading journals.⁷³

Although the ASM appears inclined to err in favor of publishing sensitive research, the existence of censorship policies may nonetheless discourage submissions of sensitive research in the first place. In like manner the NAS Genomic Committee discourages research in a similar manner by

70 Harmon, *supra* note 21, at 15.

71 <http://dictionary.reference.com/search?q=flagged>
(Last checked April 22, 2005).

72 See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11, at 97.

73 See COMMITTEE ON GENOMICS DATABASES FOR BIOTERRORISM THREAT AGENTS, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 13 at 1.

recommending “improved screening of experiments before they are conducted.”⁷⁴

Therefore, if an apparent decrease in the number of sensitive submissions to Editors Group journals is reported in the near future, this finding should not provide solace to any who want to believe that the problem is going away. Statistics from journals complying with the censorship agreement reporting on the frequency of dual use submissions may well be saddled with a confounded statistic due to policies discouraging submission of sensitive articles to their journals.⁷⁵ Thus, the U.S. is at risk of creating a blind spot in an area of study critical to national security and, worse yet, may eventually purge itself of leadership in the study of deadly pathogens through such policies. In this connection, it is important to be mindful of the global nature of the scientific community. The fact that Thomson ISI indexes more than 8,000 scientific journals in thirty-eight languages⁷⁶ is a sobering reminder that the remedy for this issue must be compatible with the global community of science.

If an appropriate outlet for sensitive articles is not created, dual use research articles may gravitate toward the safe harbor of second tier journals around the world or nontraditional outlets. The challenge of creating a classification mechanism that crosses international borders must not serve as a deterrent to fashioning remedies at the global level. Bioterror is a global issue and will require a global response. Fortunately, there is some evidence of a U.S. trend toward international cooperation in counterterrorism and biosecurity. These efforts include participation in an eight country consortium of health ministers,⁷⁷ the 2002 agreement between the U.S. and Russia to hunt for stray radioactive materials in the former Soviet

74 Schmid, *supra* note 9.

75 Vastag, *supra* note 6 at 689. Approximately 1% of total submissions to Proceedings of the National Academy of Sciences were flagged for extra review between 2002 and 2003.

76 David A. King, *The Scientific Impact of Nations: What Different Countries get for their Research Spending*, 430 NATURE 311-316 (2004).

77 Marc L. Ostfield, *Bioterrorism as a Foreign Policy Issue*, XXIV, no. 1, SAIS REVIEW 131-146 at 139. (2004).

Republic out of concern for dirty bombs⁷⁸ and the extant agreement restricting the storage and study of variola.⁷⁹ Recent cooperation between the Pentagon and key allies is consistent with this trend. The Pentagon recently set a precedent by inviting allies into classified discussions on future military missions and combat forces levels.⁸⁰

A. A PROPOSAL FOR DUE PROCESS VETTING

The instant proposal is designed to move the discussion of remedies for the open science dilemma toward specific and valid measures. Aside from the fatally flawed approaches of life science journals such as the ASM and PNAS, proposals on the biosecurity threat have been broad in scope. These proposals include a call for increased funding for a national plan,⁸¹ a Biosecurity Convention affiliated with the UN,⁸² and a Biosecurity Trust modeled after the International Red Cross.⁸³ It can be argued that the Biosecurity Convention and Biosecurity Trust are appropriate approaches because they are consistent with the “denationalization of information infrastructures” posited by Mayer-Schoenberger and Brodnig.⁸⁴

78 Richard Stone, *New Effort Aims to Thwart Dirty Bombers*, 296 SCIENCE 2117 (2002). (Detailing how Russia/United States agreement to join forces in an effort to hunt down stray radioactive materials, potentially usable for to construct dirty bombs, across the former Soviet Union)

79 See News: Biodefense, vol 307, *supra* note 34. *Unnoticed Amendemnt Bans Synthesis of Smalpox Virus*, SCIENCE, March 11, 2005, at 1540.

80 Thom Shanker, *Pentagon Invites Allies for First Time to Secret Talks Aimed at Sharing Burdens*, N.Y. TIMES, Mar. 18, 2005, at A10.

81 Jim A. Davis, *The Looming Biological Storm: Misconceptions and Probable Scenarios*, 17 AIR & SPACE POWER J. 57 (2003).

82 Michael Barletta, Amy Sands, Jonathan Tucker, *Keeping Track of Anthrax: The Case for a Biosecurity Convention*, 58 BULL. ATOM. SCIENTISTS 57 (2002).

83 Robert H. Sprinkle, *The Biosecurity Trust*, 53 BIOSCIENCE 270 (2003).

84 Viktor Mayer-Schoenberger & Gernot Brodnig, *Information Power: International Affairs in the Cyber Age*, in JOHN F. KENNEDY SCHOOL OF GOVERNMENT, HARVARD

The forces behind the trend of nation-states abdicating control over information to the global arena, such as the in the case of the internet,⁸⁵ appear to be strong. It is unlikely, however, that the U.S. government will abdicate control over sensitive information related to biosecurity within its borders in exchange for a mere voice at an international body any time soon. If the U.S. takes an international approach toward sensitive life science research, it will likely be limited to strategic alliances with countries producing the bulk of cutting-edge research.⁸⁶

The instant proposal puts forth specific mechanisms that work from the premise that researchers should be able to operate as freely as possible. A scientist should not be deterred from any line of inquiry due to fear that the dedicated effort of weeks, months, or years of work will eventually collect dust in the basement of the Pentagon or face rejection from the academic community because there is no safe outlet for it. Such a systemic failure would certainly prove detrimental to national interests.

A fear of government involvement in prepublication vetting rightfully causes concern among many, and serves as an impediment to progress on this matter as well. The overclassification of information by the government is a problem that has plagued the government before⁸⁷ and after 9/11.⁸⁸ The

UNIVERSITY, FACULTY RESEARCH WORKING PAPERS SERIES (Nov. 2001), *at* [http://ksgnotes1.harvard.edu/Research/wpaper.nsf/rwp/RWP01-044/\\$File/rwp01_044_schoenberger.pdf](http://ksgnotes1.harvard.edu/Research/wpaper.nsf/rwp/RWP01-044/$File/rwp01_044_schoenberger.pdf) (last visited April 21, 2005), at 10.

⁸⁵ *Id.* at 23.

⁸⁶ King, *supra* note 73, at 311 (“This group [of 31 countries] accounted for more than 98% of the world’s highly cited papers.... The world’s remaining 162 countries contributed less than 2% in total....The nations with the most citations are pulling away from the rest of the world. The G8 countries are in this premier division, apart from Russia...”).

⁸⁷ See REPORT OF THE COMMISSION ON PROTECTING AND REDUCING GOVERNMENT SECRECY CHAIRED BY DANIEL PATRICK MOYNIHAN, Mar. 3, 1997. available at <http://www.access.gpo.gov/congress/commissions/secrecy/> (last visited Apr. 12, 2005).

⁸⁸ Trent Lott & Ron Wyden, *Hiding the Truth in a Cloud of Black Ink*, N.Y. Times, Aug. 26, 2004. at A27.

transparency and lines of communication built into the DPVS will help safeguard against the government's tendency to over-classify. The DPVS includes checks and balances on both government and non-government personnel (hereinafter NGP) involved in the process.

Whether or not a version of this DPVS is implemented, bioscience vetting will be a modern certainty akin to increased security measures at laboratories, national borders, and airports. Thus, unavoidable issues in need of attention concern the timing, participants, and consequences of vetting. The challenge is to create an effective and timely communication mechanism that affords due process protections for NGPs in the event the government exercises classification authority against the wishes of an NGP with standing in the process.

B. DUE PROCESS VETTING SYSTEM OVERVIEW

The DPVS is a comprehensive system that enables immediate and informed communication between the scientific and national security communities on new research in line for publication and public release. The rapid communication on potentially sensitive research enables immediate cooperative vetting of flagged articles between the scientific community and the relevant government authority. The DPVS also provides temporary safe harbor for sensitive research by consensus rather than unilateral classification imposed by the government. In the rare occasion when the government needs to classify a research article absent consensus, the government will have notice of the article before it reaches the presses and the scientific community will have ample opportunity to be heard through a fair hearing on the matter if desired. As previously stated, for the purposes of this discussion, the administrative board charged with federal authority will be deemed a new federal agency called the Biologic Regulatory Commission (BRC).

Therefore, once consensus is reached between the BRC and the scientific community, the article will either be published or tracked for up to five years in a Least Restrictive Classification (LRC) system, which restricts release of the article to bona fide researchers within a national or international academy of biodefense researchers with a need for access to sensitive research. Limiting access to research is an

unfortunate but necessary evil that is finding greater acceptance in the scientific community. In addition to the Editors Group, leaders in the community such as Dr. Anthony Fauci are on the record as acknowledging this fact.⁸⁹ The NAS Genomic Committee, likewise, discussed the option at its workshop.⁹⁰ If, however, consensus is not met on placement of an article in LRC status, then any party involved in the initial risk assessment of the article may demand an administrative hearing, which will result in either release for publication or a security classification. If the matter remains contested, then the case can be appealed to the federal courts as a last resort. An important benefit of the system is that it is easy to participate in and not unnecessarily intrusive. The Least Restrictive principle is likewise compatible with National Security Decision Directive 189 (Hereinafter NSD-189), which states that “fundamental research should be unrestricted to the maximum extent possible.” NSD-189 is likewise endorsed by the NAS Terrorism Committee.⁹¹ As comprehensive as this system is, the most involved components lay dormant unless and until problems arise. This approach is beneficial because it provides a safe and productive outlet for sensitive research that would otherwise be rejected and lost due to censorship policies in place at the nation’s major bioscience journals.

An important feature of the DPVS, compared to the ASM model, is that due process vetting may be triggered at the outset by a researcher submitting an article for publication or any other NGP in the process desiring a joint review of the article. This feature is particularly helpful in lending a voice to authors who fail to see eye-to-eye with their powerful journal editors on the treatment of their sensitive research. In addition, there is far less resistance to the vetting process in the DPVS compared to the ASM model. Absent a NGP request at the outset, vetting in the DPVS is triggered by attainment of a predetermined score on the Risk Assessment Scale set by the BRC. (See Chart1) The RAS surveys opinions of informed reviewers including the

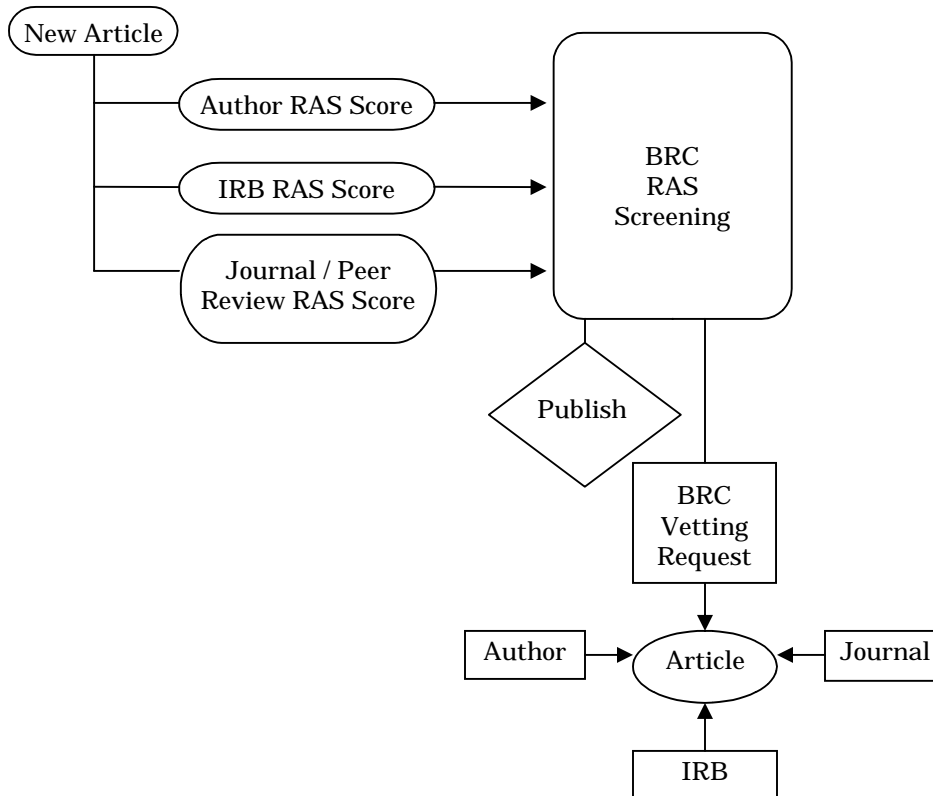
89 Check, *supra* note 46.

90 See COMMITTEE ON GENOMICS DATABASES FOR BIOTERRORISM THREAT AGENTS, NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES *supra* note 13 at 39.

91 See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11 at 8.

author of the article, the author's Institutional Review Board or Institutional Biosafety Committee (IBC), and finally the journal interested in publishing the article.

Chart 1. RAS Flow Chart



The author's IBC is recommended here as a suitable choice for the same reasons IBCs was recommended for use in the review of experiments of concern by the NAS Terrorism Committee. The NIH already requires the registration of IBCs for organizations conducting recombinant DNA research.⁹² However, the Institutional Review Board of a university may in fact be a superior choice due to the likelihood of greater balance on the board with better resistance to the forces of scientific politics. Furthermore, reliance on IRBs would further administrative economy if the DPVS is also utilized for review of sensitive research from other disciplines conducted at the institution.

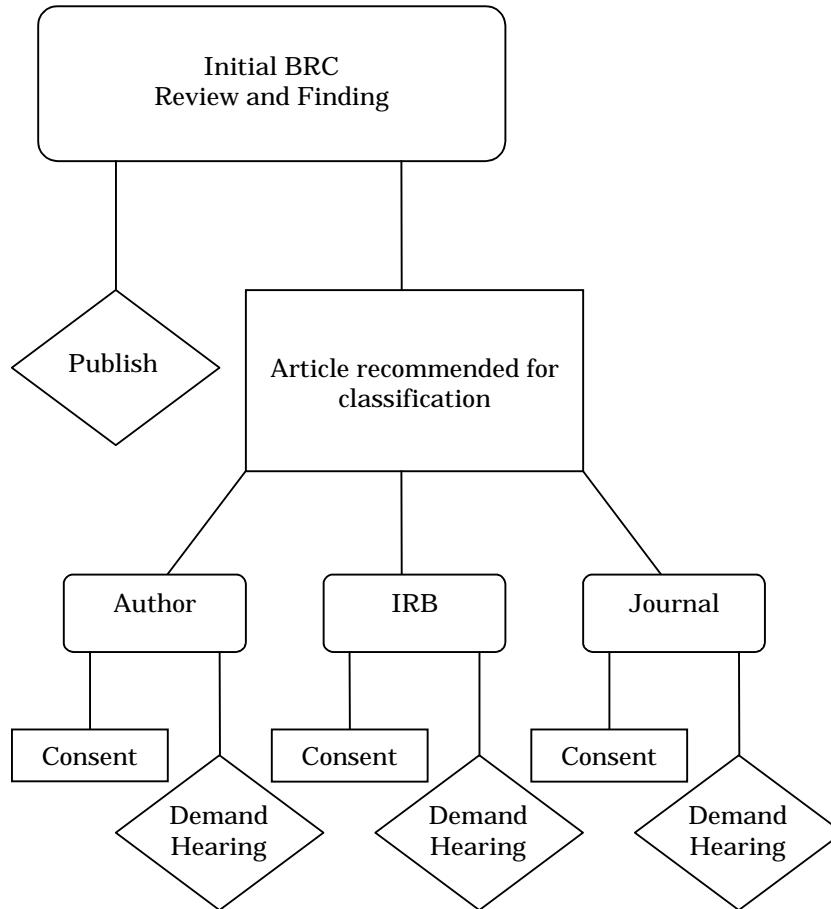
92 See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11 at 115.

The eighteen-item Likert point RAS assigns numeric ratings to questions on national security concerns. Therefore, if the scale is calibrated from one to five with higher numbers associated with greater risk, the BRC committee can set the point at which it wants to review articles. Thus, the BRC will receive notice of articles of interest without interfering with the vast flow of articles traveling between the nation's laboratories and journals.

If, however, an article is selected for review by the BRC, all RAS reporters will have standing in the DPVS and have a right to be heard at the initial review. RAS reporters will also have an opportunity to contribute to a consensus on the article. If any of the RAS reporters object to the BRC's recommendation to temporarily classify the article after team review, then any dissenting party may request an administrative hearing on the issue. If a party with standing contests an administrative hearing determination to classify the article in question, then a qualified objecting party may then take the matter as a prior restraint challenge to the federal court system. (See Chart 2)

Otherwise, when there is a consensus for temporary classification, the article will be deemed as published by the accepting journal and held to a least restrictive access standard by the publishing journal for a five-year or lesser period. After the initial classification period the article will automatically be declassified and available for public distribution by the journal. If, however, any original party with standing or the BRC wishes to continue classification for an extension, a review must be held to consider the risk presented by the article in the current state of science and security.

Chart 2.DPVS Flow Chart, Round 1.



C. RISK ASSESSMENT SCALE

The Risk Assessment Scale is a key feature of the DPVS. Devising a method to weigh the risk posed by research articles is widely known to be difficult and even “squishy”⁹³ or “tricky.”⁹⁴ The fact that the scientific community is still striving to define dangerous science does not help the situation.⁹⁵ The editor of

⁹³ Erika Check, *Health Chiefs poised to step up US scrutiny of microbe research*, 425 NATURE 647 (2003). (quoting Gigi Kwik of the Center for Civilian Biodefense Strategies at Johns Hopkins University).

⁹⁴ Harmon, *supra* note 21, at 15.

⁹⁵ See ASM Press Release, American Society for Microbiology, American Society for Microbiology Cautions that Scientific Publication Restraints May Have Negative Impact on

Science magazine, Donald Kennedy, went so far as to say, “[i]t is impossible to gauge if a research finding could ever be used for nefarious purposes.”⁹⁶ Mindful of the challenge, the RAS at least attempts to address these problems by helping measure the potential risk presented by articles submitted for publication in bioscience journals. Questions utilizing the Likert point technique provide numeric responses to opinions about the potential dangers presented by an article in line for publication. Thus, a meta-analysis of RAS scores enables a rapid view of a vast survey of articles running through the publication process. The DPVS provides a critical mechanism for identifying articles that need to be flagged for heightened scrutiny. This mechanism also assures that benign articles move to press swiftly with the benefit of documentation assuring its compatibility with national security interests.

RAS subscale items address the degree to which the prospective article presents danger to human life, livestock, and agriculture on several axes. Additional subscales address financial and educational barriers to using the proposed article for malevolent purposes. Finally, the scale addresses whether the publication of the proposed article affects a previously released article by converting it into a sensitive article when linked to the forthcoming article.

The scale would work best as a submission requirement to be completed independently by the author, the author’s IRB-if interested-and the journal or its peer reviewers. The completed scales would then be submitted to the BRC for tabulation. The scaled responses could be submitted electronically and downloaded into a system that analyzes the vast collection of expert opinions of articles under review at the nation’s bioscience journals. Thus, it would be possible to oversee the flow of a vast number of articles with a minimal degree of intrusion. In addition, repeated blind assessments from multiple sources would help provide data on the validity of the RAS.

Public Health and Safety. Washington, D.C., (Oct. 10, 2002) (on file with author).

⁹⁶ Vastag, *supra* note 6, at 686-690.

1. GENERAL RISK SUBSCALE

The first question is the trigger question for any party with standing. It provides an immediate flagging mechanism for the BRC. (See Table 1)

Table 1. General Risk Subscale

1. The degree to which public release of this paper presents risk to society:				
1 Unforeseeable	2 Remote	3 Possible	4 Likely	5 Imminent Or Request Immediate Review

Subsequent flag questions are derived from the NAS Terrorism Committee report which identified concern over articles that reveal: a) how to make a vaccine ineffective, b) resistance to antibiotics or antiviral agents, c) how to enhance virulence of a pathogen or render a non-pathogen virulent, d) how to increase the transmissibility of a pathogen, e) alter the host range of a pathogen, f) instructions on how to evade diagnostic/detection modalities, and g) the ability to weaponize a biological agent or toxin.⁹⁷ (See Table 1a)

Table 1a. General Risk Subscale

2. Does the paper lead to the ability to render a vaccine ineffective?				
1 Unforeseeable	2 Remote	3 Possible	4 Likely	5 Imminent
3. Could this paper contribute to increased resistance to antibiotics or antiviral agents?				

⁹⁷ See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11 at 5.

1	2	3	4	5
Unforeseeable	Remote	Possible	Likely	Imminent
4. Would this paper lead to the increased virulence of a pathogen or render a nonpathogen virulent?				
1	2	3	4	5
Unforeseeable	Remote	Possible	Likely	Imminent
5. Would this paper lead to the increased transmissibility of a pathogen?				
1	2	3	4	5
Unforeseeable	Remote	Possible	Likely	Imminent
6. Would this paper lead to an alteration in the host range of a pathogen?				
1	2	3	4	5
Unforeseeable	Remote	Possible	Likely	Imminent
7. Would this paper help enable the evasion of diagnostic/detection modalities?				
1	2	3	4	5
Unforeseeable	Remote	Possible	Likely	Imminent
8. Would this paper contribute to the weaponization of a biological agent or toxin?				
1	2	3	4	5
Unforeseeable	Remote	Possible	Likely	Imminent

2. BARRIER SUBSCALE

The barrier subscale has three questions that estimate the ease with which a malevolent actor can use the science in question. This helps determine whether this science poses a threat from bathtub hackers or more sophisticated rogue labs.⁹⁸ The items identified were education, experience, accessibility of materials, and financial resources needed to utilize this science. Financial and educational barriers to utilizing sensitive research have been identified as relevant factors in determining the risk of sensitive science in previous cases. The grand scale and surprising progress made by two college students in the R.I.S.E. bioterror plot illustrates the importance of carefully analyzing barrier factors.⁹⁹ In this connection, the classic mistake of underestimating the enemy made by the NAS Terrorism Committee is further evidence that the national security community should be involved as partners in all aspects of the open science debate. In a broad dismissal of the threat they questioned whether “bio-hackers” will ever emerge.¹⁰⁰ After the synthesis of polio at Stony Brook University in 2002, experts assessed the risk raised by this development by estimating the skill level needed to replicate this work and the cost of this undertaking.¹⁰¹ It was recently speculated that the barrier to acquiring smallpox, which is currently under lock and key in two locations in the world, was compromised by advancements in

98 See Wheelis & Dando, *supra* note 31, at 52. “Intelligence analysts believe that several developing countries currently have covert biological weapons programmes.”

99 W. Seth Carus, *R.I.S.E. (1972)*, in *TOXIC TERROR: ASSESSING TERRORIST USE OF CHEMICAL AND BIOLOGICAL WEAPONS* 55-70 (Jonathan B. Tucker, ed. 2000),

100 See COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNSEL OF THE NATIONAL ACADEMIES, *supra* note 11 at 26. The Committee also concluded that amateurs may not be successful in manipulating microbial genomes since they lack ready access to equipment and will find that “[u]nexpected difficulties often arise in this type of work.”

101 Andrew Pollack, *Traces of Terror: The Science; Scientists Create A Live Polio Virus*, N.Y. TIMES, July 12, 2002 at A1.

synthesis technology.¹⁰² The new DNA synthesis technique is recognized as a significant advancement in speed, cost, and accuracy.¹⁰³

Table 2. Barrier Subscale Questions

9. What level of education or experience is required to execute malevolent action with the information?				
1 Not Applicable	2 Ph.D.	3 Masters	4 B.A.	5 No special training necessary
10. Rate the cost barriers to malevolent use of the data:				
1 Prohibitive	2 \$1 million+	3 \$500K-\$1 million	4 \$100K- \$500K	5 < \$100K
11. Rate the accessibility of necessary materials:				
1 Theoretical or nonexistent	2 Secured by the military	3 Select Agent	4 Limited suppliers	5 Retail availability

3. DAMAGE SUBSCALE

The damage subscale breaks down the possible targets of such science and the extent of damage to each. Human health and food supply were identified as primary concerns in this area.

Table 3. Damage Subscale Questions

12. The degree to which misuse of the data could detrimentally affect human life:				
1 Temporary ailments	2 Long term illness	3 Permanent disabilities	4 Possible fatalities	5 Certain fatalities
13. Describe the scope of harm:				
1 Not Applicable	2 Isolated cases	3 Limited outbreak	4 Epidemic	5 Pandemic
14. Identify potential harm to livestock:				
1 Unforeseeable	2 Remote	3 Possible	4 Likely	5 Imminent

¹⁰² See Wade, *supra* note 10, at A17.

¹⁰³ Wade, *supra* note 10, at A17.

15. Identify potential harm to food supply:				
1 Unforeseeable	2 Remote	3 Possible	4 Likely	5 Imminent
16. Duration of contamination from the agent:				
1 Not applicable	2 Immediate dissipation	3 Dissipation in 1 to 7 days	4 Dissipation in 1 to 4 weeks	5 Dissipation in 1 month+

4. CONVERSION SUBSCALE

Since science is an accumulative endeavor, the addition of a new discovery may have implications for previously published articles in the public domain. This does not create an affirmative duty to research all possible new connections and ramifications. It does, however, offer an opportunity to reflect upon and report any known conversions of benign articles. Conversely, a new article can convert an article in LRC status into a benign article justifying early release to open publication. (See table 4)

Table 4. Conversion Subscale Questions

17. Would the publication of the proposed article heighten the risk level of any publicly available articles?				
1 Unforeseeable	2 Remote	3 Possible	4 Likely	5 Definitely
If known, cite affected articles:				
18. Would publication of the proposed article lessen the risk of a classified article?				
1 Unforeseeable	2 Remote	3 Possible	4 Likely	5 Definitely
If known, cite affected articles:				

D. BRC ANALYSIS OF NONGOVERNMENTAL PARTY RAS SCORES

The BRC will receive RAS data on all articles submitted to U.S. bioscience journals, but it will only review articles referred directly or indirectly by RAS reporters, *i.e.* by elective review or by select scores achieved on the RAS. Since the RAS uses a Likert point scale to rank degrees of risk from one to five, only articles with RAS scores reaching specified criteria by the BRC will be called up for review.

Compliance with a DPVS represents the fulcrum of cooperation and responsibility for the scientific community. The government could not review all bioscience articles submitted to U.S. journals without slowing the march of science to a crawl. Moreover, there is no way to stop the renegade author willing to take risks with national security by releasing dual use data in any available media. In a similar vein, as Dr. Fauci said, “[I]f somebody really wants to get the data anyway, they will get it.”¹⁰⁴ Thus, there is virtually no way of providing an impermeable shield for sensitive research absent anachronistic laws drawn from the dark side of the iron curtain. Thus, any system devised must rely on the good will of scientists, journals, and sponsoring institutions.

This passive screening system does have limitations. For instance, poor RAS reporting or analysis could lead to the premature release of sensitive research without review by the BRC. But the benefit of the RAS paper trail enables a review of the problem areas for future modifications of the system. Likewise, the RAS can be improved by studying its validity by comparing published articles to its archived RAS scores. Thus, the system is flexible and can be updated and revised to meet stakeholders’ needs.

1. JOINT BRC AND NGP VETTING

The BRC will make a recommendation only after all parties with standing provide a timely opinion as to the suitability of public release of the article in question. If all parties reach a consensus, then the process ends with open publication or temporary classification, i.e. LRC. If however, the BRC recommends temporary classification against the wishes of any party with standing; the objecting party may demand an administrative hearing.

2. NGP FAIR HEARING OPTION

This stage of the system is fashioned after well-established hearing and appeal mechanisms affording review of disagreements over Medicaid awards¹⁰⁵ and educational

104 Schmid, *supra* note 9.

105 42 U.S.C. § 1396a (2005).

services.¹⁰⁶ The Individuals with Disabilities Education Act allows parents to challenge the educational plan designed for their child by a school district through a “Fair Hearing.”¹⁰⁷ Professor Gostin likewise argues for the use of fair hearings during health emergencies when individuals decline treatment for infectious disease.¹⁰⁸ If, however, a dispute persists over the status of an article after the Administrative Hearing, then the adversely affected party may seek judicial review of the matter in federal courts as generally permitted in disputes against federal agency actions.¹⁰⁹

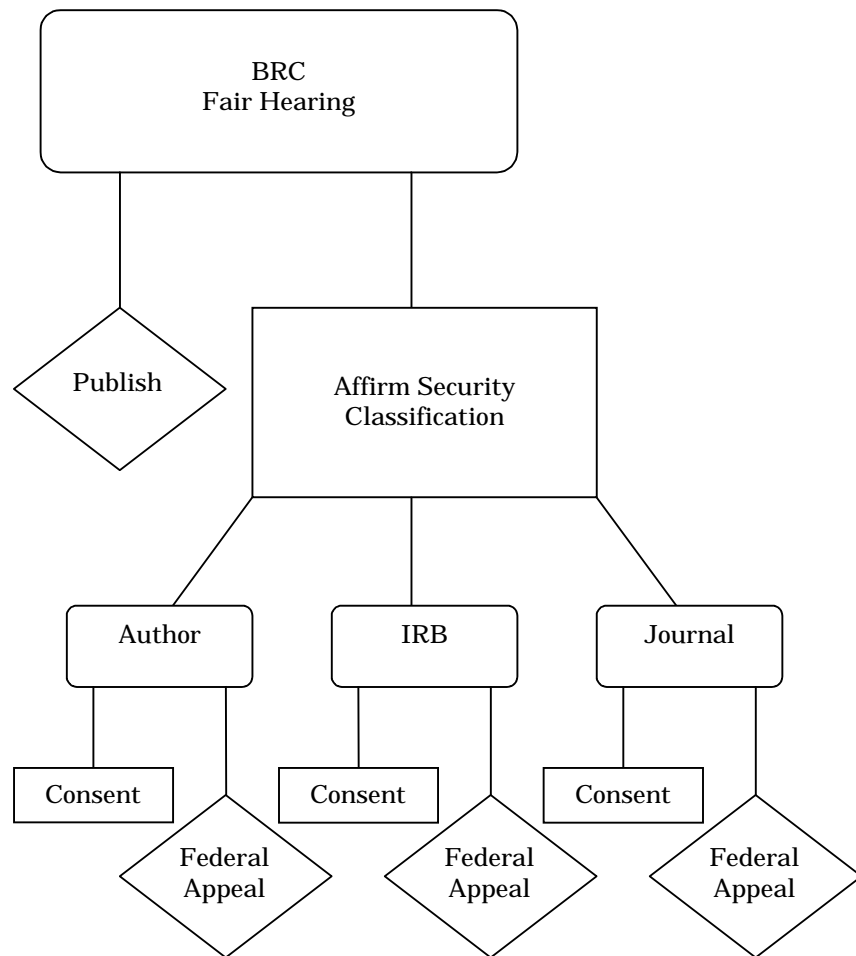
106 20 U.S.C. § 1415(f) (2004).

107 *Id.*

108 Lawrence O. Gostin, *When Terrorism Threatens Health: How Far Are Limitations on Personal and Economic Liberties Justified?*, 55 FLA. L. REV. 1105, 1165 (2003).

109 5 U.S.C. § 702 (2004).

Chart 3.



E. NGP FEDERAL APPEAL OPTION

A properly executed DPVS catches strategic data and reduces the likelihood that disputes will reach the federal courts. But the ultimate remedy of judicial intervention is available if necessary. In this connection, it is fair to say that the *Progressive* case,¹¹⁰ a key case in this area, could have been averted if the editors, the author and government had a cooperative vetting paradigm to work within before going to court.

110 *Supra* note 40.

1. DPVS STANDING

Parties with standing in the DPVS include the author of the article, the author's IRB, the journal accepting the article, and the BRC. Although the BRC would be charged with a legal duty to review articles that may present risks to society, any RAS reporter may assure that a potentially sensitive article gets flagged immediately to trigger cooperative vetting by all parties with standing in the process.

This feature improves upon the present system in several ways. First, it improves transparency by bringing more professionals into the vetting process. Instead of laying exclusive vetting responsibility in the hands of journal editors or one peer reviewer, the author, the author's IRB, peer reviewers, and BRC could share the responsibility. The wider pool of qualified reviewers will ensure a more informed and balanced discourse in the debate. Moreover, authors will have a voice in the vetting process and a direct line of communication with the BRC. Thus, authors, such as those who previously raised concerns about the risks of their own articles upon submission to scientific journals,¹¹¹ will have an opportunity to stand on equal footing with their editors when it comes to risk assessment or any challenge to classification of the article.

2. LEAST RESTRICTIVE CLASSIFICATION

One of the unspoken concerns of classification is the negative impact it could have on the advancement of careers and the prestige of institutions that thrive on research productivity. Remedies should, therefore, be sensitive to these factors. Thus, it would be extremely beneficial if journals deem embargoed articles as their duly published material. Thus, the classified article will be recognized as published in the year and volume originally designated by the accepting journal, and subsequently cited as such upon release from LRC status. Therefore, researchers and institutions will receive recognition for the contributions to science made in the article. Accessibility to the article, however, will remain restricted to qualified parties such as those in an approved academy for biodefense research for up to five years. After the embargo period, the article will automatically be declassified, unless another review is requested

111 See *supra* note 40; *supra* note 41; *supra* note 43.

by any of the original reviewing parties or the BRC. After this review a determination will be made as to reclassification or public release of the article. Disputes over classification down the road will follow the same procedure found in the first round of the DPVS.

Unlike the present system, sensitive articles will be made available to those scientists whose work will benefit from access to the cache of sensitive research. Further policy considerations will determine how wide the gate of access swings for articles in LRC status. But the degree of access can be calibrated. For instance, access can remain narrow if the current rate of production of sensitive articles remains low. If, however, the production of sensitive articles increases, the mechanism for access can be adjusted to open wider for as many qualified researchers in need of the cache as necessary. A more careful approach would entail a ranking of articles in LRC status to help balance risk of release against benefit to an investigator's lab. Further research and comment is needed to determine the specific criteria for access to the cache of sensitive articles. Denying access to research in LRC status to those with a casual interest is undesirable, but it is superior to censorship. The DPVS and Editors Group approaches both draw lines, the difference is that some researchers will have access beyond the line drawn by the former. The DPVS is certainly superior to extant censorship policies which needlessly run the risk of summarily cutting off this line of research.

Academic and research institutions need the mechanisms of the current system of open science to reward activity and assure the advancement of science. Thus, the DPVS can overlay the extant system without influencing the natural flow of articles and relationships between researchers and their journals. In this connection, the decision to classify will be based on objective measures, joint input, and be subject to appeal. Thus, if the BRC decides to classify an article after an Administrative Hearing absent a consensus, then any qualified party may then bring the matter to the federal courts as a last resort.

IV. IMPLICATIONS FOR FURTHER STUDY

Opportunities for further study and refinement of this proposal are numerous; however, there is a particular need to

assure that national remedies to the open science dilemma are globally compatible. Fortunately, the DPVS is flexible and may address this issue on a global scale in several ways. At a minimum other governments may utilize the same system in conjunction with the editorial boards in their countries. But this situation also presents the U.S. with an opportunity to continue its leadership in science rather than alienate itself with unwelcoming policies and practices.¹¹² The DPVS can work across national boundaries much like the traditional model of open science so long as allies on the war on terror can agree to LRC mechanisms. Even in the absence of classification agreements with foreign countries, individual scientists around the world could be invited into the new biodefense academy on a case by case basis. A properly constructed DPVS in the U.S. should generate reinforcing properties that attract responsible scientists--the world over--to a bona fide academy of biodefense researchers eager to work closely on common goals. Thus, the new academy could be the world's premier scientific academy with its exclusive mission, high standards and code of ethics.

V. CONCLUSION

The stakes in this debate could not be higher. The potential showdown between the scientific community and the government on open science, absent goodwill and cooperation, would certainly yield a duel of mutual destruction.

If scientific journals can cooperate by accommodating the parameters of articles in LRC status, and if professional stakeholders agree on fair scaling procedures and joint vetting, the entire field of science can move forward in a safe and efficient manner. The DPVS could provide a superior alternative to the ASM model and ad hoc approaches undertaken by the majority of U.S. bioscience journals. But, the DPVS is just a proposal, and is by no means seen as a comprehensive solution to the debate on open science. It is hoped that the flaws and virtues of this proposal will help inspire a fair and comprehensive approach to sensitive and dual use science that will accommodate the needs of all of the stakeholders in this debate.

¹¹² See *Science and the War on Terror*, NATURE, Sept. 11, 2003, at 107.