1/20/17 Revision

The Role of Export Controls in Regulating Dual Use Research of Concern: Striking a Balance between Freedom of Fundamental Research and National Security

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January 20, 2017

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Policymakers struggle with how best to regulate the dissemination of life sciences research that could, if used by malevolent actors, pose substantial biosecurity and bioterrorism concerns. Those grappling with this subset of research — referred to as "dual use research of concern" ("DURC") — have been challenged to strike an appropriate balance between unhindered scientific research and national security. Finding this balance is complicated by the fact that unrestricted release of scientific research on dangerous substances can provide the means for the research community to advance science in many ways, including by the development of cures or defenses against pathogens. However, such disseminated research or data also can be subverted by ill-intentioned actors bent on spreading disease to harm human, animal, and plant life.

This paper aims to frame policy discussions surrounding the use of the U.S. export control system as an effective tool through which to regulate DURC. The paper begins with an overview of the relevant national security directive and current DURC policies, and then it describes key provisions of U.S. export controls that regulate pathogens and toxins and the dissemination of related research. The paper concludes by considering the potential role of export controls in the context of DURC, highlighting challenges associated with reliance on this regulatory framework to limit the dissemination of information arising from DURC. As addressed in this paper, these challenges stem from export control rules themselves and from the U.S. Constitution, as well as from practical and operational realities associated with biosciences research.

I. NSDD-189 and DURC Policies: Shaping U.S. Export Controls

A. NSDD-189

The Cold War era gave rise to a bipolar trade system in which the Western and Eastern blocs vied to prevent one another from developing qualitative military edges and technological supremacy. At the same time, the U.S. government recognized the value of affording researchers the freedom to advance science through, for example, unrestricted domestic and cross-border communication and collaboration. The topic spurred national debate, leading to several studies commissioned from the National Academy of Sciences and, ultimately, to National Security Decision Directive-189 ("NSDD-189"), issued in 1985 by President Reagan. NSDD-189 established that as a matter of U.S. policy, unless otherwise controlled by statute, "fundamental research," the results of which are ordinarily shared broadly within the scientific community, that is produced through federally funded programs or at institutions supported by federal funds would, to the maximum extent possible, remain unrestricted.[1] When national security interests

[1] National Security Decision Directive 189, *National Policy on the Transfer of Scientific, Technical and Engineering Information*, Sept. 21, 1985 ("NSDD-189") (defining "fundamental research" as "basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons").

require control, NSDD-189 provides that the mechanism available to the government is classification of the data.

The approach expressed in NSDD-189 has remained a fixture of contemporary export control laws, which quote the directive almost verbatim, and serves as a central touchstone in the ongoing DURC debate.

B. 2012 and 2014 DURC Policies

Like NSDD-189, the DURC framework, embodied in a regulatory policy published in 2012 and in a more robust, supplemental policy in 2014, applies exclusively to research that is conducted or funded by the U.S. government or at institutions supported by government funding.[2] These policies are further narrowed by applying to research involving only 15 high-impact biological agents and toxins,[3] for which research produces, aims to produce, or can be reasonably anticipated to produce any of seven specifically designated results that enhance the danger of these agents.[4] The policies currently apply only to the categories described above, and call for voluntary acceptance and implementation by privately funded researchers and by those working on different pathogens. The Government has stated that the policies could be expanded in scope in the future, but it has not done so to date.[5]

When the policies do apply, research institutions are required to develop risk mitigation plans and present them for approval to the relevant U.S. government funding agency. Non-

[2] *See* U.S. Dept. of Health & Human Services, Public Health Emergency, Science Safety Security, *U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern* (March 29, 2012) ("2012 DURC Policy"), https://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf. DURC is defined as "life sciences 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."

[3] *See* 2012 DURC Policy at Section III.1 and U.S. Dept. of Health & Human Services, Public Health Emergency, Science Safety Security, *U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, Section 6.2.1 (effective date Sept. 24, 2015) ("2014 DURC Policy"), https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf (listing the following 15 pathogens: avian influenza virus (highly pathogenic), bacillus anthracis, botulinum neurotoxin, burkholderia mallei, burkholderia pseudomallei, ebola virus, foot-and-mouth disease virus, francisella tularensis, Marburg virus, reconstructed 1918 Influenza virus, Rinderpest virus, toxin-producing strains of Clostridium botulinum, variola major virus, variola minor virus, and yersinia pestis).

[4] *See* 2012 DURC Policy at Section III.2 and 2014 DURC Policy at Section 6.2.2 (listing the seven categories of experiments as follows: "(a) Enhances the harmful consequences of the agent or toxin; (b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification; (c) Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies; (d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin; (e) Alters the host range or tropism of the agent or toxin; (f) Enhances the susceptibility of a host population to the agent or toxin; or (g) Generates or reconstitutes an eradicated or extinct agent or toxin listed [as one of the 15 designated agents]").

[5] *See* 2012 DURC Policy at Section II and 2014 DURC Policy at Section 1 (clarifying that the policies would be updated as necessary "following domestic dialogue, engagement with international partners, and input from interested communities including scientists, national security officials, and global health specialists").

compliance with the plans could jeopardize continued U.S. government funding, but does not result in civil or criminal penalties.

For those seeking greater control over DURC, the limited scope of these policies may increase motivations to look to export controls as a viable regulatory net to cast over a broader spectrum of DURC research activities. Indeed, the DURC policies themselves emphasize that export controls may regulate research and publication activities well beyond the confines of the policies.[6]

II. U.S. Export Controls as Relevant to DURC

To support national security and foreign policy objectives, and pursuant to international agreements, the U.S. government regulates the export, as well as subsequent reexport or retransfer abroad,[7] of a broad range of items through a comprehensive system of export controls administered by the Departments of State and Commerce. The State Department's Directorate of Defense Trade Controls ("DDTC") administers the International Traffic in Arms Regulations ("ITAR"), which regulate trade in defense articles and defense services. The Commerce Department's Bureau of Industry and Security ("BIS") administers controls in the Export Administration Regulations ("EAR") over "dual use" commodities, software, and technology (items with both civil and weapons or proliferation-related applications), as well as various commercial and less-sensitive defense items.[8]

These controls apply to, among many other items, an array of toxicological agents, including the 15 pathogens identified in the DURC policies, as well as related technology/technical data and software. Criminal and civil penalties for violations of the regulations can be severe,[9] and have been enforced in the research context.[10]

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[6] 2014 DURC Policy at Section 1.

[7] A reexport in the context of U.S. export controls refers to a movement of an item from one country to another, after the item has left the United States. A retransfer (also called an "in-country transfer") is a change in the end use or end user of the item in a foreign country after it has left the United States.

[8] Note that the term "dual use" in the DURC context is not intended to indicate which export control regulations control these items. Some DURC items could be controlled not by the EAR (which regulate dual use items), but by the ITAR.

[9] *See* Export Administration Act, 50 App. U.S.C. § 2401 et seq., and its current implementing legislation under 50 U.S.C. §§1701 - 1706 (providing, in the context of the EAR, criminal penalties of up to 20 years imprisonment and $1 million per violation, administrative monetary penalties up to the greater of $289,238 per violation or twice the value of the non-compliant transaction (whichever is higher), seizure and forfeiture of the items involved, and denial of export privileges); 22 U.S.C. §§2778, 2779a, and 2780 (providing, in the context of the ITAR, criminal penalties of up to 20 years imprisonment and $1 million per violation, administrative monetary penalties up to $1.094 million, seizure and forfeiture of the items involved, and denial of trade privileges through statutory and administrative debarment).

[10] *See* Press Release, U.S. Attorney's Office for the Eastern District of Tennessee, Former Univ. of TN Prof. Begins Serving Four-Year Prison Sentence on Convictions of Illegally Exporting Military Research Data (Feb. 1, 2012) (announcing that a former University of Tennessee professor had been convicted and imprisoned for releasing ITAR-controlled technical data to foreign students at university research laboratories and after the students had returned to their respective countries); *see also* Matter of Microwave Engineering Corporation, Respondent, Entered June 20, 2016 (confirming respondent's consent agreement with the Department of State under which respondent

(continued…)

The reach of both regulatory regimes is broad, and embraces both items exported from the United States, as well as reexports and retransfers abroad of U.S.-origin items and, in some cases, foreign items with controlled U.S.-origin content. In the case of the ITAR, even a minute amount of U.S. content incorporated into a foreign-made item or incorporated into foreign-origin technical data generally renders the foreign item or data subject to the ITAR. Further, the ITAR control foreign items manufactured from ITAR-controlled technical data or defense services. In the context of the EAR, controls may apply to foreign products or data with more than *de minimis* controlled EAR content, or which are produced from sensitive U.S.-origin data or are the direct product of complete plants (e.g., production or manufacturing facilities) or major components of plants that have been developed from such sensitive data. Both the EAR and ITAR also control "deemed exports," which include transfers of controlled data in the United States to a foreign person (i.e., an individual who is not a U.S. citizen or U.S. lawful permanent resident), and "deemed reexports," which include transfers outside the United States of controlled data to foreign persons who are nationals of countries other than the country where the release or transfer takes place.

While the EAR and ITAR vary slightly in the way they control technology/technical data, each generally aims to assert controls over information required for the development, production, or use of controlled items. For example, just as controlled pathogens being delivered from the United States to a foreign laboratory would be subject to U.S. export controls, so too would the exchange of certain information relating to those pathogens between U.S. and foreign researchers, absent an exemption or carve-out of controls (discussed below).

With respect to technology controls, the EAR are narrower in scope than the ITAR. The ITAR control all information required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance, or modification of defense articles enumerated on the ITAR's U.S. Munitions List ("USML"), and also control defense services, a broadly defined concept embracing assistance to foreign persons with respect to U.S. or foreign defense articles (even when no technical data is exchanged). The EAR generally control technology for the development, production, or use of items controlled on the EAR's Commerce Control List ("CCL"). Both exclude from such controls non-technical marketing materials, general descriptions related to a product's function or purpose, and general scientific, mathematical, or engineering principles commonly taught to students enrolled at academic institutions.

Further, in keeping with NSDD-189, neither the ITAR nor the EAR asserts control over the dissemination of certain forms of publicly available information, which includes the results of "fundamental research." These limits on the application of U.S. export controls to results of fundamental research are central to any discussion on DURC and are a direct reflection of NSDD-189 and its continued effect of preserving open science in the face of national security concerns.

agreed to pay $100,000 in civil penalties for a single incident of releasing controlled technical data under the ITAR to a foreign employee working in respondent's office in Massachusetts).

A. The ITAR and Bioweapons

1. Recent Revisions to the ITAR's Biological Toxins Category

Prior to December 31, 2016, Category XIV of the ITAR's USML controlled all "[b]iological agents and biologically derived substances specifically developed, configured, adapted, or modified for the purpose of increasing their capability to produce casualties in humans or livestock, degrade equipment or damage crops," as well as related technical data and defense services.[11] However, effective December 31, 2016, this language has been replaced, clarifying that the ITAR control only the most highly sensitive pathogens that have been effectively weaponized through gain-of-function intervention.[12] Other pathogens subject to U.S. export controls would be regulated by the EAR.

The changes are part of a broad multi-year export control reform effort that has been reshaping the USML and CCL, aimed at imposing the tightest controls on the most sensitive items. In addition, the revisions reflect Presidential Executive Order 13546 of 2010, entitled "Optimizing the Security of Biological Select Agents and Toxins in the United States." Grappling with classic DURC tensions, this Executive Order recognizes that a "robust and productive scientific enterprise that utilizes biological select agents and toxins" is "essential to both public health and national security," but that, at the same time, such an enterprise poses risks of the agents and toxins being *"*lost, stolen, or diverted for malicious purposes.*"*[13]

The revised USML controls begin by enumerating 12 "Tier 1" pathogens, referring to those pathogens designated by the Departments of Health and Human Services and Agriculture as agents "presenting the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence," and which "pose a severe threat to public health and safety."[14] Each of these 12 "Tier 1" agents are listed in the 2012 and 2014 DURC policies.[15]

These "Tier 1" agents, along with their derived substances and related technical data, will be subject to the strict controls of the ITAR if two conditions are met. First, the agents must take the form of "[g]enetically modified biological agents…[b]eing any micro-organisms/toxins or

[11] 22 C.F.R. §121.1, Category XIV(b), (m).
[12] Dept. of State, Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII, 81 Fed. Reg. 49,531, 49,532 (July 28, 2016) (to be codified at 22 C.F.R. pt. 121) (clarifying that the revised controls capture the same biological agents and biologically derived substances that were previously subject to the more broadly framed control).
[13] Exec. Order No. 13546, 75 Fed. Reg. 39,439 (July 2, 2010).
[14] U.S. Federal Select Agent Program, General FAQ's About Select Agents and Toxins, at FAQ No. 6, https://www.selectagents.gov/faq-general.html.
[15] Of the 15 agents listed in the 2012 and 2014 DURC Policies, the revised USML Category XIV(b) omits the avian and reconstructed 1918 influenza viruses. The USML also designates "Botulinum neurotoxin producing species of Clostridium," as opposed to the two separate listings in the 2012 and 2014 DURC policies of "Botulinum neurotoxin" and "Toxin-producing strains of Clostridium botulinum."

their non-naturally occurring genetic elements."[16] Second, the modifications must be known or reasonably expected to result in gain-of-function characteristics that increase either their "[p]ersistence in a field environment (i.e., resistance to oxygen, UV damage, temperature extremes, arid conditions, or decontamination processes)," or their "ability to defeat or overcome standard detection methods, personnel protection, natural or acquired host immunity, host immune response, or response to standard medical countermeasures."[17]

In addition, revised USML Category XIV now controls many of the pathogens designated in the EAR's CCL, including all of the 15 DURC pathogens, if they are physically modified, formulated, or produced in any of four enumerated ways and, in addition, are known or can reasonably be expected to lead to particular gain-of-function characteristics that increase their harmfulness (such as by increasing resistance to immunities, modifying dispersal characteristics, or in other listed ways).[18]

Equipment specially designed for the dissemination and dispersion of these biological agents is similarly ITAR-controlled, as is equipment specially designed under a Department of Defense contract to test these agents. Revised Category XIV(f)(2) now also includes "[a]ny equipment, containing reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under a Department of Defense contract or other [Department of Defense] funding authorization, for the detection, identification, warning, or monitoring of" either the particular agents enumerated above or any other agent specified in the relevant Department of Defense contract, grant, or other funding authorization.[19]

The Category XIV(f)(2) equipment and related items referenced in the preceding paragraph become ITAR-controlled regardless of the percentage of Department of Defense funding.[20] By contrast, certain vaccines, antibodies, and other items become subject to the ITAR only if they were funded exclusively by the Department of Defense. Specifically, vaccines developed exclusively through funds provided by the Department of Defense that are specially designed for the sole purpose of protecting against Category XIV biological agents and their biologically derived substances are ITAR-controlled, as are three other Department of Defense

[16] *See* Amendment to ITAR, 81 Fed. Reg. at 49,536 (explaining in a regulatory note to the revised USML that the term "non-naturally occurring" is defined to mean "that the modification has not already been observed in nature, was not discovered from samples obtained from nature, and was developed with human intervention").
[17] *Id.* at 49,536.
[18] *Id.* (listing CCL-controlled agents governed by the ITAR, if they are "[p]hysically modified, formulated, or produced as any of the following: (A) 1–10 micron particle size; (B) Particle-absorbed or combined with nano-particles; (C) Having coatings/surfactants, or (D) By microencapsulation," provided these agents are known to or reasonably expected to "result in an increase in any of the following : (A) Persistence in a field environment (i.e., resistant to oxygen, UV damage, temperature extremes, arid conditions, or decontamination processes); (B) Dispersal characteristics (e.g., reduced susceptibility to shear forces, optimized electrostatic charges); or (C) The ability to defeat or overcome: standard detection methods, personnel protection, natural or acquired host immunity, or response to standard medical countermeasures").
[19] *Id.*
[20] *Id.* at 49,534 (explaining that when ITAR Category XIV does not require "exclusive funding by the Department of Defense…there is no *de minimis* funding level that triggers control…" and further articulating the State Department's view that "the exclusive [Department of Defense] funding requirement narrows the range [of control] to an appropriate level").

funded vaccines (recombinant botulinum toxin A/B vaccine, recombinant plague vaccine, and trivalent filovirus vaccine).[21] With respect to the genetically modified Tier 1 agents, even when they are naturally occurring, exclusive Department of Defense funding will trigger ITAR control for related antibodies, recombinant protective antigens, polynucleotides, biopolymers, or biocatalysts (including their expression vectors, viruses, plasmids, or cultures of specific cells modified to produce them).[22]

Defense articles and defense services controlled by the ITAR require State Department authorization to all destinations, for all end uses. While the ITAR contain some license exemptions (for example, providing avenues for license-free trade with key allies of Canada, Australia, and the United Kingdom, subject to many conditions), these exemptions are few and narrow. In addition, indicative of the ITAR's tight web of controls over defense articles and defense services, the ITAR also control temporary exports from and temporary imports into the United States of defense articles, and brokering of regulated items, as well as requiring U.S. manufacturers of controlled items to register with the State Department, even if they do not export the regulated items.

2. Related ITAR Technical Data Controls and Carve-Outs from Control

Although a degree of relief can be found in provisions that exclude ITAR control over public domain information, these provisions have been narrowly construed by the Department of State.

ITAR controls do not extend to information in the public domain, which is defined to include information that is published and generally accessible or available to the public through: (i) sales at newsstands and bookstores; (ii) generally available subscription services; (iii) periodicals' mailing privileges; (iv) libraries open to the public; (v) patent filings available at any patent office; (vi) unlimited distribution at conferences, meetings, seminars, trade shows, or exhibitions, generally accessible to the public, in the United States; (vii) government-approved public releases; or (viii) certain forms of fundamental research at accredited institutions of higher learning in the United States.[23] When unclassified technical data that would otherwise be subject to control under the ITAR meets any of these criteria, it is considered in the public domain and therefore beyond the scope of controls of the ITAR.

The eighth and final subsection of the ITAR's public-domain information carve out, which exempts limited forms of fundamental research, is the ITAR's encapsulation of NSDD-189. For the fundamental research provision to apply, however, the information must be shared broadly in the scientific community, which, as per the regulations, would not be the case if the researcher or university accept restrictions on publication or if the subject of the research is

[21] *Id.* at 49,538; *see id.* at 49,538 (controlling also all modeling and simulation tools, including certain software, "for chemical or biological weapons design, development, or employment developed or produced under a Department of Defense contract or other funding authorization . . . ").
[22] *Id.* at 49,537 (controlling also various reagents, including several reagents under the Joint Biological Agent Identification and Diagnostic System).
[23] 22 C.F.R. §120.11(a)(1)-(8).

government-funded and subject to access and dissemination controls.[24] The research also must be produced at an "accredited institution[] of higher learning in the U.S." for it to be categorized as fundamental research under the ITAR. Accordingly, fundamental research relating to an ITAR-controlled defense article generated in the United States outside the auspices of an accredited institution of higher learning would be regulated by the ITAR unless it fits into one of the other carve-outs or exclusions from ITAR control.

The State Department has taken the position that the eight categories of "public domain" information are exhaustive, with information publicly disseminated in other ways remaining subject to the ITAR. This position was reiterated in September 2016, when a federal appeals court ruled that the Department of State, through the ITAR, could deny a U.S. citizen the ability to share privately-generated, unclassified information with the public through the Internet. The information at issue was a computer-aided-design file of a gun that would allow anyone to produce firearms using commercially available 3-D printers. In a 2-1 ruling, the court sided with the State Department, determining that the government's "exceptionally strong interest in national defense and national security outweighs Plaintiff['s] very strong constitutional rights under these circumstances." The court accepted the State Department's position that the ITAR's public domain exception was not available because the intangible and informal mode of dissemination of the computer file had failed to correspond to any of the ITAR's eight enumerated public domain provisions; had the data been published in materials available at a public library or newsstand, instead of the Internet, the ITAR public domain provision likely would have applied. The majority decision prompted a vigorous dissent that, based on First Amendment considerations, would have permitted dissemination without prior State Department authorization.

It might seem arbitrary in today's era to distinguish publication in materials available at brick-and-mortar institutions (such as libraries or newsstands) from publication through the Internet. However, even if the ITAR afforded more flexibility regarding acceptable modes of dissemination of information in the public domain, applying the ITAR, and export controls more generally, to fundamental biosciences research remains challenging, as discussed further in Part III.

B. EAR Controls on Biological Materials and Related Research

1. Biological Agents and Toxins and Related Technology Controls

Because the ITAR cover only a narrow swath of DURC research, the EAR, as opposed to the ITAR, are the more likely regulatory system to affect life sciences researchers.[25]

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[24] *Id*. at §120.11(a)(8)(i)-(ii) (providing that the fundamental research exclusion will not apply to university research if "(i) The University or its researchers accept other restrictions on publication of scientific and technical information resulting from the project or activity, or (ii) The research is funded by the U.S. Government and specific access and dissemination controls protecting information resulting from the research are applicable").

[25] *See* National Institutes of Health, Tools for the Identification, Assessment, Management, and Responsible Communication of DURC: A Companion Guide to the United States Government Policies for Oversight of Life Sciences DURC (2014) at 83 [hereinafter *DURC Companion Guide*] (noting that the order of review under the EAR (continued…)

Entries on the EAR's CCL are identified by alpha-numeric designations, known as "Export Control Classification Numbers," or "ECCNs." Category 1 of the CCL, entitled "Special Materials and Related Equipment, Chemicals, 'Microorganisms' and 'Toxins'," asserts EAR control over, *inter alia*, identified biological agents, pathogens (human, animal, and plant), toxins, genetic elements and genetically-modified organisms, vaccines, immunotoxins, medical products, chemicals, and microorganisms, as well as certain related technology and software.

Within Category 1, ECCN 1C351 is of particular relevance to the DURC discussion as it controls each of the 15 pathogens designated in the 2012 and 2014 DURC policies (along with more than 50 other harmful microbes).[26] ECCN 1C353 is also noteworthy as it controls, among other items, genetic elements and genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of most of the organisms, including each of DURC's 15 identified agents, which are designated in ECCN 1C351. Of more direct relevance for purposes of DURC, however, is that the EAR impose similar restrictive controls, in ECCNs 1E001 and 1E351, on the underlying technology related to these organisms' "development" and "production," as those terms are broadly defined,[27] as well as technology related to their disposal.

Generally speaking, not all items controlled on the CCL require export licensing to all destinations, as the United States government relies on other countries' export control systems in part to help satisfy U.S. goals in cases where the items are the focus of multilateral controls. However, the organisms listed in ECCN 1C351 and 1C353, and their underlying development, production, and disposal technology, have been identified as raising such grave chemical and biological weapons proliferation concerns that they require Commerce Department authorization for export or reexport to every country in the world.[28] This may take the form of Commerce Department specific licenses or reliance, where applicable, on license exceptions in the EAR.

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and ITAR provides that the USML be considered before reviewing the CCL in assessing the export controls applicable to an item).

[26] Note that EAR controls apply to these organisms only when they have not been physically modified, formulated, or produced in any of the enumerated ways that lead to gain-of-function characteristics that increase their harmfulness (in which case they would be controlled instead by the ITAR).

[27] *See* Export Administration Regulations ("EAR"), 15 C.F.R. Part 772 (defining "production" technology as including "all production stages, such as: product engineering, manufacture, integration, assembly (mounting), inspection, testing, quality assurance" and defining "development" technology as "related to all stages prior to serial production, such as: design, design research, design analyses, design concepts, assembly and testing of prototypes, pilot production schemes, design data, process of transforming design data into a product, configuration design, integration design, layouts").

[28] But as per ECCN 1C991.a, vaccines against the agents listed in ECCNs 1C351 and 1C353 are subject to less stringent export controls that require, due to anti-terrorism concerns, authorization under the EAR only for export or reexport to sanctioned countries or restricted end uses or end users. By contrast, medical products that contain certain of the agents in ECCN 1C351 are more tightly controlled, requiring authorization not only for export or reexport to U.S.-sanctioned countries and restricted end uses and end users, but also to numerous other countries as well, including some U.S. allies.

2. Exclusions from Control

Part 734 of the EAR identifies a variety of publicly available information that is not "subject to the EAR." Two categories of such information discussed below are technology that is "published" or that results from fundamental research. By comparison to the ITAR, the EAR have taken a somewhat more flexible approach towards fundamental research, allowing it to remain outside the scope of the EAR even when it becomes subject to certain dissemination restrictions.

a) Published Information under the EAR

Under the EAR, information is considered "published," and thereby outside the scope of the EAR, if it is (i) unclassified and (ii) "has been made available to the public without restrictions upon its further dissemination."[29]

The EAR include several examples of qualifying publication methods. The regulations explain that information is deemed published for purposes of the EAR when disseminated through widely available subscriptions; made publicly available at libraries or other public collections; communicated at generally accessible conferences that are open to qualified members of the public; or uploaded to the Internet on publicly available websites. Additionally, the regulations exclude from the EAR's control any pre-published work submitted with the intention of making the work publicly available, "(i) To domestic or foreign co-authors, editors, or reviewers of journals, magazines, newspapers or trade publications; (ii) To researchers conducting fundamental research; or (iii) To organizers of open conferences or other open gatherings."[30]

In view of the above provisions, the EAR are ostensibly quite limited in their ability to govern DURC when the research results are made available through broad release to the interested public. However, in some circumstances, such broad release of research might not be available due, for example, to funding-related limitations or because of publisher-imposed limitations regarding the substance of the research. Such cases are addressed by the EAR in the context of "fundamental research."

b) Fundamental Research under the EAR

The results of fundamental research are outside the scope of EAR controls if those results are "intended to be published."[31] This criterion, "intended to be published," is fulfilled under the regulations when the relevant "researchers are free to publish the 'technology' or 'software' contained in the research without restriction."[32]

[29] 15 C.F.R. §734.7(a).
[30] *Id.* at §734.7(a)(5)(i)-(iii).
[31] *Id.* at §734.8(a).
[32] *Id*. at §734.8(b).

No formal definitions exist in the EAR as to what constitutes publication "without restriction" for purposes of the fundamental research exclusion from EAR control, but some guidance is offered through the rules' discussion of prepublication reviews and in their presentation of illustrative examples of publication restrictions that would not impact the characterization of research as fundamental research.

Regarding prepublication reviews, the EAR explain that three types of such reviews would not jeopardize eligibility of fundamental research to remain free of EAR control. These three forms of prepublication review are: (i) reviews conducted solely to ensure that a publication would not compromise patent rights (provided the review causes no more than a temporary delay in publication of the research result); (ii) reviews conducted by a research sponsor solely to ensure the publication does not divulge proprietary information that the sponsor has furnished to the researchers; and (iii) reviews conducted in accordance with policies and procedures of federal agencies or federally funded research and development centers ("FFRDCs") and pertaining to research conducted by scientists and engineers on behalf of FFRDCs.[33]

As prepublication reviews often may not fall within any of the above three categories, the regulations provide notes to help illustrate cases in which limited restrictions on publication, as a result of prepublication review processes or government-imposed national security controls, would not, in and of themselves, trigger export controls. The first note, discussing when an item is "intended to be published," addresses temporally-limited research restrictions and provides that when researchers voluntarily accept publication restrictions, the research may once again become decontrolled for EAR purposes if and to the extent such restrictions expire or are removed. In a similar vein, Note 2 establishes that research voluntarily subjected for government review could still be deemed freely published fundamental research provided its publication is consistent with any controls resulting from the review. In contrast to the voluntary controls discussed in Note 2, Note 3 concerns U.S. government funded research subject to government-imposed controls, such as due to national-security concerns. The EAR allow for even this type of research to avoid control, provided that the researchers have satisfied any applicable government-imposed restrictions and, under such restrictions, are permitted to publish the information. In short, these two final notes clarify that when portions of DURC or other research become subject to dissemination restrictions, the remaining unclassified research can be published free from export controls, assuming all requirements of the EAR are met; a similar clarification does not exist under the ITAR.

III. Analysis: Are Export Controls an Effective Tool in Controlling DURC-Related Research?

There are many challenges in relying on export controls to limit the dissemination of the results of DURC. These challenges stem from export control rules themselves and from the U.S. Constitution, as well as from practical and operational realities.

[33] *Id.*

A. The Inherent Limitation of Export Controls: A Focus on International Transfers from the United States or Involving Foreign Persons

First and foremost, by definition, export controls do not regulate domestic activities of U.S. persons.[34] DURC, or even biological WMDs, can be shared among U.S. persons within the United States and would remain entirely free of export controls. Thus, while export controls can assist in combating the international proliferation of biological agents and mitigating state-to-state biosecurity threats, the ITAR and EAR and their enacting statutes do not authorize the government to combat dissemination of technology or other items wholly within the United States, between U.S. persons. Other types of laws or regulations would need to be utilized for that purpose.

Further, while these regulations apply "deemed export controls" to foreign nationals within the United States, threats of bioterror can and have emanated from activities of U.S. citizens operating fully within the United States. For example, in 1995, no export control laws were violated when two U.S. citizens were arrested for stockpiling in the United States the bacterium causing the Bubonic plague (*Yersinia pestis*), which they obtained through mail order from a laboratory in Maryland.[35]

B. Permanent Import of Pathogen Research: A Gap in Governance

Similarly, export controls are concerned predominantly with the outbound flow of items, including controlled technical data/technology. These regulations therefore would not afford the U.S. government with particularly effective tools for regulating DURC research being permanently *imported into* the United States.

While the ITAR regulate the temporary import of defense articles (such as, for example, ITAR-controlled hardware being temporarily returned to the United States for repair), they do not control permanent imports, and the EAR simply do not apply to imports. The regime that does regulate permanent imports into the United States is administered by the Department of Justice, Bureau of Alcohol, Tobacco, Firearms and Explosives ("ATF").[36] However, the ATF's U.S. Munitions Import List ("USMIL") does not regulate permanent import of biological agents or related technical data, regardless of how dangerous such agents might be.[37]

[34] The ITAR do require U.S. persons/companies that manufacture defense articles to register with the State Department, even if they are not exporting the defense articles. *See* 22 C.F.R. §122.1(a). This requirement includes an exemption from registration for persons whose "only pertinent business activity is confined to the production of unclassified technical data only. . . ." *Id.* at §122.1(b)(2).

[35] *See* Karl Vick, *Man Gets Hands on Bubonic Plague Germ But That's No Crime,* Washington Post, December 30, 1995.

[36] *See* 27 C.F.R. Part 447.

[37] The USMIL does regulate, in its Category XIV, certain chemical agents, such as lung irritants, vesicants, and tear gases. *See* 27 C.F.R. § 447.21, Category XIV.

C. Distinct Policy Objectives and Regulatory Methodologies

Recently, at least some U.S. export control regulators have articulated the position that DURC and export control policy objectives are fundamentally different. Thus, in the context of the State Department's revision of ITAR controls on toxicological agents, public commentators suggested easing export controls because DURC policies, together with other government programs, provided adequate biosecurity oversight. The State Department rejected this assertion and explained that DURC policies and related government programs "are not munitions export control regimes and do not share the national security and foreign policy objectives of the ITAR" and "address largely unrelated regulatory concerns."[38]

In fact, although the U.S. export control system serves various U.S. foreign policy objectives that are not necessarily germane to DURC considerations, DURC and export control policies do share the aim of safeguarding national security. In this respect, DURC policies and the ITAR overlap at least in part as to their objectives and concerns when it comes to DURC agents. The EAR, in addressing technologies with a dual use character, contain provisions that are closer still conceptually to DURC policies. Nonetheless, there is something inherently incongruous in relying on export controls to regulate DURC.

This incongruity stems from the manner in which provisions for fundamental research have been incorporated within export control regulations. Generally, export controls apply in large part based on an item's technical characteristics, with items that create greater security and other risks being subjected to more stringent levels of control. However, when it comes to determining whether fundamental research is exempt from export controls, the inherent character of the research is largely irrelevant. Instead, contextual questions regarding who conducts or funds the research and, most importantly, whether the researchers intend for the research to be published, determine whether export controls apply. This point can be illustrated through Commerce Department examples that were published to clarify when information would and would not constitute fundamental research:[39]

> Example: Government-funded researchers studying Bacillus anthracis accept national security prepublication review of their research. If the group complies with the review requirement and does not communicate this research without the required reviews, their research remains fundamental research. However, any of the information resulting from this research that is restricted from publication becomes subject to the EAR.

In the same publication, the Commerce Department admitted that similarly controlled research could be shared globally without restriction when produced through private means, free of dissemination restrictions:

[38] Amendment to ITAR, 81 Fed. Reg. at 49,533.
[39] *See* U.S. Dept. of Commerce, Bureau of Industry and Security, Export Control Reform FAQs, (Sept. 1, 2016), at pp. 4, 5, https://www.bis.doc.gov/index.php/2012-03-30-17-54-11/ecr-faqs.

> Example: There is a joint U.K./U.S. university-based research project on vector identification for Marburg virus with no restrictions on publication of the results of the research or of any technology released to the researchers. The research would be considered fundamental and the information resulting from this research, such as the results and methods, are not subject to the EAR. There would be no "deemed export" [authorization] required for foreign nationals working at the U.S. university and no export license required for discussing research methods and outcomes between the two universities. An export license would be required for the export of the Marburg virus samples to the U.K. university.

A system that calls for export control determinations based upon external criteria that do not necessarily correlate with the particular risks inherent in an item is inconsistent with biosecurity needs. Indeed, benign projects involving controlled items with publication restrictions could be subject to export controls, whereas highly dangerous projects pursued for publication and undertaken without publication restrictions might be exempt. In addition, assessing the application of export controls based on a researcher's intent to publish, as opposed to the character and level of sensitivity of the research content, can be subjective and challenging. With limited enforcement resources and the challenge of determining intent, regulators may prefer instead to invest their energy into ensuring compliance with more conventional trade activities.

D. Export Controls' Limits on Controlling Public Information

Defining "fundamental research" based upon whether it is meant for broad publication is not the required interpretation of NSDD-189, although this is how it has been applied in practice within U.S. export controls. Indeed, NSDD-189's definition of "fundamental research" — "basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community" — could have been interpreted such that publication was meant to serve as a useful indicator, rather than as the determining factor, when identifying work as fundamental research. However, this has not been the approach taken in the ITAR and EAR: publication, along with the nature of any restrictions, is a controlling factor in determining whether the regulations' "fundamental research" provisions should apply.

In essence, the fundamental research carve out from export control restrictions lacks independent, substantive meaning, and is in reality a subcategory of broader regulatory provisions focusing on public domain information. However, while this interpretational approach may fulfill the policy objectives of export control regulators, it severely constrains this system's ability to effectively govern DURC. It means that export controls simply do not apply to situations in which research is intended to be published or is otherwise properly released into the public domain. Indeed, under the EAR, researchers can freely share their research with the public, such as by uploading their research results to the Internet, unabated by EAR controls. The ITAR similarly do not apply to information released to the public, provided that the mode of release corresponds to the publication methods delineated in the regulations (such as being made available at public libraries, through newsstands, etc.). These fundamental EAR and ITAR limitations make it exceedingly difficult for these regimes to effectively control dissemination of

DURC if the researchers intend to publish their research results, which is often the ultimate end goal of researchers, and have no funding-related restrictions on their freedom to do so.

E. Constitutional Constraints

There are also inherent Constitutional limitations on the manner that export control laws can restrict communication of private, unclassified information. While the 3-D printing litigation discussed above shows that the State Department prevailed in its efforts to limit the free flow of private information related to the ITAR-controlled defense articles in that case, the government's regulatory purview in this regard is not unlimited.

In 1978, for example, an earlier federal appeals court decision, which again sided with the government, determined that Constitutional protections of free speech prevent criminalizing the dissemination of general scientific and technological information unless it is directly related to defense articles and is exported with the knowledge that it would be used to produce or operate munitions.[40] Surrounding this decision, and against the backdrop of debate over restricting cryptography information, the State and Justice Departments exchanged several memoranda that expressed the view that ITAR controls limiting communication of information could be unconstitutional violations of free speech.[41]

Then, in response to the 1993 World Trade Center and 1995 Oklahoma City bombings, and in response to the incident described above involving the mail-ordered Bubonic plague bacterium, a law was passed that tasked the U.S. Attorney General with conducting a study regarding government control over publicly available information concerning weapons of mass destruction. The report concluded that "[t]he First Amendment imposes significant constraints on the ability of the federal government to restrict publication of [WMD] information."[42] Moreover, the Attorney General acknowledged in the report that "anyone interested in manufacturing a…weapon of mass destruction can easily obtain detailed instructions for manufacturing and using such a device, both from legitimate publications and from so-called 'underground' publications [a]nd, presumably, most if not all of the writers and publishers of such publications do not obtain the information unlawfully, or from classified sources."[43]

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[40] *United States v. Edler Indus. Inc.*, 579 F.2d 516 (9th Cir. 1978).

[41] *See*, *e.g.*, Memorandum from John M. Harmon, Assistant Attorney General, Office of Legal Counsel, to Dr. Frank Press, Science Advisor to the President (May 11, 1978) (using "prior restraint" as the doctrine through which to assess the ITAR's constitutionality and determining then that "it is our conclusion that the present ITAR licensing scheme does not meet constitutional standards [of free speech]"); *but see* Memorandum from Theodore B. Olson, Assistant Attorney General, Office of Legal Counsel (July 1, 1981) (addressing the 1978 memorandum provided to Dr. Frank Press and concluding that it was "not certain whether a court would find that the revised ITAR are so substantially overbroad as to be void and unenforceable in all their applications, or decide to save the regulations through a narrowing construction" and suggesting that the "best legal solution is for the Department of State, not the courts, to narrow the ITAR so as to make it less likely that they will apply to protected speech in constitutionally impermissible circumstances").

[42] Dept. of Justice, Report on the Availability of Bombmaking Information, the Extent to Which Its Dissemination is Controlled by Federal Law, and the Extent to Which Such Dissemination May Be Subject to Regulation Consistent With The First Amendment to the U.S. Constitution (1997).

[43] *Id.*

Thereafter, developments in deemed export regulations spurred significant responses from the scientific community, leading U.S. regulators to adopting a reserved approach to the controls.[44] The September 2001 World Trade Center attacks elicited substantial U.S. government scrutiny over continued relevance of NSDD-189 and its flexible regulatory approach, but the directive survived.[45] In 2008 and 2010, Department of Defense memoranda reaffirmed the importance of ensuring that acquisition terms in Department of Defense contracts and grants preserve flexibilities afforded to fundamental research, as enshrined in NSDD-189.[46]

These latent tensions were recently addressed in September 2016, in the context of the 3-D printing litigation, which may be but a harbinger of continued pressure on U.S. regulatory control over the communication of sensitive, privately-generated information. Indeed, in the 3-D printing matter, the court recognized that weighty issues of freedom of speech and the ITAR are still unresolved, and a scathing dissent argued that the government's attempt to restrict uploading such information to the Internet "appears to violate the [ITAR's] governing statute, represents an irrational interpretation of the [ITAR], and violates the First Amendment…"[47]

Thus far, the U.S. judiciary, up to but not including the U.S. Supreme Court, has sided with the State Department and has afforded it broad discretion to restrict citizens from communication of ITAR-controlled information. But asserting a broader export control paradigm to restrain DURC could easily reignite the tough Constitutional questions addressed only in part over the years. Export control regulators are not able to forecast how any particular court, including the Supreme Court, would rule with respect to Constitutional challenges, creating a considerable disincentive against aggressive expansion of the export control regime.

F. Creating an Incentive Not to Collaborate

Biosciences research is built on a strong foundation of collaboration between scientists and government agencies. Indeed, since the Asilomar Conference on Recombinant DNA in 1975, where biologists committed to self-governance for fostering biosafety and biosecurity, the public-private relationship in the field of biology has been largely collaborative. Maintaining this rapport is critical in light of the risks involved in DURC and because of the challenge of containing the spread of dangerous research information through traditional legal tools, such as export controls. Yet, this collaborative spirit could be undermined by imprudently imposing an overly expansive set of new, DURC-driven export control requirements on biosciences researchers.

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[44] *See, e.g.*, Samuel A. W. Evans & Walter D. Valdivia, *Export Controls and the Tensions Between Academic Freedom and National Security*, 50 Minerva (Special Issue) 169, 182 (2012).

[45] *See* Letter from Condoleezza Rice, Assistant to the President for Nat'l Sec. Affairs, to Dr. Harold Brown, Co-Chairman, Ctr. for Strategic & Int'l Studies (Nov. 1, 2001), https://fas.org/sgp/bush/cr110101.html (stating that the George W. Bush "…Administration will review and update as appropriate the export control policies that affect basic research in the United States. In the interim, the policy on the transfer of scientific, technical, and engineering information set forth in NSDD-189 shall remain in effect").

[46] Memorandum from John J. Young to Sec'ys of the Military Dep'ts (June 26, 2008); Memorandum from Ashton B. Carter to Sec'ys of the Military Dep'ts (May 24, 2010).

[47] *Def. Distrib. v. U.S. Dep't of State*, 838 F.3d 451, 463 (5th Cir. 2016).

Indeed, well-intentioned scientists already face challenges in remaining compliant with U.S. export controls, especially given the highly fluid nature of the scientific process. For example, scientists might set out on a project with confidence that their work is free from the controls of the ITAR's USML and the EAR's CCL, but these controls ultimately could apply to the products and technology they develop if unexpected research results arise. This is illustrated in the seminal DURC matter in which Australian researchers set out to create a virus to render female mice infertile, but inadvertently created a genetically enhanced mousepox virus with potential bioweapons applications.[48] In cases of such unforeseeable research outcomes, projects might not initially raise concerns about dual use or defense trade controls, but could easily end up triggering these onerous controls on the unexpected resulting products.

Further, even as currently formulated, the ITAR and EAR interact with DURC in a way that could chill collaboration and pre-publication review. Specifically, as explained in the DURC Companion Guide, drafted by the National Institutes of Health to assist researchers in complying with the 2012 and 2014 DURC policies, identifying a project as DURC does not directly affect whether research results are subject to export controls, but "certain risk mitigation measures (e.g., the imposition or acceptance of restrictions on publication) MAY affect whether the research is subject to the EAR. Institutions and researchers should be aware of this possibility" (emphasis in original).[49] This refers to the fact that whereas properly released publicly available information is not subject to U.S. export controls, DURC researchers who accept restrictions on the dissemination of their research could foreclose eligibility for the public domain provisions of the ITAR and the EAR and, consequently, trigger the full breadth of the U.S. export system, at least with respect to the restricted research, even though accepting such restrictions in the vein of collaboration and self-imposed control is potentially protective of national security interests. In light of potentially severe penalties for non-compliance, scientists might be incentivized to avert risk mitigation entirely (so as to avoid export controls), even with respect to highly sensitive biosciences research.

In short, the current export control system is an imperfect fit to scientific research. But forcing a more stringent export control paradigm on the scientific community in order to further restrict DURC might garner opposition and chill vital public-private collaboration. Scientists could undertake efforts to avoid regulations or to contest regulatory rulings in adversarial ways. Perhaps the most grievous outcome of bolstering export controls over DURC would be if scientists abandon otherwise vital life sciences research or if, in response to an uptick in export enforcement in the biosciences community, talented students and principal investigators elect alternative research fields. While the risks posed by DURC might justify stricter export controls, policymakers should consider the costs, including the cost of corroding the collaboration that has traditionally framed the government's relationship with the scientific community.

[48] *See* 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), *in* Carole Baskin and Todd Richarson, Dual Use Research Policy Implementation, 7 St. Louis U. J. Health L. & Pol'y 59 2013-2014 at n. 28.

[49] DURC Companion Guide, *supra* n. 25, at Appendix 5, Part 3, p. 84.

IV. Conclusion

Sharing information is the basis of good science, which in turn is the basis for improving the world we share. At the same time, ill-intentioned state and non-state actors can leverage this collaborative spirit to advance their destructive agendas. DURC falls within the eye of this storm of clashing values, presenting intractable challenges for policymakers. And while export controls can certainly shelter classified or otherwise restricted information from being shared internationally, this system of rules, at its core, is not structured to prevent the free flow of unclassified scientific information, or to control wholly domestic U.S. activities. Attempts to rely on export controls for this purpose may prove futile or, worse, could run afoul of well-rooted Constitutional norms and lead to disincentives against continued private-sector collaboration with the government.