Saint Louis University Journal of Health Law & Policy

Volume 7
Issue 1 *Regulating Dual-Use Research in Life Sciences*

Article 6

2013

# Life Sciences Dual Use Research of Concern, Public Health and Safety, and the Doctrine of Unconstitutional Conditions

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# LIFE SCIENCES DUAL USE RESEARCH OF CONCERN, PUBLIC HEALTH AND SAFETY, AND THE DOCTRINE OF UNCONSTITUTIONAL CONDITIONS

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## I. INTRODUCTION

Legitimate scientific research, if misused or misapplied, can pose a possible or real threat to public health, our conceptions of morality, or even life as we know it. The existence of such "dual use research of concern" (DURC)[1] poses difficult legal questions regarding the appropriate balance between competing interests in public safety and freedom of expression, including questions about the advisability of using the law as the tool to balance these interests.

Recently, such difficult questions were presented by life sciences DURC when two teams of government-funded researchers succeeded in transforming the usually difficult-to-transmit avian influenza virus into an airborne virus easily transmissible between mammals.[2] The scientists reported the results of their experiments to the National Institute of Allergy and Infectious Diseases (NIAID), the public agency that funded the experiments, and also sought to publish the results in mainstream, well-

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1. Dual Use Research of Concern in the context of the life sciences is defined as "research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." *See* OFF. SCI. & TECH. POLICY, UNITED STATES GOVERNMENT POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN 2 (2013) *available at* http://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf.

2. Martin Enserink, *Controversial Studies Give a Deadly Flu Virus Wings*, 334 SCIENCE 1192, 1192 (2011).

respected scientific journals.[3] NIAID requested that the National Science Advisory Board for Biodefense (NSABB) review the manuscripts to determine whether publication might trigger national security concerns.[4] Initially, after reviewing the manuscripts, the NSABB recommended redacting them to remove the methodology and details that could enable replication of the experiments.[5] Much of the scientific community argued that compliance with this request would eviscerate the nature of scientific experimentation, which requires that results of experiments be replicable by others in order to allow the continued growth of scientific knowledge.[6] Therefore, the NSABB's request generated a major controversy within the scientific and legal communities. This request illustrated the difficulty of reconciling the needs and culture of the scientific community for openness and collaboration to advance science, with the needs and culture of the government for secrecy to ensure national security when DURC is produced.

Ultimately, the NSABB reversed its position, and the two papers were published without incident (to date).[7] Nevertheless, the difficulty of balancing the government's power to control and direct the course of scientific research to protect the public from harm, with the needs of scientists for freedom to experiment and communicate their results in the name of science, remains unresolved. The federal government funds a large portion of the scientific and life sciences research done in the U.S.[8] The tool it traditionally uses for controlling scientific research is to place contractual limitations on how such research is conducted, and/or how and to whom it is communicated.[9] However, such government-imposed limitations on conducting scientific research, or publishing the results of the research, may impinge on the scientists' First Amendment rights of free expression, thus triggering legal review under the doctrine of unconstitutional conditions.

3. *Id.*

4. *Id*.

5. *Oversight Hearing on Biological Security: The Risk of Dual-Use Research: Hearing Before the U.S. S. Comm'n on Homeland Sec. & Gov't Affairs*, 112th Cong. 8 (2012) [hereinafter *The Risk of Dual-Use Research*] (Testimony of Anthony S. Fauci, M.D., Director, Nat'l Inst. of Allergy & Infectious Diseases).

6. *See* Enserink, *supra* note 2, at 1193. *See*, *e.g.*, Victoria Stodden, *The Scientific Method in Practice: Reproducibility in the Computational Sciences* 3 (MIT Sloan School Working Paper No. 4773-10, 2010), *available at* http://ssrn.com/abstract=1550193.

7. Brendan Maher, *Bird-Flu Research: The Biosecurity Oversight*, 485 NATURE 431, 434 (2012).

8. NATIONAL SCIENCE BOARD, NSB 12-01, SCIENCE AND ENGINEERING INDICATORS 2012, 4-13 (2012), *available at* http://www.nsf.gov/statistics/seind12/pdf/c04.pdf.

9. *See* Steve Keane, *The Case Against Blanket First Amendment Protection of Scientific Research: Articulating a More Limited Scope of Protection*, 59 STAN. L. REV. 505, 514-15 (2006).

The unconstitutional conditions doctrine is the principle that states the government cannot require a person to forego a constitutional right in order to receive a government-conferred benefit.[10] Often, the right at issue in unconstitutional conditions cases is the right of free speech or freedom of the press under the First Amendment. Although the U.S. Supreme Court has decided numerous cases involving assertions of the doctrine of unconstitutional conditions by those seeking a government benefit, its jurisprudence in this area has been inconsistent. It has not spoken on the doctrine's application to scientific research, and its pronouncements provide conflicting clues as to how it would apply the doctrine to government attempts to control DURC through conditions on funding of research or publication of research results.

This article explores the application of the doctrine of unconstitutional conditions as it applies to DURC, particularly in the area of life sciences research. Part II briefly reviews the jurisprudence of the doctrine of unconstitutional conditions, and then focuses on how the courts have applied the doctrine in cases where the government imposes restrictions on recipients of federal funds that implicate their First Amendment rights of free expression. This would be the most common posture in which a case involving DURC would arise. Part III reviews the federal government's current policy regarding funding and communication of life sciences DURC, ongoing efforts to refine and implement the policy, and whether the current policy is likely to be found to violate the doctrine of unconstitutional conditions. Part IV suggests that rather than ban or classify life sciences DURC, the government can carefully craft restrictions to define the limits on government-funded research that allow life sciences DURC to be conducted and communicated while minimizing the risk of violating the doctrine of unconstitutional conditions and preserving the scientific method. Such an approach is more likely to protect us than the use of more draconian methods of ensuring secrecy. This approach will not endanger our place amongst the global community of life sciences and international public health experts, but will ensure that we continue to have a place at the table while keeping a watchful eye on the work that is being done.

## II. THE DOCTRINE OF UNCONSTITUTIONAL CONDITIONS AND GOVERNMENT FUNDING

The doctrine of unconstitutional conditions is implicated when the government seeks a *quid pro quo* that limits the exercise of a person's

10. Regan v. Taxation with Representation of Washington, 461 U.S. 540, 545 (1983) (citing Perry v. Sindermann, 408 U.S. 593, 597 (1972)).

constitutional rights in exchange for a government benefit.[11] The doctrine has been asserted in connection with a wide variety of government benefits. Receipt of tax deductions,[12] tax-exempt status,[13] government employment,[14] direct funding for participation in a government program,[15] government funding to assist in carrying out one's core, non-governmental functions,[16] and funding to participate in a government-created limited public forum[17] have all been deemed to be government benefits that trigger scrutiny under the doctrine. The doctrine is implicated both by conditions on government benefits that compel speech[18] and by conditions that require the recipient to refrain from speaking.[19] Generally, the doctrine prevents the government from doing indirectly, through the withholding of a benefit, what it could not do directly through regulatory or statutory command.[20] The doctrine applies even when the government has no obligation to offer the benefits in the first place.[21]

Although the government has "wide latitude to set spending priorities," the doctrine of unconstitutional conditions clearly applies when the government acts under its Spending Clause authority as a disburser of federal funds or a subsidizer of private activities.[22] Although the usual way for a party to object to a condition placed on the receipt of federal funds is to decline the funds, a party cannot be forced to choose between exercising its constitutional rights under the First Amendment and receiving a government benefit or subsidy.[23] In particular, the government cannot use the provision or refusal to provide a benefit in order to suppress ideas that it deems "dangerous."[24] And when the government does place conditions on funding that implicate the recipient's First Amendment rights, they need to

11. BLACK'S LAW DICTIONARY 1664 (9th ed. 2009).

12. Speiser v. Randall, Assessor of Contra Cnty., Cal., 357 U.S. 513, 529 (1958).

13. *Regan*, 461 U.S. at 545.

14. *Perry*, 408 U.S. at 597.

15. *See* Rust v. Sullivan, 500 U.S. 173, 198-99 (1991); Legal Servs. Corp. v. Velazquez, 531 U.S. 533, 533, 548 (2001).

16. *See* Fed. Commc'ns Comm'n v. League of Women Voters of Cal., 468 U.S. 364, 378 (1984); Nat'l Endowment for the Arts et al. v. Finley et al., 524 U.S. 569, 587 (1998); United States v. Am. Library Ass'n, Inc. 539 U.S. 194, 211 (2003); Agency for Int'l Dev. v. Alliance for Open Soc'y Int'l, Inc., No. 12-10, slip op. at 12 (June 20, 2013).

17. *See* Rosenberger et al. v. Rector of the Univ. of Va. et al., 515 U.S. 819, 829 (1995).

18. *See Agency for Int'l Dev.*, No. 12-10, slip op. at 12.

19. *See Legal Servs. Corp.*, 531 U.S. at 544.

20. *See Perry*, 408 U.S. at 597.

21. *See Agency for Int'l Dev.*, No. 12-10, slip op. at 8.

22. *Finley*, 524 U.S. at 588. *See Agency for Int'l Dev.*, No. 12-10, slip op. at 8.

23. *See Finley,* 524 U.S. at 587. *See Agency for Int'l Dev.*, No. 12-10, slip op. at 7-8.

24. *See* Regan v. Taxation with Representation of Washington, 461 U.S. 540, 550 (1983).

be precisely targeted at the dangers that may exist to justify the abridgment of the right to free expression.[25]

The context of the speech that is sought to be restricted is also relevant to determine whether a condition placed on government funding is unconstitutional. Restrictions that are placed on areas that have been traditionally public forums for expressive activity are particularly suspect, as are restrictions that attempt to leverage government funding to regulate private speech that the speaker undertakes outside of the contours of the government-funded program.[26]

There are a number of complicating factors and uncertainties that make it difficult to determine whether a condition put on government funding is likely to pass constitutional muster. Disagreement amongst members of the Supreme Court about how to characterize or weigh these factors has led to a large number of closely split decisions regarding the application of the doctrine of unconstitutional conditions to government funding.[27] Therefore, it is extremely difficult to predict whether any specific condition will pass muster. Many, if not all, of these complicating factors and uncertainties are present when the subject of the government funding is life sciences DURC. Thus, as will be discussed in Part III, any effort by the government to articulate an effective and legally sustainable approach to controlling DURC is likely to be difficult, complex, and may need to be undertaken on a case-by-case basis.

Nevertheless, we can draw some guidance from the case law regarding what kinds of restrictions on life sciences DURC the courts will look upon favorably and unfavorably. One factor that the Court has considered significant is whether or not the expressive activity that was sought to be prohibited or restricted can be segregated from other, non-government funded activities that a grant recipient undertakes.[28] Generally, when a restriction is limited to a grant recipient's work in the government-funded program, leaving the recipient free to speak on the restricted topic in other contexts, the restriction will be upheld (provided it is not otherwise objectionable).[29] For example, in *Rust v. Sullivan*, a provision of a statute

25. *See* Fed. Commc'ns Comm'n v. League of Women Voters of Cal., 468 U.S. 364, 380 (1984).

26. *See Agency for Int'l Dev.*, No. 12-10, slip op. at 11; Rust v. Sullivan, 500 U.S. 173, 197-99 (1991); Bd. of Trs. of Stanford Univ. v. Sullivan, 773 F.Supp. 472, 476-77 (D.D.C. 1991).

27. *See, e.g.*, United States v. Am. Library Ass'n, Inc. 539 U.S. 194, 197 (2003) (six-justice plurality, with three dissenters); Legal Servs. Corp. v. Velazquez, 531 U.S. 533, 533 (2001) (five-four decision); *Rust*, 500 U.S. at 173 (five-four decision); *Fed. Commc'ns Comm'n*, 468 U.S. at 354 (five-four decision).

28. *See Rust,* 500 U.S. at 197.

29. *Id.* at 199.

was upheld that prevented recipients of government funding for family planning services from counseling clients about abortions or referring clients for abortions.[30] The restriction was upheld because it was couched in terms of a prohibition on the government-funded *project*, rather than a prohibition aimed at the *recipient* of the government funds.[31]

In its most recent term, the Court reiterated this distinction between conditions on speech that are confined to the actual government spending program being funded, and conditions that seek to regulate speech outside of the boundaries of the government program itself.[32] The former were cited with approval, while the Court struck down as unconstitutional a requirement that a recipient of federal funds affirmatively espouse a point of view that was not limited to its work within the scope of the government-funded program.[33]

Yet, even in making this distinction, the Court has not been entirely consistent. For example, consistent with this policy, in *Federal Communications Commission v. League of Women Voters*, the Court struck down a prohibition on editorializing by noncommercial educational broadcasting stations who received grants from the Corporation for Public Broadcasting (CPB), noting that even a station that received only one percent of its overall income from the CPB would be barred from all editorializing.[34] The Court reasoned that such a station could not segregate its activities according to the source of its funding.[35] Further, in *Legal Services Corporation v. Carmen Velazquez*, the Court struck down a requirement that legal services providers funded by the Legal Services Corporation (LSC), which distributes federal funds to grantees who provide legal services to low-income and indigent clients, refrain from trying to amend or challenge then-existing welfare laws.[36] The prohibition in *Velazquez* was interpreted to apply not only to cases or clients that were funded by the LSC, but also to any work by a recipient of LSC funds, regardless of whether or not she was acting on behalf of a LSC-funded

30. *Id*. at 177-78.

31. *Id*. at 196-97.

32. *See Agency for Int'l Dev.*, No. 12-10, slip op. at 8.

33. *Id*. at 12. The requirement at issue was that a group or organization accepting the federal funds have "a policy explicitly opposing prostitution and sex trafficking." *Id*. at 1.

34. *Fed. Commc'ns Comm'n*, 468 U.S. at 365.

35. *Id*. at 400. The Court contrasted this situation with the situation presented by a non-profit §501(c)(3) organization prohibited from lobbying by tax-exemption law, but that could establish a separate §501(c)(4) affiliate to pursue its lobbying efforts, without forfeiting its tax-exempt status. *Id*. It then stated that the educational broadcasting station could not segregate its activities according to the source of its funding in the same manner, although it did not say why that would not be possible. *Id*.

36. Legal Servs. Corp. v. Velazquez, 531 U.S. 533, 547-48 (2001).

client.[37] In striking down this restriction, the Court did not specifically state that the funding condition was unconstitutional because it attempted to restrict speech outside of the context of the federally funded program; rather, it focused on its belief that there would likely be no alternative source for a client to receive the type of advocacy that the government sought to restrict.[38]

This was unlike the situation approved in *Rust*, where, according to the Court, the client seeking family planning services was not required to forego the government-funded services in order to receive abortion counseling through an alternative channel.[39] The Court did not explicitly state that the application of the restriction on speech to both the government-funded program and to the privately funded activities in *Velazquez*. Nevertheless, the blanket prohibition on advocating for amendment or change of welfare statutes by LSC funding recipients is the functional equivalent of the leveraging prohibition seen in other cases just viewed from the perspective of the services recipients, rather than from the perspective of the funding recipients.[40]

First Amendment restrictions on the receipt of government funds have been upheld in some cases where the government-funded program cannot be segregated from privately funded programs. In *United States v. American Library Association, Inc.*, the Court upheld a requirement that libraries receiving funds under two programs designed to help the libraries must provide internet access to patrons and install software to block access to pornographic images.[41] Although the libraries could not determine whether a particular patron's internet use was being funded by the federal programs or by other funds, and the purposes of the two federally funded programs could not be segregated from the general purposes of a public library, the Court, in a plurality opinion, upheld the software requirement against a challenge that it was an unconstitutional condition.[42] Rather than focusing on the non-segregable nature of the government-funded and non-

37. *Id*. at 538.

38. *Id*. at 535.

39. Rust v. Sullivan, 500 U.S. 173, 214 (1991). *See also Velazquez,* 531 U.S. at 546-47.

40. *See Velazquez,* 531 U.S. at 547-48.

41. United States v. Am. Library Ass'n, Inc. 539 U.S. 194, 199 (2003).

42. *Id*. at 199, 208. The two federal programs at issue were the E-rate program, 47 U.S.C. §254(h)(1)(B), and the Library Services and Technology Act (LSTA), 20 U.S.C. §9101 et seq. *Id*. at 201-02. The purpose of the E-rate program was "[to] help open new worlds of knowledge, learning, and education to all Americans . . ." *Id*. at 212. The purpose of the LSTA was "to stimulate excellence and promote access to learning and information resources in all types of libraries for individuals of all ages." *Id*. Clearly, these purposes are indistinguishable from the mission of a public library, regardless of the source of funding.

government-funded activity and the activity funded by other sources, the Court's plurality characterized the software requirement as a permissible condition to ensure that the "public funds be spent for the purposes for which they were authorized."[43]

Characterizing a restriction on protected speech or expression, as a means of ensuring that public funds be spent for the purposes for which they were authorized by the government, has also been used to justify restrictions surrounding applications for competitive government funding — a context that is most directly applicable to a potential restriction on National Institutes of Health (NIH) or National Science Foundation (NSF) funding for life sciences DURC. The difficulty in such cases is ensuring that the restriction is specific enough to achieve its goals without seeming to target only ideas that are deemed "dangerous" by the government.[44] A funding restriction that is clearly content-based and prevents an otherwise qualified proponent with a seemingly "dangerous" idea from competing for funding would be a clear-cut example of an unconstitutional condition on government funding.[45] Such a restriction would likely be deemed to cross the line from a definition of purpose "into a penalty on disfavored views," designed to have a coercive effect and chill expression that the government deems undesirable.[46]

In the context of competitive funding, as illustrated in *National Endowment for the Arts v. Finley,* there is difficulty in distinguishing between permissible funding criteria that are designed to ensure that public funds are used for their intended purpose, and impermissible content-based restrictions on expression of "dangerous" ideas.[47] In *Finley*, Congress responded to a public outcry about government funding for art, which many believed to be provocative and unworthy of government support, by amending the statutes that established criteria by which the National Endowment for the Arts (NEA) chose projects to fund.[48] The amended statute required the NEA to "tak[e] into consideration general standards of decency and respect for the diverse beliefs and values of the American public."[49]

43. *Id*. at 211-12.

44. *See* Nat'l Endowment for the Arts et al. v. Finley et al., 524 U.S. 569, 585 (1998).

45. *Id*. at 587 (citing Regan v. Taxation with Representation of Washington, 461 U.S. 540, 550 (1983)).

46. *Id*. at 587.

47. *Id*. at 583-86.

48. *Id*. at 574-75.

49. National Endowment for the Arts, 20 U.S.C. § 954(d)(1) (2011). The provocative works of art that prompted the amendment of the statute were a retrospective of photographer Robert Mapplethorpe's work, which included homoerotic photographs, and a photograph by Andres Serrano entitled "Piss Christ," which consisted of a crucifix immersed in urine. *Finley*, 524 U.S. at 574.

Four performance artists who had been recommended by a panel to be approved for NEA grants prior to the amendment of the statute, but were subsequently denied funding, challenged the amended statute.[50] They claimed that the provision requiring the NEA to consider "general standards of decency" violated their First Amendment rights by injecting viewpoint-based restrictions into government funding that was protected speech.[51]

Although the Court did not explicitly discuss the doctrine of unconstitutional conditions, it drew heavily on prior cases that applied the doctrine to strike down government restrictions on expressive conduct.[52] It ultimately distinguished those cases from the case at bar and upheld the statute.[53] The Court noted that in the context of funding for the arts, unlike in many other contexts, the government does not encourage a diversity of views and is mandated to make aesthetic judgments.[54] Because the challenge to the statute was facial, not as-applied, the case was distinguishable from a hypothetical case where the NEA used its power to invoke a penalty on disfavored viewpoints, which the Court said would be prohibited even in a government subsidy situation.[55] The Court drew a clear distinction between situations where the government is acting as a patron by awarding competitive funding, and those where the government is directly regulating speech, stating that "Congress has wide latitude to set spending priorities" in the context of awarding competitive funding, whereas it has more limited power to directly regulate or criminalize speech.[56] The Court

50. *Finley,* 524 U.S. at 577.

51. *Id*. at 577-78. They also claimed that the NEA had "failed to follow proper statutory procedures . . . had breached the confidentiality of their grant applications," and that the provision in question was void for vagueness. *Id*. at 577. An additional amendment to the statute, requiring all grantees to certify in writing that they would not use federal funding to create projects that could be considered obscene and did not have "serious literary, artistic, political, or scientific value," was invalidated previously as unconstitutionally vague by a federal district court. Dep't. of the Interior & Related Agencies Appropriations Act, 103 Stat. 738-42 (1990). *See also Finley,* 524 U.S. at 575.

52. *Finley,* 524 U.S. at 621 (citing Massachusetts v. Oakes, 491 U.S. 576, 584 (1989)).

53. *Id.* at 586.

54. *Id*. Thus, the case was distinguishable from cases where the government creates a limited public forum, and then denies access to the forum by certain disfavored groups. *See* Rosenberger et al. v. Rector of the Univ. of Va. et al., 515 U.S. 819, 834 (1995).

55. *Finley,* 524 U.S. at 586-87.

56. *Id*. at 587-88. A concurrence by Justice Scalia, joined by Justice Thomas, suggested even further deference to Congress is warranted in the context of competitive funding. *Id*. at 590. The concurrence states that content and viewpoint-based criteria are constitutional grounds upon which to evaluate grant applications. *Id*. Justices Scalia and Thomas noted that they regard the distinction between abridging speech and funding it as a "fundamental divide," and that the First Amendment is inapplicable to funding decisions. *Id*. at 599.

reasoned that without such latitude, the government would be unable to sponsor any competitive funding programs.[57]

The Court in *Finley* also acknowledged the importance of the context in which the speech is regulated when determining whether a condition imposed on the receipt of government funds is constitutional.[58] In areas that have traditionally been open to free expression "or have been expressly dedicated" to free speech, the government's ability to control speech within that forum is subject to greater scrutiny, even when the restriction is limited to speech within a government-funded project.[59] According to the Court,

> [T]he university is a traditional sphere of free expression so fundamental to the functioning of our society that the Government's ability to control speech within that sphere by means of conditions attached to the expenditure of Government funds is restricted by the vagueness and overbreadth doctrines of the First Amendment.[60]

Because the majority of life sciences DURC is done in the university setting (including the avian influenza DURC that sparked the most recent controversy over publishing restrictions), judicial pronouncements regarding attempts to use research funding to restrict expressive conduct in the university setting are particularly applicable to determining what restrictions on DURC will pass constitutional muster.

There is little case law addressing restrictions on research funding in the university setting.[61] Nevertheless, in one case squarely on point, the NIH included a confidentiality clause in a grant for research into the development of an artificial heart.[62] The confidentiality clause required researchers "to obtain government approval before publishing or otherwise

57. *See id*. at 587-88.

58. *See id*. at 590-91.

59. *See* Rust v. Sullivan, 500 U.S. 173, 200 (1991) (citing United States v. Kokinda, 497 U.S. 720, 726 (1990)).

60. *Rust*, 500 U.S. at 200. *See also Rosenberger*, 515 U.S. at 836 (discussing the importance of the university setting as "the center of our intellectual and philosophic tradition.").

61. There is, however, a fair amount of legal commentary on the subject of whether scientific research is entitled to any kind of First Amendment protection, and if so, the appropriate scope of such protection. *See*, *e.g.*, Steve Keane, *supra* note 9, at 505; Barry P. McDonald, *Government Regulation or Other "Abridgements" of Scientific Research: The Proper Scope of Judicial Review Under the First Amendment*, 54 EMORY L. J. 979 (2005). However, all agree that expression carried out in the course of performing scientific research, and communication of the results of scientific research are entitled to First Amendment protection. For purposes of this article, I presume that protected communication about scientific research is not segregable from the research itself. Therefore, the doctrine of unconstitutional conditions is triggered at all stages of the research.

62. Bd. of Trs. of the Leland Stanford Junior Univ. v. Sullivan, 773 F. Supp. 472, 473 (D.D.C. 1991).

publicly discussing preliminary research results."[63] Stanford University submitted a proposal to do the research but objected to the confidentiality clause.[64] When the government and Stanford could not agree on the clause, the contract was awarded to a different university. Stanford sued the government claiming the clause was "an illegal prior restraint on speech and an unconstitutional condition on a government benefit."[65]

First, the *Stanford* court noted that the restriction failed the segregability test of *Rust v. Sullivan*.[66] Under the confidentiality clause, the Stanford researchers could not speak about the artificial heart research outside of the context of the government-funded research program.[67] In addition, the *Stanford* court noted that the subject of the lawsuit, a restriction on speech at a university, was "the very free expression that the Rust Court held to be so important to the functioning of American society . . . ."[68] Taking a strong position in favor of academic freedom, the *Stanford* court said:

> Stanford University, a premier academic institution, engaged in significant scientific and medical research for the benefit of the American people, is not *ipso facto* compelled under the law to surrender its free speech rights and those of its scientific researchers to a 'contracting officer' merely because a regulation issued by defendants so directs. There exists, after all, the *First Amendment to the Constitution*, the supreme law of the land, which protects those very rights.[69]

The *Stanford* court concluded that the confidentiality clause, when applied to the university setting, was an unenforceable, unconstitutional condition.[70] The court ordered that the contract, without the confidentiality clause, be awarded to Stanford University.[71]

63. *Id*.
64. *Id*.
65. *Id.* at 473-74.
66. *Id*. at 476.
67. *Bd. of Trs. of the Leland Stanford Junior Univ.*, 773 F.Supp. at 476.
68. *Id*. at 477.
69. *Id*. at 478.
70. *Id*. at 479. The *Stanford* court was also less than convinced that any harm would flow from publication of the preliminary research results concerning the artificial heart. The government's purported reason for the confidentiality clause was to protect the public health and safety by protecting prospective patients from "unwarranted hope." *Id*. at 477 n.16. The *Stanford* court called this "a strange and attenuated way of protecting health and safety." *Id*. A court considering a similar confidentiality clause concerning DURC might be less skeptical about the government's claims of public harm that would result from premature or unauthorized publication of the results, and more inclined to defer to the government's request to block disclosure. *See*, *e.g.*, United States v. Progressive, Inc., 467 F. Supp. 990, 996 (W.D. Wis. 1979) (in a case where the United States sought an injunction against a magazine seeking to publish details about how to build an atomic bomb, the judge, while acknowledging the government's heavy burden of proof to suppress publication, noted that

When deciding whether such a restriction or prohibition of speech is constitutional, the courts have also considered the practical effect that tying government funding to restricting free expression is likely to have on the overall exercise of First Amendment rights in American society.[72] The *Stanford* court recognized that very few sizable undertakings in the modern world are not supported in some manner by government funds.[73] It reasoned that if the government's position regarding the confidentiality clause was accepted as law, it would present an "enormous threat" to First Amendment rights, and indeed, to a "free society."[74]

Often, the governmental funding agency occupies a dominant role in the financing of the contemplated endeavor.[75] In such cases, receiving the government funding is like an "imprimatur" that acts as a proxy for merit and value.[76] When the selection criteria for government funding from a government agency that is dominant in the field are viewpoint-based, they have a chilling effect on the exercise of First Amendment rights outside of the context of the government-funded project.[77] Furthermore, when it is customary for private donors to match government funds awarded under competitive grants, the chilling effect of the funding restriction is magnified.[78] In the context of funding for scientific research, including

"[a] mistake in ruling against the United States could pave the way for thermonuclear annihilation for us all. In that event, our right to life is extinguished and the right to publish becomes moot." The judge issued the injunction.). *See also*, L. A. Powe, Jr., *The H-Bomb Injunction*, 61 U. COLO. L. REV. 55 (1990).

71. *Bd. of Trs. of the Leland Stanford Junior Univ.*, 773 F. Supp. at 479.

72. *Id.* at 478.

73. *Id.*

74. *Id.*

75. *See, e.g.*, Nat'l Endowment for the Arts et al. v. Finley et al., 524 U.S. 569, 621-22 (1998) (Souter, J., dissenting); Rosenberger et al. v. Rector of the Univ. of Va. et al., 515 U.S. 819, 835 (1995). The recent case of *Nat'l Fed. of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012), adds an interesting wrinkle to the doctrine of unconstitutional conditions when the recipient of federal funds is a state institution. In NFIB, the Supreme Court held, for the first time, that the conditions placed on an offer of federal money under a Spending Clause program (Medicaid) amounted to inappropriate "coercion" of the states, and could not be enforced. *Id.* at 2603-04. Central to the Court's reasoning on this point was the extremely large portions of state budgets that are comprised of federal Medicaid funds. *Id.* at 2604-05. If funds for DURC are offered to a state institution, such as a state university, with onerous restrictions on the right of free expression, and the funds are vital to the continuation of the university's research mission, under NFIB, it is possible that a court could consider the conditional funding an offer the state cannot refuse, and could strike the conditions down as overly coercive.

76. *Finley*, 524 U.S. at 622 (Souter, J., dissenting), (quoting Bella Lewitzky Dance Found. v. Frohnmayer, 754 F. Supp. 774, 783 (C.D. Cal. 1991)).

77. *See Finley*, 524 U.S. at 622 (Souter, J., dissenting).

78. *Id.*

DURC, competitive grant-based funding from the NIH, NSF, or other government agencies may occupy the role of primary funding source.[79] Thus, any restriction placed on the conduct or publication of DURC has the potential to chill scientific research beyond the context of government-funded research, as well as within government-funded projects.[80] Preventing this effect requires that restrictions be carefully considered, as they may adversely affect the ability of an applicant to advance her research agenda outside of, as well as within the scope of, the government-funded project.

In the context of life sciences DURC, all of the factors that the Court has considered significant when distinguishing between unconstitutional conditions and permissible restrictions on funding of government projects are present. The research usually takes place in a traditionally open forum, such as a university.[81] The government funding agencies are dominant in the market for funding, and the government's pronouncements on the fundability of the research are often taken as statements about the merit of the proposal.[82] Government and private funds are often mixed together to fund a single project, and the availability of private funds may also depend on whether the project is publicly funded.[83] Because of the large number of factors that affect the constitutionality of restrictions placed on government funding, and the even larger number of combinations of these factors that might attach to any particular offer of funding, it is extremely important that any restrictions placed on the conduct or publication of government-funded DURC be narrowly tailored to protect the public or the country's national security in a manner that places the least amount of restrictions on constitutionally protected expression.[84]

79. *See* OFF. SCI. & TECH. POLICY, *supra* note 1, at 14.

80. The federal government appears to recognize this chilling potential. In the proposed United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, the government notes that "designating research as DURC should not be seen as a negative categorization . . . As a general matter, designation of research as DURC does not mean that the research should not be conducted or communicated." *Id.* at 3.

81. *See* Keane, *supra* note 9, at 532.

82. *See id.*

83. *See id.*

84. The question of whether scientific research of any kind is protected by the First Amendment is unresolved. *See, e.g.*, *id.* at 523 (arguing that scientific research is protected by the First Amendment in only limited circumstances, when it constitutes "expressive" conduct); McDonald, *supra* note 61, at 986 (arguing that there is no First Amendment right of scientific research per se, but restraints on such research could trigger incidental restrictions on expression that is protected under the First Amendment); Cass. R. Sunstein, *Is There a Constitutional Right to Clone?*, 53 HAST. L. J. 987, 1003 (2002) (stating that the jurisprudence in the area is "ill-developed"). A discussion of whether scientific research is protected by the First Amendment is beyond the scope of this article. It is generally agreed that communication of research results or discussion of research (non-classified) is expression protected by the First

## III. CURRENT GOVERNMENT EFFORTS TO RESTRICT OR CONTROL EXPRESSIVE CONDUCT IN LIFE SCIENCES DURC

Concerns about the wisdom and public safety surrounding life sciences DURC is not new.[85] Nevertheless, the anthrax attacks of 2001, which followed closely on the heels of the terrorist attacks on September 11th (9/11), heightened awareness about life sciences DURC and its potential to endanger public health and safety and added some urgency to the debate about controlling the flow of such information.[86] After the anthrax attacks, some scientific professional societies and the editors of major journals in the life sciences considered instituting policies restricting publication of information on DURC that could pose national security risks, but ultimately rejected such an approach in favor of self-regulation.[87] This was not surprising. Unlike other areas of scientific research which have a history and culture of secrecy and cooperation with the national security community, life sciences researchers have no such established culture.[88]

### *A. The Fink Report and the National Science Advisory Board for Biodefense*

The federal government recognized the tensions between minimizing or eliminating the potential threats to national security and public health threats by life sciences DURC with the legitimate needs of life sciences researchers to communicate research in sufficient detail to permit peer review for validity and reproducibility in order to advance biomedical and life sciences research.[89] Therefore, in 2003, "the [National Academy of Science] (NAS) appointed a committee to propose a framework that could be used to minimize national security and public health threats posed by [life sciences] DURC without undermining biomedical research and science."[90] The committee produced a comprehensive report in 2004, popularly known as

Amendment. *See* Miller v. Cal., 413 U.S. 15, 22-23 (1973); Bd. of Trs. of the Leland Stanford Junior Univ., 773 F. Supp. 472, 477; Keane, *supra* note 9, at 520-23. This article focuses on attempts to restrict the expressive conduct involved in both the production and publication of life sciences DURC.

85. *See* Vickie J. Williams, *The "Jurassic Park" Problem—Dual-Use Research of Concern, Privately Funded Research and Protecting Public Health*, 53 JURIMETRICS 361, 363-66 (2013) (summarizing historical efforts to control communication and publication of DURC).

86. *Id*. at 366.

87. COMM. ON RESEARCH STANDARDS & PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NAT'L RESEARCH COUNCIL, BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM 97 (2004) [hereinafter FINK REPORT], *available at* http://www.nap.edu/catalog/10827.html.

88. *Id*. at 85.

89. Williams, *supra* note 85, at 366.

90. *Id.* at 367; Ruth R. Faden & Ruth A. Karron, *The Obligation to Prevent the Next Dual-Use Controversy*, 335 SCI. 802, 802-03 (2012).

the *Fink Report* (named after committee chair, Professor Gerald R. Fink, of the Massachusetts Institute of Technology), which suggested a multiple-pronged approach to national safety and life sciences DURC.[91] Although the *Fink Report* made recommendations regarding the education of scientists concerning the risks of DURC, training methods for personnel involved in DURC, and physical containment of potentially dangerous pathogens, it did not recommend expansion of the use of the *classified* or *top secret* designations for such research.[92] The committee was very concerned about the risk of a "chilling effect" that such designations would have on life sciences research, and the danger that such an effect would pose to continued progress in the areas of life sciences research and public health.[93] The committee endorsed a "softer" approach, recommending creation of the NSABB, a body of experts that would act as a liaison between the government and the life sciences community to facilitate oversight and review of DURC.[94]

The federal government followed the committee's recommendations and established the NSABB.[95] The NSABB consists of a broad spectrum of experts including, "scientists, lawyers, infectious disease experts, scientific editors, and public health experts."[96] The avian influenza experiments, discussed in Part I, were the first time that the NSABB recommended that scientific manuscripts be redacted to exclude experiment methodology and details to prevent replication of the experiments prior to publication.[97] Although the authors and the journal editors agreed to consider the recommendation, it was on the condition that the government would allow restricted circulation of the complete manuscripts to those with a legitimate need for the information.[98] While the issue was being discussed, the World Health Organization weighed in with its opinion, concluding that publication

91. FINK REPORT, *supra* note 87, at 111-26.

92. *Id*. at 118.

93. *Id*.

94. *Id.* at 110-11.

95. NAT'L SCI. ADVISORY BD. ON BIOSECURITY, ENHANCING RESPONSIBLE SCIENCE CONSIDERATIONS FOR THE DEVELOPMENT AND DISSEMINATION OF CODES OF CONDUCT FOR DUAL USE RESEARCH, 1, 30 (2012), *available at* http://oba.od.nih.gov/oba/biosecurity/documents/COMBINED_Codes_PDFs.pdf.

96. *See The Risk of Dual-Use Research*, *supra* note 5, at 12 (testimony of Dr. Paul S. Keim, Acting Chairman, National Science Advisory Board for Biosecurity).

97. *Id.* at 6 (testimony of Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases).

98. Statement by Dr. Bruce Alberts, Editor-in-Chief, Sci., Regarding Publication of H5N1 Avian Influenza Research (Dec, 20, 2011), http://www.aaas.org/news/releases/2011/media/1220herfst_statement.pdf).

of the full manuscripts was preferable from a public health perspective.[99] One of the scientist-authors, Dr. Yoshihiro Kawaoka, Ph.D., advocated publicly for wide dissemination of the research so that researchers from other areas could contribute to the vital field of influenza research.[100] Ultimately, after reviewing additional data and the revised manuscripts, the NSABB withdrew its recommendation for redaction and the manuscripts were published in full.[101]

### *B. The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*

Current U.S. policy regarding the funding and control of DURC contemplates close cooperation and partnerships between the NSABB, private researchers, and the funding agencies, as suggested by the *Fink Report*. This approach is reflected in the official guidance documents and pronouncements that the government has produced since the controversial avian influenza experiments.

While the avian influenza controversy continued to percolate without a resolution, the U.S. issued its Policy for Oversight of Life Sciences Dual Use Research of Concern (Dual Use Policy).[102] The Dual Use Policy is designed to address existing, unclassified, ongoing research that has already been funded, as well as research that has been previously proposed but is pending a funding decision.[103] It is specifically limited to work with one of 15 identified biological agents and toxins (including avian influenza

99. *The Risk of Dual-Use Research, supra* note 5, at 8-9 (2012) (statement of Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases), *available at* http://www.hsgac.senate.gov/download/2012-04-26-fauci-testimony-biological-security.

100. Yoshihiro Kawaoka, *Flu Transmission Work is Urgent*, 482 NATURE 155, 155 (2012).

101. The influenza research community also initiated a voluntary moratorium on avian influenza research, that lasted for approximately one year. *The Risk of Dual-Use Research*, *supra* note 5, at 7; Denise Grady, *Research to Resume on Modified, Deadlier Bird Flu*, N.Y. TIMES, Jan. 24, 2013, at A8. The United States released new guidelines for such research on Feb. 22, 2013, thus allowing such research to resume in the United States, or elsewhere with American funding. *See* DEP'T OF HEALTH & HUMAN SERVS., A FRAMEWORK FOR GUIDING U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FUNDING DECISIONS ABOUT RESEARCH PROPOSALS WITH THE POTENTIAL FOR GENERATING HIGHLY PATHOGENIC AVIAN INFLUENZA H5N1 VIRUSES THAT ARE TRANSMISSIBLE AMONG MAMMALS BY RESPIRATORY DROPLETS, *available at* https://www.phe.gov/s3/dualuse/Documents/funding-hpai-h5n1.pdf (last visited Aug. 5, 2013) [hereinafter FRAMEWORK].

102. DEP'T OF HEALTH & HUMAN SERVS., UNITED STATES GOVERNMENT POLICY FOR OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN, 1 (2012), *available at* http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf.

103. *Id.* at 3.

virus).[104] It is also limited to seven categories of experiments that utilize these agents, which are considered to be most likely to produce DURC.[105] Its main proposed method for controlling expressive conduct in the context of life sciences DURC is through the development of a risk mitigation plan with cooperation between the federal funding agency and the institution or researcher.[106] This plan can include "[d]etermining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly."[107] If such measures prove inadequate to mitigate the risks posed by the research, the federal funding agency may request voluntary redaction of communications or publication, may classify the research, or may terminate or refuse to provide research funding.[108]

Experts in life sciences research and public health who are reviewing the Dual Use Policy have pointed out many of the problems with this approach because it can lead to uncertainty about the constitutionality of any actions taken under the Policy that restrict communications regarding the research or its results.[109] They point out that the lack of uniform standards or guidelines among funding agencies with regard to what constitutes risk could pose "significant security and compliance challenges for institutions receiving funding from more than one government agency," perhaps foreshadowing a challenge to a restriction based on the inability to segregate the restricted research from non-restricted research, or based on competing restrictions.[110] They have also pointed out that the Dual Use Policy does not provide research institutions or agencies with sufficient guidance on how to minimize the risk that misuse could occur once results, methods, or information generated by the research are communicated.[111]

104. *Id* at 2.

105. *Id*. at 2-3.

106. *Id*. at 3.

107. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 102, at 3.

108. *Id*. at 3-4.

109. *See* American Association for the Advancement of Science, Report of a Meeting on "Bridging Science and Security for Biological Research: A Discussion about Dual Use Review and Oversight at Research Institutions" held at AAAS headquarters in Washington D.C. 13-14 Sept. 2012, http://www.aaas.org/cstsp/programs/bridging-science.shtml [hereinafter Bridging Science].

110. *Id*.

111. *Id*. at 22. *See also* Leslie Gielow Jacobs, *A Troubling Equation in Contracts for Government Funded Scientific Research: "Sensitive But Unclassified" = Secret But Unconstitutional*, 1 J. NAT'L SECURITY L. & POL'Y 113, 141 (2005) (arguing that the government's expanded use of the designation "sensitive but unclassified" for scientific information and research since 9/11 is unconstitutional because of imprecise definitions, requirements of enforcement by prepublication review, and lack of a sufficient link between the information and a clear national security danger).

This may be an indication that it will be extremely difficult, if not impossible, to narrowly tailor any restriction to mitigate the specific harm contemplated, a constitutional requirement for restrictions of speech, absent a complete moratorium on publication or communication, for example, classifying the research.[112]

To the extent that the Dual Use Policy applies to research that has already been undertaken, attempts to block publication or otherwise control communications after the funding has already been awarded would be akin to a government agency that agreed to fund a project in the arts and then, upon reviewing the resulting work of art either while in progress or upon completion, imposed a new criterion tailored to that project so that it could not be shown to its intended audience. Whereas in *National Endowment for the Arts*, the Court upheld subjective criteria on funding of arts projects that could be considered viewpoint-based or content-specific as part of a competitive funding process.[113] It would have been quite a different case if the National Endowment for the Arts (NEA) had funded the projects, viewed the completed work, and then deemed it unacceptable for public viewing.[114]

The experts also noted that overly restrictive policies are likely to have a chilling effect on research that falls under the Dual Use Policy, with concomitant negative effects on biodefense preparedness, health and agriculture, and increased vulnerability to biological threats.[115] They also recognized the incompatibility of redacting scientific publications to remove information that supports the quality and reproducibility of the research in question with the very nature of the scientific endeavor and academic freedom.[116] The experts discussed the reality that scientific research is communicated to various audiences through various venues throughout the lifetime of a research project, and how that reality is incompatible with attempts to censor, redact, or embargo results and methods, particularly in an era of instantaneous communication through the Internet and social media.[117] The report discussed that DURC can emerge from work that is not

112. *See* Jacobs, *supra* note 111, at 142-44.

113. *Finley*, 524 U.S. 569, 587.

114. *Id.* at 571.

115. Bridging Science, *supra* note 109, at 22.

116. *Id.* at 23.

117. *Id.* The experts have also discussed the problems surrounding life sciences DURC in the international arena, which poses additional challenges to controlling DURC from misuse. *See* American Association for the Advancement of Science, Proceedings from the Meeting on "Bridging Science and Security for Biological Research: International Science and Security" held at AAAS headquarters in Washington D.C. 4-5 Feb. 2013, http://www.aaas.org/cstsp/files/International-Science-and-Security-AAAS-AAU-APLU-FBI_2013.pdf. A discussion of the international implications of trying to control DURC is beyond the scope of this article, but the control of the spread of information about DURC internationally may trigger regulations

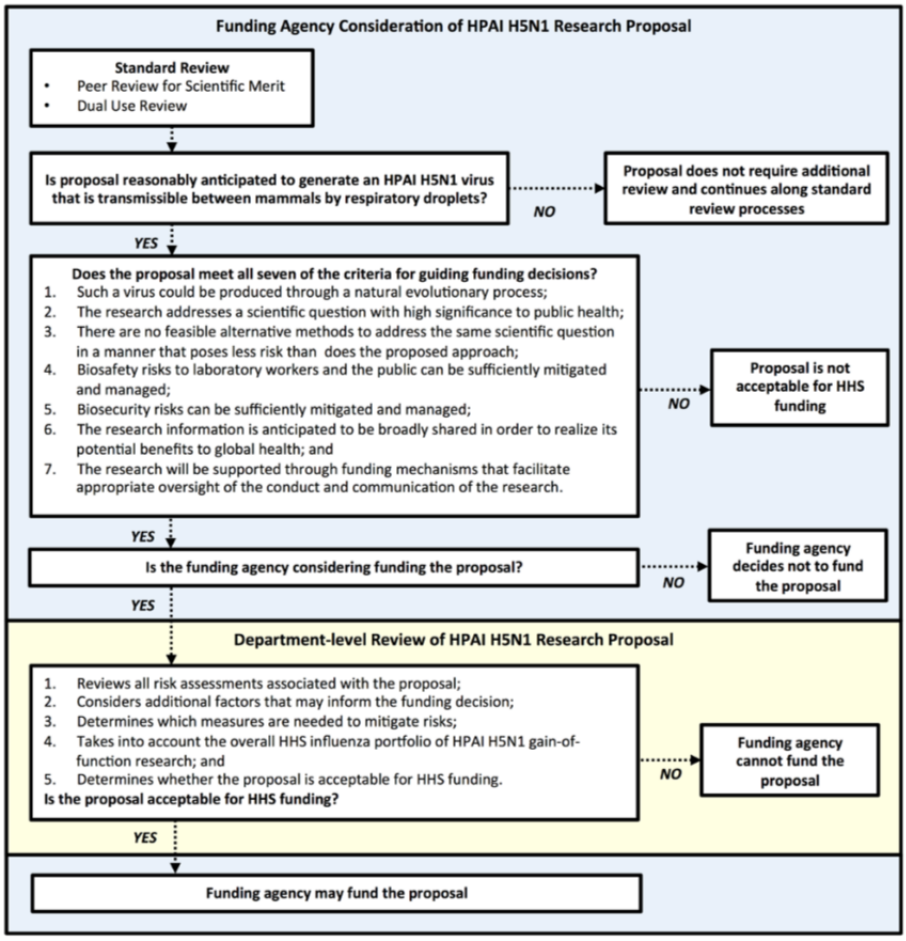
related to work with the select agents that are subject to the Dual Use Policy.[118] Finally, the report noted that expansion of the government's review of scientific research for DURC that is outside of the scope of the Dual Use Policy's 15 select agents might be prudent.[119]

### C. *A Framework for Guiding U.S. Department of Health and Human Services Funding Decisions with Regard to Avian Influenza H5N1 Research Proposals*

The first indication of how the U.S. will make future funding decisions for projects that implicate life sciences DURC since the avian influenza experiments appeared in guidelines recently issued by the U.S. Department of Health and Human Services (HHS).[120] The guidelines were published as *A Framework for Guiding U.S. Department of Health and Human Services Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets*[121] (Framework), and is designed to "ensure a robust review of research proposals prior to making a funding decision," taking into consideration all risks and benefits of the proposal.[122] Among the criteria the funding agency will use to determine funding are whether the research information is intended to be broadly shared in order to "realize its potential benefits to global health," and whether the research "will be supported through funding mechanisms that facilitate appropriate oversight of the conduct and communication of the research."[123] The complete funding agency consideration process is reproduced below:[124]

regarding export controls. Indeed, the avian influenza researchers had to receive permission under export control regulations to publish their papers. *See* Bridging Science, *supra* note 109, at 10.

118. Bridging Science, *supra* note 109, at 24.
119. *Id.*
120. *See* FRAMEWORK, *supra* note 101, at 2.
121. *See id.*
122. *Id.*
123. *Id.* at 5.
124. *Id.* at 4.




With regard to controlling communication of DURC, the Framework does very little to address the concerns regarding vagueness that were raised by the experts reviewing the Dual Use Policy. Instead, the funding criteria contains a vague statement that the funding mechanism must facilitate "appropriate oversight" of the communication of research, and explicitly states that HHS must consider each proposal on a case-by-case basis.[125]

The Framework also contemplates a departmental-level review to "consider proposals in the context of the entire HHS research portfolio" of avian influenza research.[126] At this level, HHS can determine whether the risks associated with the project are unjustified in light of other, similar

125. FRAMEWORK, *supra* note 101, at 3, 5.
126. *Id.* at 7.

research that HHS or other federal agencies currently support with funding.[127] If the department-level review determines that the proposal is unacceptable for HHS funding, the proposal is deemed ineligible for funding agency support.[128] The Framework does not contain any appeal mechanism for applicants denied funding outside of HHS.[129]

### *D. U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*

In order to enlist the cooperation and expertise of the institutions that actually conduct life sciences DURC, and perhaps to respond to some of the criticisms regarding the vagueness of the restrictions on communication and publication of DURC contained in the Dual Use Policy, the U.S. published the proposed *Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (Institutional Oversight Policy) in February 2013.[130] Unfortunately, the Institutional Oversight Policy raises more constitutional questions than it answers.

The Institutional Oversight Policy takes a holistic approach to life sciences DURC. Rather than view methodologies, products, technologies, or publication as separate steps in the process that are subject to separate criteria and controls, the Institutional Oversight Policy considers the entire course of research as a whole product.[131] This closely reflects the reality of how scientific research is conducted and communicated. The Institutional Oversight Policy includes an acknowledgement of the importance of "free and open conduct and communication of life sciences research" to the scientific enterprise and encourages continuation of such conduct and communication as a goal of both the government and the institutions engaged in the research.[132] The Institutional Oversight Policy sets forth an organizational framework for the institutional oversight process that places joint responsibility for reviewing projects that could implicate life sciences DURC on the principal investigator, the institution receiving federal funding, and the funding agency.[133] This process is set forth below:[134]

127. *Id*.

128. *Id*.

129. *See id*. (explaining that if applicants are denied, they may "resubmit their proposal during a future grant cycle).

130. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, 78 Fed. Reg. 12369-70 (Feb. 22, 2013).

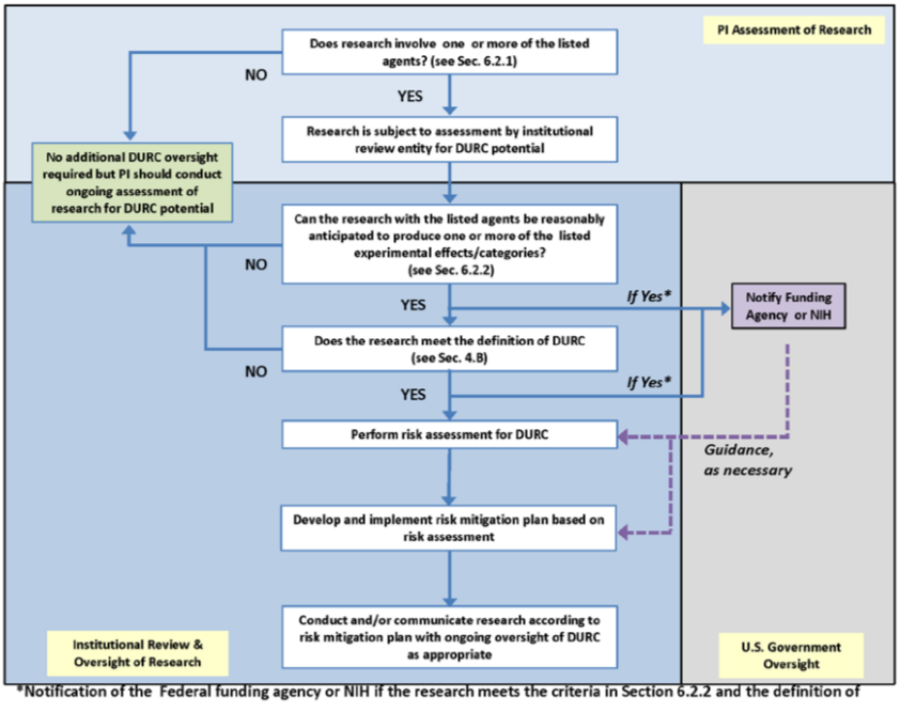
131. *See* OFF. SCI. & TECH. POLICY, *supra* note 1, at 3.

132. *Id.* at 5.

133. *Id.* at 8-9.

134. *Id.* at 9.

**Steps in the Institutional Review and Oversight of Dual Use Life Sciences Research**




*Notification of the Federal funding agency or NIH if the research meets the criteria in Section 6.2.2 and the definition of DURC in Section 4.B can be concurrent.

In addition, the Institutional Oversight Policy makes it clear that it is the responsibility of the principal investigators is "to communicate DURC in a responsible manner" while affirming that such communication "is an essential activity that occurs throughout the research process," not just at the point of publication.[135]

Perhaps the most interesting part of the Institutional Oversight Policy, from the standpoint of the constitutional implications of restrictions that might be included in a funding decision, or a risk mitigation plan that is required by the government in order to receive funding, is the application of the policy to "[i]nstitutions within the United States that receive federal funds to conduct or sponsor life sciences research, and conduct or sponsor research that is within the scope identified in Section 6.2, regardless of source of funding."[136] The government's justification for this broad application of the policy is that it "promotes more meaningful oversight of DURC at the institutional level and fosters uniform approaches to the

135. *Id.* at 9-10.

136. *Id.* at 6. The policy also applies to foreign institutions "that receive federal funds to conduct or sponsor research" that is covered under the scope of the policy. *Id.*

responsible conduct and communication of all research that may raise DURC concerns at an institution."[137]

Through this broad application of this policy, the government is placing a condition on the *recipient* of federal funds, not just on the *project* that is being federally funded. The U.S. Supreme Court has recently said that this type of leveraging of a restriction on a government spending program to apply to privately funded speech is impermissible, even when the restriction is relevant to the objectives of the federal program.[138] Even though this scope of restriction may be practical, in light of the fact that it is common for research money from both public and private sources to be pooled together to fund a single project, it squarely implicates the unconstitutional conditions doctrine as it has been applied in such pooling situations in the past.[139]

The obligation to engage in monitoring and risk mitigation continues beyond the initial funding stage. Failure to comply with the Institutional Oversight Policy may result in termination of federal funding or loss of future federal funding opportunities.[140] Therefore, it is "an ongoing condition on researchers' speech and activities," rather than solely a funding selection criterion.[141] The Supreme Court has held that restrictions on federal funding that go beyond selection criteria must be scrutinized closely to determine their true purpose.[142] Even in light of the case for ongoing review and monitoring of DURC, the government has a compelling purpose to require projects to be related to the scope of federally funded projects, but it is less

137. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, *supra* note 114, at 12372.

138. *See* Agency for Int'l Dev. v. Alliance for Open Soc'y Int'l, Inc., No. 12-10, slip op. at 8 (June 20, 2013) ("the relevant distinction that has emerged from our cases is between conditions that define the limits of the government spending program — those that specify the activities Congress wants to subsidize — and conditions that seek to leverage funding to regulate speech outside the contours of the program itself."). *See also* Bd. of Trs. of Stanford Univ. v. Sullivan, 773 F.Supp. 472, 476 (D.D.C. 1991) (explaining that the Court in *Rust* made a distinction between an individual's denial for benefits due to his own speech and the use of the public funds for the purposes intended.).

139. *See, e.g.*, Fed. Commc'ns Comm'n v. League of Women Voters of Cal., 468 U.S. 364, 399-401 (1984) (explaining that because restricted government funds could not be segregated from private funds being used for the same project, the restriction constituted impermissible leveraging of the federal funding to regulate private speech outside of the scope of the federally funded program). United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, 78 Fed. Reg. 12369-72 (Feb. 22, 2013).

140. OFF. SCI. & TECH. POLICY, *supra* note 1, at 6.

141. *Agency for Int'l Dev.*, No. 12-10, slip op. at 12.

142. *See* Rust v. Sullivan, 500 U.S. 173, 193, 196 (1991) (The challenged regulations were simply "designed to ensure that the limits of the federal program are observed," and "that public funds [are] spent for the purposes for which they were authorized.").

clear whether it can use its authority as leverage to monitor what is being done in privately funded programs.[143]

### *E. Additional Legal Complications in Protecting Government-Funded Materials*

It is difficult to walk the fine line between protecting DURC from misuse by crafting precise, viewpoint-neutral funding conditions that are limited to the scope of the actual federal program being funded, and those overbroad prior restraints on speech and expression that are likely to suppress ideas that the government considers "dangerous" and have an unacceptable chilling effect on protected speech, even without any additional complicating factors. This would be true even in the absence of any additional complicating factors. The availability to the public of tools like the Freedom of Information Act (FOIA) and state open records laws, which can be used to access risk assessments of DURC that could provide enough information to facilitate misuse of DURC, makes it even more difficult to control DURC in order to prevent misuse.[144] The culture of openness of public records is not only limited to FOIA and state open records laws. On the same day that the federal government issued the Institutional Oversight Policy for comment, it also issued a policy "direct[ing] each Federal agenc[ies] with over $100 million in annual . . . research and development expenditures to develop a plan to support increased public access to the results of research funded by the Federal Government."[145] Although national security should be considered when developing such a plan, the policy of the Obama administration is clearly turned towards greater transparency of federally funded materials as compared to some prior administrations; thus, complicating the efforts the administration is making to protect DURC from misuse.[146]

## IV. PROTECTING GOVERNMENT FUNDED DURC FROM MISUSE WHILE PRESERVING FREEDOM OF EXPRESSION IN SCIENTIFIC RESEARCH

Inevitably, there are trade-offs between open dialogue and national security when we consider whether and how to restrict communication of DURC. This is true whether we are talking about communication between researchers within the contours of a particular project, communication of

143. *Bd. of Trs. of Stanford Univ.*, 773 F. Supp. at 475.

144. *See* Bridging Science, *supra* note 109, at 24.

145. Memorandum from John P. Holdren, Dir., to Heads of Exec. Dep'ts and Agencies 2 (Feb. 22, 2013).

146. *See id.* at 2-3; Jacobs, *supra* note 111, at 120 (discussing differences between the Clinton and Bush administrations in how they treat responses to FOIA requests for information that might be considered sensitive with regard to homeland security).

research results in an academic setting, or formal publication of research in peer-reviewed journals. In today's world of nearly instantaneous communication via the Internet, WikiLeaks, and Twitter, any action to restrict communication of DURC, even formal classification of research, is bound to be imperfect.[147] Furthermore, classification of life sciences DURC will have an inevitable chilling effect on researchers' willingness to engage in such research.[148] Because life sciences DURC is by its very nature an international endeavor, all that a high degree of secrecy is likely to accomplish is a relocation of this important work to locations outside of the U.S. and a turn towards private funding sources where the government will have virtually no control over the research nor any ability to use its results to react to a public health or national security threat presented by DURC.[149] In addition, with regard to naturally occurring pathogens such as the avian influenza virus, the U.S. is heavily dependent on cooperation from other countries to supply American researchers with samples of the pathogens. If the research results could not be shared between these governments and the foreign researchers that are supplying the pathogens for the research, it is most likely that foreign entities will stop supplying the U.S. with such pathogens. Secrecy is also anathema to the scientific endeavor and the nature of life sciences research, which has always relied on the free inflow and outflow of information and results to build upon prior work and to serve the greater good.[150]

Life sciences DURC presents a *perfect storm* for the application of the doctrine of unconstitutional conditions in the context of government funding. Virtually every factor that the courts have said must be considered when applying the doctrine and do complicate the analysis in the typical life sciences DURC case. These factors include the following: it typically takes place in a traditional forum for the free and open exchange of ideas, restrictions placed on communications tend to be vague and imprecise

147. Even classified information can be leaked or transmitted to those who might seek to misuse it to our detriment. Consider the current case of Edward Snowden, the National Security Agency contractor accused of leaking top-secret, classified information about a government surveillance program to Wikileaks. *See, e.g.*, Jim Heintz, *Edward Snowden Has Entered Russia, Lawyer Says*, THE HUFFINGTON POST, Sept. 4, 2013, http://www.huffingtonpost.com/2013/08/01/edward-snowden-russia_n_3688225.html.

148. *See* Bridging Science, *supra* note 109, at 22 (stating that there has already been a chilling effect on scientists researching with select agents because of "overly restrictive policies").

149. With regard to privately funded DURC within the United States, it is likely that any such research is being conducted for ultimate commercial gain. Williams, *supra* note 85, at 374. Therefore, it may be possible to control the conduct and communication of such research through the use of the patent law. *Id.*

150. *See* McDonald, *supra* note 61, at 1021.

because of the uncertainty of the results of the research, there is a serious need for international cooperation and openness in order to conduct the research, and government-funded research is usually not segregable from privately funded research.[151] It is also virtually impossible to restrict only the program, rather than a recipient of the funding because of the nature of the scientific endeavor. On the other hand, the risk of harm if life sciences DURC is misused could not be greater, as it could threaten the very survival of the human species. Given the high stakes involved, what is the best course for us to take?

Prior case law suggests that considering potential danger of misuse at the point of making a funding decision for a competitive grant is more likely to pass constitutional muster than attempts to restrict communication of information once the research is underway.[152] Therefore, including an assessment for the potential for a proposed project to produce DURC and its misuse in funding criteria for a grant, and then using the results of the assessment in making a funding decision is the preferred methodology for controlling misuse. From a practical standpoint, it will be virtually impossible to restrict communications that take place between researchers while they carry out the research, although background checks and guidelines for communications carried out while actually working on the government-funded projects are certainly available and desirable.

Restrictions on DURC imposed at the funding stage are much more likely to be characterized as a permissible means of ensuring that government funds are used for their intended purpose than as a prohibited unconstitutional condition on a government benefit.[153] The difficulty that the government will face is in appropriately characterizing conditions on the receipt of the funds in a manner that is constitutionally acceptable and sufficiently specific. Risk mitigation plans that require research results to be subject to government pre-publication review or be redacted prior to publication in a peer-reviewed journal would most likely be considered classic prior restraints. Prior restraints are the most disfavored type of restraint on speech, permitted "only in exceptional cases."[154] In addition, attempts to censor or block publication based on a pre-publication review by the funding agency will, by necessity, be content-based rather than content-neutral. Thus, they would most likely trigger a heightened level of scrutiny by a court to ensure that the restriction is narrowly tailored to avert the feared danger and that there is no better or less restrictive way to

151. *See* Keane, *supra* note 9, at 520, 532; *See* McDonald, *supra* note 61, at 1022.

152. Rust v. Sullivan, 500 U.S. 173, 193, 198 (1991).

153. *Id.* at 198.

154. Bd. of Trs. of Stanford Univ. v. Sullivan, 773 F.Supp. 472, 474 (D.D.C. 1991) (quoting Near v. Minnesota, 283 U.S. 697, 716 (1931).

achieve the same purpose.[155] The government would be required to explain the danger in some detail and to convince a court that it had a "compelling interest" in preventing publication of the material.[156] This need to explain the danger, in and of itself, could provide more information to those who would seek to misuse DURC than the government is comfortable revealing.[157]

Therefore, the government is left with three basic approaches to controlling DURC without triggering the doctrine of unconstitutional conditions. The first approach is to not conduct the DURC at all or ban certain types of experiments or procedures that are most likely to produce DURC that could be misused. This is a choice that governments make when proposed research presents a clear moral dilemma and a less clear physical danger, such as proposals for certain stem cell research or certain types of cloning.[158] This approach is likely to be constitutionally sound, but may put the U.S. at a disadvantage as compared to other nations that are less concerned about DURC or have fewer legal protections on speech and expression.[159] In addition, most life sciences DURC consists of basic research, rather than applied research.[160] Basic research, which is not directed towards producing a specific product or addressing a specific need, is more likely to lead to broad-reaching discoveries that can then be used in applied research to develop solutions to specific problems.[161] A ban on basic research could hobble American scientific and engineering innovation, putting the U.S. at a competitive disadvantage for years to come.

The second approach that the government could take is to classify all DURC and criminalize the unauthorized communication of DURC. This is

155. *See* McDonald, *supra* note 61, at 1025-27.

156. *Id.* at 1013-14.

157. *Id.* at 1025. Although the government could request an *in camera* examination of evidence, or request that the record be sealed, the more people who have knowledge of the potentially dangerous information, the more likely it is that the information will be leaked or inadvertently revealed.

158. *See, e.g.*, Keane, *supra* note 9, at 516-18; McDonald, *supra* note 61, at 1018, 1024.

159. Brazil, China, India, South Korea, and Singapore are among the many countries expanding their biological research capacity and workforce. NATIONAL SCIENCE FOUNDATION, SCIENCE AND ENGINEERING INDICATORS O-7, O-8 (2012), *available at* http://www.nsf.gov/statistics/seind12/figures_tn1.htm (last visited August 5, 2013).

160. Basic research is defined as "systematic study directed toward fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind." Applied research is defined as "systematic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met." NATIONAL SCIENCE FOUNDATION, OFFICE OF MANAGEMENT AND BUDGET CIRCULAR A-11, *available at* http://www.nsf.gov/statistics/randdef/fedgov.cfm (last visited August 5, 2013).

161. *Id.*

the approach that the government has taken with atomic energy research and nuclear weapons development.[162] This would require a sea change in the culture of life sciences research, which has traditionally been carried out by researchers in academic institutions with a goal of open flow of inputs and outputs, publication, and broad dissemination of results.[163] Although this approach is likely to be constitutionally acceptable, we are likely to lose a whole generation of research and researchers while those who are uncomfortable with, unwilling, or unable to work in a classified environment leave the industry and new personnel are trained. Furthermore, while the government's position is that wide dissemination of information concerning nuclear weapons research is not in the public interest or in the interest of national security,[164] its position regarding dissemination of life sciences research that could constitute DURC is far less clear. Life sciences DURC can be used to better the public health on an international scale, and broad dissemination of the results of DURC, if not misused, may enhance national security if they are used to stop a pandemic or to produce a vaccine that can be used worldwide. Although classification of life sciences DURC would minimize the likelihood that DURC will be misused, it is not the preferred method of controlling misuse.

Finally, the government can continue to fund DURC through competitive grant making and can use funding conditions to "ensure that th[ose] funds are properly applied to the prescribed use."[165] However, merely calling a condition on grant funding a definition of the program will not necessarily insulate the condition from a challenge to its constitutionality.[166] The courts will look to its overall effect, beyond the label placed on the condition by the government.[167] A condition that reaches beyond the federally funded project and restricts what the grantee can do or say when working on other projects is likely to be invalidated.[168] Likewise, conditions that restrict the grantee's

162. *See id.* at 1022.

163. *See id.* at 1022-23 (explaining that "a researcher desiring . . . information . . . would be barred from acquiring it without government authorization, even from another researcher who would have been willing to share it absent such restrictions.").

164. *See id.* at 1023.

165. Rust v. Sullivan, 500 U.S. 173, 195, n.4 (1991). These funding conditions can be combined with current restrictions on the availability of dangerous materials and greater scrutiny of those who work with such materials to ensure greater national security. *See* CENTERS FOR DISEASE CONTROL AND PREVENTION: OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE, CDC SELECT AGENT PROGRAM (2008), *available at* http://www.cdc.gov/phpr/documents/DSAT_brochure_July2011.pdf.

166. Legal Servs. Corp. v. Velazquez, 531 U.S. 533, 547 (2001).

167. *See* Agency for Int'l Dev. v. Alliance for Open Soc'y Int'l, Inc., No. 12-10, slip op. at 8, 11 (June 20, 2013).

168. *See id.* at 12.

work or communications on projects where federal funds are mixed with private funds restrict recipients, not programs, and are likely to be susceptible to a constitutional challenge.[169] Therefore, a restriction placed on communications of DURC that is part of a risk mitigation plan put in place to comply with the current draft of the Institutional Oversight Policy is likely to be vulnerable to constitutional challenge,[170] because the current draft of the policy places oversight requirements on non-federally funded research as a condition of receiving federal funds.[171]

Beyond these broad guidelines, when it comes to distinguishing "between conditions that define a federal program and those that reach outside it,"[172] we will have to review specific risk mitigation plans on a case-by-case basis to determine the constitutionality of the plan.

## V. CONCLUSION

Life sciences DURC presents unparalleled opportunities for enhancements to public health and national security, as well as unparalleled possibilities for national and global disaster. Trying to ensure that we reap the benefits of such research without unleashing catastrophe also presents difficult challenges to preservation of our fundamental freedoms of expression. In a global environment, conducting all such research in secret or banning the conduct of life sciences DURC is not wise or practical, and might actually produce the bad effect that we would be trying to avoid.

Because the government is a major financial sponsor of life sciences DURC, one would assume that the government can control the conduct and dissemination of such research. But the doctrine of unconstitutional conditions limits what restrictions the government can place on protected expressive conduct, especially when the government's intent is to suppress ideas that can be dangerous. Although the government is permitted to place conditions on research that define the scope of the funded project, it is not permitted to leverage those restrictions to control speech or expression outside of the scope of the project. In the context of science and scientific communication, it is particularly difficult to segregate conduct that takes place within the scope of the federally funded project from conduct that is

169. *See* Fed. Commc'ns Comm'n v. League of Women Voters of Cal., 468 U.S. 364, 400 (1984); *Rust*, 500 U.S. at 180 (noting that the federally funded program subject to the restriction on speech was required by regulation to be "physically and financially separate" from other projects that engaged in the prohibited activities).

170. *See* OFF. SCI. & TECH. POLICY, *supra* note 1, at 10.

171. *See id.* at 12.

172. "Definition more precise must abide the wisdom of the future." *Agency for Int'l Dev.*, No. 12-10, slip op. at 11 (quoting Steward Machine Co. v. Davis, 301 U.S. 548, 591 (1937)).

outside of the scope of the project. The very nature of the scientific endeavor, academic freedom, and the culture of life sciences research work against the ability to make such distinctions.

Therefore, a mix of voluntary policing by the scientific community, coupled with carefully crafted definitions that limit the scope of federally funded life sciences research that is likely to produce DURC, is the more appropriate means of protection. This is the course that the government is currently on and should continue to pursue. Project scope definitions should avoid outright restrictions on publication or communication of research to avoid triggering the doctrine of unconstitutional conditions. Limits placed on each funded project should be reviewed on a case-by-case basis to ensure that the government is not seeking to leverage its funding to regulate expression outside of the contours of the funded program itself.

History tells us that:

> Every major technology — metallurgy, explosives, internal combustion, aviation, electronics, nuclear energy — has been intensively exploited, not only for peaceful purposes but also for hostile ones. Must this also happen with biotechnology, certain to be the dominant technology of the coming [21st] century?[173]

As government policy on life sciences DURC continues to evolve with the science, experts will need to continue their vigilance to protect public health, national security, and our fundamental freedoms, even when these interests seem on first glance to be mutually incompatible. This work will not be easy, but it is vitally important to preserving a robust scientific community, our fundamental freedoms of expression, and our health, national, and personal security.

173. BRIDGING SCIENCE AND SECURITY FOR BIOLOGICAL RESEARCH, INTERNATIONAL SCIENCE AND SECURITY 5 (Feb. 4-5 2013), *available at* http://www.aaas.org/cstsp/files/International-Science-and-Security-AAAS-AAU-APLU-FBI_2013.pdf (quoting Matthew Meselson).