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to:

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23 April 2013

Re: Comments on the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

Dear Dr. Jones,

Thank you very much for the opportunity to comment on the U.S. Government's (USG) proposed Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. As someone who has actively studied and published on the technical and social issues of dual-use research and technology for nearly a decade, I appreciate the chance to share my thoughts with the Government, and would welcome any further involvement the Government may desire. The comments expressed here are my own, and are not necessarily endorsed by the University of California. I have divided my comments into more general ones regarding the policy as a whole, and specific comments addressing questions raised in the Request for Comments.¹

General Comments

Scientists are not trained to consider the malicious implications of their research. Quite the opposite. Most scientists, if concerned at all about applications, will likely only consider the beneficial ones.

From the earliest schooling students receive about science, they are encouraged to focus on the benefits of a scientific way of thinking and the beneficial uses to which scientific advancements might be put. By the time they are graduate students, they will likely have gone through at least of decade of teaching that reinforces these views. Indeed, many scientists engage in a career in research with the express purpose of advancing knowledge to benefit humanity. Very little, if any, of the training these future Principle Investigators (PIs) receive is focused on the ways research might be purposefully used

¹ "Notice; Request for Comment: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern." *Federal Register* Vol. 78, pp. 12369–12372. Available at: <https://federalregister.gov/a/2013-04127>

for harm. Yet **the current form of this policy places a heavy burden on PIs to be able to constantly be thinking in precisely NOT the way they have been trained.** We cannot realistically expect such a policy to have any great practical success.

There are two primary ways we—the combined academic, industrial, and governmental communities—might address this deficiency. First, we should acknowledge that **the traditional version of the “social contract for science”**—where the scientific community retains a high degree of autonomy from the government with the promise of producing benefits to society from federal funds for research—is **no longer an adequate basis for forming policy**, particularly when focused on the nexus of security, academic, and economic concerns.² The breakdown of the social contract mirrors the irrelevance, particularly in this case, of trying to distinguish between fundamental and applied research.³ In acknowledging this, we would immediately see that placing almost all of the responsibility on the PI to be aware of what research might constitute a national or international security concern has major flaws. The initial, as well as ongoing, assessment of what counts as a DURC should be a collaborative process between academic, industrial, and governmental (particularly the health, security, and intelligence) communities. This policy as currently fashioned raises barriers to that dialogue. A clear illustration is Figure 1 in the Proposed Policy. It clearly shows that the PI's assessment of research comes first, rather than being in tandem with any governmental or other oversight. This is in contrast to the USG's March 29, 2012 *Policy for Oversight of Life Sciences Dual Use Research of Concern* document.⁴ There, it is clear that the government will be conducting its own review process. It is not at all clear how the review process within the government will relate to the institutional review process proposed in this new policy. See comments on Question 10 below.

Second, we should recognize that **DURC training requires the fundamental reassessment and reformation of scientific training in general.** This of course cannot be done within the scope of the current policy, but the USG should recognize the scale of the issue that it is addressing in this policy, and seriously consider fostering a broader dialogue on how to re-envision the role of science in the state. If scientists are going to have a fundamental role in the security of society, the articulation of this role should happen at the earliest stages of training.

As the life science community is currently given a tremendous amount of leeway in determining the “consequences of misuse,”⁵ the initial formulation of this policy will likely fail as soon as there is misuse of a high consequence that the research community did not foresee.⁶

It is important that the USG consider how blame will be attributed when, not if, this governance system fails. Taken together, this Proposed Policy and the March 29, 2012 policy provide contradicting answers to the blame question. While providing the academic community with the freedom to govern their own research, the government is placing its faith in that community to keep it safe. But should harmful use result, it is likely that the government will receive the brunt of the criticism for believing that academics can seriously place the security of the nation over the advancement of science.

² See Owen, R., Bessant, J. & Heintz, M. eds., 2013. *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, London: John Wiley & Sons Inc. See also Evans, S.A.W. & Valdivia, W.D., 2012. “Export Controls and the Tensions Between Academic Freedom and National Security”. *Minerva*, 50(2), pp.169–190.

³ Narayanamurti, V., Odumosu, T. & Vinsel, L., 2013. “RIP: The Basic/Applied Research Dichotomy.” *Issues in Science and Technology*, 29(2). Available at: <http://www.issues.org/29.2/Venkatesh.html>.

⁴ Available here: <http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>

⁵ Proposed Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (hereafter “Proposed Policy”), Section 3.D.

⁶ See also my comments on Question 10 below.

As currently envisioned, this policy is best seen as an insurance mechanism for both the government and the academy against future public cries for change when an eventual malicious use of research occurs. It is a document that reaffirms the belief in the separation of fundamental research and the state, rather than a document that seeks to create a constructive and continuing dialogue between the academy, the state, and industry.

Focus should be placed on fostering a dialogue between PIs, institutional reviewers, and the health, security, and intelligence communities.

In the construction of the federal and institutional review boards the focus should be on fostering dialogue between these different communities. These boards should be composed of a core set of people who are knowledgeable in the review process itself (as the process is new, these people do not exist yet) and a rotating group of members who together represent the academic, governmental (e.g. health, security, intelligence), and economic concerns of research that is potentially DURC. Having members of government (or social scientists focused on the political/security aspects of research) on institutional review boards will likely not be an easy or comfortable task, but it has much more of a chance of actually identifying DURC and developing effective risk management strategies than having review bodies that only have expertise on one aspect of the multi-faceted DURC problem.

The construction of risks and benefits is heavily based on institutional context, training, and the social groups of the individuals making the determination.

Building on the points discussed above, any meaningful characterization of risks will need to occur through a deliberation between communities with very different goals and structures of organization. A long history of social scientific research demonstrates that it is to be expected that these communities, by themselves, will have significantly different ways of constructing what counts as an adequate risk, and even what it is that is at risk. Left to their own, then, institutional review bodies and federal review bodies will often have very different outcomes from their risk assessment processes. With each coming up with a risk management plan, the PI will likely be left with an apparently impossible dilemma of trying to choose between accepting what she/he sees as an overly constraining governmental assessment (which would ensure continued funding) or a more liberal academic assessment (which would allow more freedom of research). The closer these two review bodies work with each other and the PI—in a way that understands that each community will have very different ways of framing what counts as a risk, and what counts as an adequate level of that risk—the more likely it is that any decision will be practically acceptable and implementable by all communities.

The policy should be a ‘living document’, open to amendment or revision at regular periods through an ongoing conversation with the security and life science communities.

Effective policies are only those which are enacted in practice. The focus of the USG on soliciting “feedback on the experience of institutions in implementing the Policy”⁷ is to be commended, but there are points in the Request for Comment that suggest the USG thinks there might be a ‘final’ form of the policy.⁸ Rather than seeking a final form with a permanent scope, the USG should strengthen and routinize the lines of communication and feedback that allow the document to be modified on a regular basis to reflect the changing institutions, content, and context of research and policy.

⁷ Proposed Policy, Section 1.

⁸ E.g. Question 12.

Comments to Specific Questions

Question 5 - Should research that has undergone institutional DURC review but has been determined not to be DURC be monitored for emerging DURC issues? If so, how often should such review take place?

Yes. This process should be the responsibility of both the institutional review body and the PI. The PI should be encouraged to return to the review body whenever new concerns arise. In doing so, any hindrances on the PI should be minimal, to encourage her/him to make this routine practice. The review body itself should take the initiative to check research developments as they occur. One simple way to do this would be to have a member of the review body sit in on an occasional lab group meeting or read/listen to the latest publications of the lab group.

Question 9 - The USG is developing a document that contains the following analytic tools and guidance to assist in implementation of the Policy...Are there any additional tools or guidance documents that would be useful in implementing and complying with this Policy, once finalized?

Yes. While it is impossible to assess the adequacy of a document that is not yet produced, the USG should consider several points in the production of this document. When thinking about the **understanding and identification of DURC**, it is important that those engaged in the process (not just the PI, but review boards, students, and governmental liaisons) remember that labeling research as DURC involves an assessment not only of the scientific and technological aspects of the research, but also of the potential environments within which it might be maliciously developed and used. Expertise is therefore needed not only from those engaged in the research, but also from those who have knowledge of the likely malicious actors and environments.

When looking at **training and education on DURC**, the document should likewise outline methods that will **develop strong and ongoing links between the scientist**, who has a narrow area of specialization, **and other colleagues who focus on the identification and prevention of malicious use**. Students and researchers must be taught that the burden of responsibility for the benevolent development of research is shared among a broad community of practitioners, from government liaisons to colleagues in the social sciences, industry partners, and foreign individuals and institutions. An adequate oversight system will be much easier to implement if each of those involved in the oversight more clearly understands that they only have a piece of the picture in considering what counts as DURC and how it should be managed. Responsible development should reinforce the lines of communication and trust between, say, the researcher on the lab bench, members of the institutional review body, and researchers and practitioners addressing security issues more broadly.

Question 10 - Are there any conflicts or challenges posed by implementing both [this policy and the March 29, 2012 policy]? Should research institutions review projects for DURC issues prior to proposals being submitted to a funding agency for review? (If not, funding agencies implementing the March 29 Policy will not have the benefit of input from institutional dual use review when reviewing research proposals for DURC.) If so, should the PI and/or institution designate on the grant application that such a review has taken place and indicate its findings?

It is not clear how institutional review bodies and federal review bodies will interact. Will the decision of one trump the other? Will there be a transparent process of arbitration? The Proposed Policy is worded in a way that implies the PI holds all the cards in making an initial determination of whether her/his research is potentially DURC. If the government instead begins this process, as implied in the March 29, 2012 policy, what role will the PI and the institutional review body have in the government's assessment? **It is easy to foresee the turf wars between these two bodies becoming**

polarized in the unfruitful and all-too-familiar characterizations of academic freedom versus national security.

With this foresight, we should be seeking instead to build strong and continuing lines of communication between the PI and the governmental and institutional review bodies. It is all too easy to underestimate the work involved in developing and maintaining these lines of communication, as the scientific and security communities since World War II have tried to prevent much of this communication under the guise of maintaining academic freedom. One way this policy may begin the shift to a more fruitful dialogue is through **creating collaborative learning environments where governmental, industrial, and academic members can speak frankly (and possibly confidentially) about how the current and proposed systems do not work and might change.**

In addition, DURC is increasingly being conducted in industry settings, yet there is no meaningful discussion in this policy on how to address this growing concern. This ability for the government to completely not address this issue was noted a decade ago in the 2004 National Research Council report on *Biotechnology Research in an Age of Terrorism*,⁹ and yet little appears to have changed.

The government has had nearly a decade since the Fink Report to assess not only the role of industry, but the ability of institutional review boards in handling questions about experiments of concern. Yet, lessons learned from that process do not appear in the current policy. For example, in seeking to not duplicate further oversight efforts within an institution, this policy will likely be implemented through mechanisms like the institutional review boards that caused so many problems after the Fink Report.

Question 12 - Is the scope of the proposed Policy appropriate? If not, why not? Should the scope be expanded to all select agents, microbes, or all life sciences? If so, why? What factors should be considered in determining the final scope of oversight? What criteria might be used to determine what research should/should not be subject to oversight? If the Policy, once finalized, were expanded to cover other types of life sciences research (i.e. beyond the 15 listed agents), what effect, if any, would it have on your ability to conduct that research?

Limiting the initial scope of the policy to the 15 listed agents is understandable, as this policy is to be “updated, as needed, following domestic dialogue, international engagement, and input from interested communities including scientists, national security officials, and global health specialists.”¹⁰ The flip side of this statement is that **the USG and others should not be thinking in terms of developing a “final” scope of this policy** (see my general comment on making this a “living document”). In its current form, the policy provides a limited initial scope to test the institutions and procedures needed to implement it in practice. Indubitably, research conducted on other agents will be of concern in certain situations, and at some point this policy should address that fact. The question should not be if, but when and how.

Central to the expansion of the policy should be discussion early on regarding novel methods of engagement between the policy, academic, and industry communities that allow for concerns to be raised and addressed without the strenuous procedures often needed to work on select agents. When implementing the initial version of the policy, careful thought should be given to whether the way institutions are being reconfigured makes sense only in the case of select agent work—and thus would not be adequate to expand to a wider range of life science research—or if these reconfigurations might also make sense to the broader life science community. Researchers who already know that their topics of study might cause harm, for example, are much more likely to engage in more formalized oversight procedures with steeper consequences for improper action, while more informal procedures might be more likely to be enacted within the wider community.

⁹ Known commonly as the Fink Report

¹⁰ Proposed Policy, Section 1.

I hope you find these comments helpful. Many of the points discussed here will likely require substantial changes in the policy to be meaningfully enacted. The point that is perhaps the easiest to enact is also the one that opens the door to the other points: the need, expressed in the proposed policy, to have a continuing collaborative dialogue on this policy's development between the governmental, academic, and industrial communities. Please do not hesitate to follow up on any points that are not clear. I look forward to the final version of the policy, and to monitoring how it is enacted in practice.

Sincerely,

A handwritten signature in cursive script that reads "Sam A. W. Evans".

Samuel A. W. Evans