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## Regulating Dual Use Research to Promote Public Trust: A Reply to Dr. Franz

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## **REGULATING DUAL USE RESEARCH TO PROMOTE PUBLIC TRUST: A REPLY TO DR. FRANZ**

ROBERT GATTER\*

Elsewhere in this issue, Dr. David Franz makes a persuasive argument that protecting the public against risks posed by dual use research of concern (DURC)<sup>1</sup> requires strong leadership among scientists who manage the laboratories in which such research takes place.<sup>2</sup> Among other things, he calls on scientists, regulators, and others interested in DURC oversight to devote as much attention to developing stronger laboratory leadership as has been spent on creating rules and regulations.<sup>3</sup>

Importantly, Dr. Franz is skeptical of the government's regulating scientists and research institutions, including the newly proposed federal rules concerning DURC.<sup>4</sup> He writes that regulations cannot make us safe in the face of dual use risks and that, instead, they create compliance tasks that distract scientists and divert resources from research.<sup>5</sup>

More fundamentally, Dr. Franz depicts life science research as "over-regulated" and argues that such regulation is antithetical to maintaining

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\* Professor of Law and Co-Director, Center for Health Law Studies, Saint Louis University School of Law. Thank you to Dr. David Franz for sharing his experience, his intellect, and his open-minded curiosity with me as I developed the theme for this essay based on conversations with him as part of planning the symposium *Regulating Dual Use Research*, at the symposium, and while driving to the airport at its conclusion. He makes intellectual curiosity and public service a way of life.

1. "Dual Use Research of Concern" is "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, material, or national security." NAT'L INST. OF HEALTH, NIH POLICY ON MITIGATING RISKS OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN (2013), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-107.html>.

2. See David R. Franz, *Dual-Use Dilemma: Crying Out For Leadership*, 7 ST. LOUIS U. J. HEALTH L. & POL'Y 53-56 (2013).

3. *Id.* at 51-53.

4. See NAT'L INST. OF HEALTH, *supra* note 1.

5. See Franz, *supra* note 2, at 50 ("At least anecdotally, compliance with these regulatory approaches has forced laboratories to hire additional contractors to manage the programs, which has diverted funds from legitimate research, subsequently slowing progress. Even with these regulations in place, the U.S. Government cannot assure increased security.").

laboratories as “communities of trust” in which safe and productive research can take place.<sup>6</sup> Indeed, this is the closing message of his article. After acknowledging that regulations are necessary to establish “the boundaries of the playing field and the rules of the game,” he observes that, in the context of DURC, “[t]he safety rulebook in a high-containment infectious disease laboratory is *thick* . . . .”<sup>7</sup> Moreover, he explains that many of the rules respond to the conduct of very few bad actors, and yet those rules apply to every scientist and lab worker.<sup>8</sup> From this, Dr. Franz warns that, “[w]hen rules for the few become too disruptive to the work of the many, communities of trust can break down.”<sup>9</sup> Meanwhile, “[l]aboratories with exceptional leaders armed with well thought-out, and *thin* . . . rulebooks,” he says, “will always be safer, more secure, and far more productive than labs where the many are overregulated . . . .”<sup>10</sup>

Dr. Franz’s observations bring into play a complicated relationship between regulation and trust, which has significant implications for how the law should be used to steer conduct with respect to DURC in life science research. Both trust and regulation are necessary components to the research enterprise. I defer to Dr. Franz’s view that trust among laboratory workers and scientists is vital to safety and productivity. Equally vital, however, is *public* trust in researchers and research institutions. Put another way, it is not enough for scientists to trust each other and the leadership of their research institutions; the research enterprise generally must also be trustworthy to the public at large.

Controversy over the publication of two studies in which scientists manipulated the genes of a certain strain of highly pathogenic avian influenza (H5N1) to create new pathogens that are easily transmissible among ferrets (a model for human influenza transmission) draws into question the trustworthiness of researchers and research institutions.<sup>11</sup> This research involved significant risks to public safety by creating new and potentially virulent pathogens that could be accidentally released or misused, and demonstrated methods for creating other potentially dangerous pathogens, which could be misused in war or bioterrorism.<sup>12</sup> Yet, it does not appear that those risks were acknowledged or discussed by the

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6. *Id.* at 12.

7. *Id.* at 57.

8. *See id.*

9. *Id.*

10. *See Franz, supra* note 2, at 57.

11. *See id.* at 43.

12. *See id.*

scientists or research institutions involved until just before the studies were to be published, and then only when outsiders raised questions.<sup>13</sup>

Under these circumstances, regulators, legislators, news media, and voters are more than justified to question whether research oversight is sufficient to assure public safety. The public may fairly interpret the story of the ferret flu studies as an example of how a single-minded drive toward discovery can blind scientists to the full measure of the risks their work imposes on the public.

The ferret studies were designed to create new influenza strains that were not only highly pathogenic, but also easily transmissible between mammals.<sup>14</sup> It was no surprise, then, that each of the studies resulted in new strains of H5N1 that were transmitted between ferrets.<sup>15</sup> Given the risks inherent in the objectives and design of these experiments, why were the public safety risks not discussed and compared to the benefits of the research until the eleventh hour prior to publication, well after the studies were completed? Why did the lead researchers not present a risk-benefit analysis as part of their research proposals? Why did their research institutions not require such a risk-benefit analysis as a condition for allowing the studies to be conducted on their premises? Why did the National Institutes of Health (NIH) approve government funding for each of the studies without first conducting a risk-benefit analysis and without first questioning whether the value of two studies was worth doubling the safety risks to the public?

The thesis of this essay is that a discovery imperative lies at the core of science, that this drive to discover causes scientists to undervalue research risks, and that public trust in life sciences research requires a regulatory check on that bias. Despite Dr. Franz's observation that research regulation diminishes trust within laboratories, I argue that the right kind of regulation will create a foundation for public trust in researchers and their institutions. Moreover, I claim that the newly proposed DURC regulations are the right kind of regulation.

#### A. *The Ferret Studies, Their Approval, and Their Publication*

In 2012, two different research teams completed similar experiments proving that H5N1 is susceptible to genetic modifications that will make it

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13. *Id.*

14. *Id.*

15. See Sander Herfst et al., *Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets*, 336 *SCI.* 1534, 1539 (2012); Masaki Imai et al., *Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5NA/H1N1 Virus in Ferrets*, 486 *NATURE* 420, 427 (2012).

easily transmissible among humans.<sup>16</sup> As an avian influenza, H5N1 most commonly infects a variety of domestic and wild birds.<sup>17</sup> Yet, it is capable of leaping the species barrier to infect humans.<sup>18</sup> To date, more than 600 human infections have been recorded worldwide with a mortality rate of close to 60%.<sup>19</sup> Despite these infections, there has not been an outbreak of H5N1 among humans because the strains of H5N1 involved in these infections were not easily transmitted from human-to-human through, for example, sneezing.<sup>20</sup> This led some scientists to question whether H5N1 poses much of a pandemic threat.<sup>21</sup> These scientists hypothesized that the genetic alterations necessary to permit an avian H5N1 to both infect a human and to become easily transmissible among humans are so numerous as to be highly unlikely to ever occur in nature.<sup>22</sup> To address this hypothesis, the two research teams designed experiments to identify what, if any, genetic modifications to H5N1 would make it easily transmissible among humans.<sup>23</sup>

Both of the studies were funded in part by the National Institute of Allergy and Infectious Diseases (NIAID), which is the division of NIH responsible for influenza research.<sup>24</sup> Yet, the funding review at NIH and NIAID was purely scientific and was unlikely to have included any assessment of the dual use risks posed by either project. Federal regulations provide that NIH assess “the scientific merit and significance of the project, the competency of the proposed staff . . . the feasibility of the project, the likelihood of its producing meaningful results, the proposed project period, and the adequacy of the applicant's resources available for the project . . . .”<sup>25</sup> Likewise, grant application guidelines under the NIAID state that reviewers should judge an application solely on “its ability to make a strong

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16. See Herfst et al., *supra* note 15, at 1541; Imai et al., *supra* note 15, at 420.

17. Q&A on Avian Influenza, EUROPEAN CTR. FOR DISEASE PREVENTION & CONTROL, [http://ecdc.europa.eu/en/healthtopics/avian\\_influenza/basic\\_facts/Pages/QA-avian-influenza.aspx](http://ecdc.europa.eu/en/healthtopics/avian_influenza/basic_facts/Pages/QA-avian-influenza.aspx) (last visited October 23, 2013); *Avian Influenza: Brief Background*, UNIV. OF MINNESOTA CTR. FOR INFECTIOUS DISEASE RESEARCH & POLICY, <http://www.cidrap.umn.edu/infectious-disease-topics/avian-influenza-bird-flu#overview&1-3> (last updated June 12, 2013).

18. *Avian Influenza*, WORLD HEALTH ORG., [http://www.who.int/mediacentre/factsheets/avian\\_influenza/en/index.html](http://www.who.int/mediacentre/factsheets/avian_influenza/en/index.html) (last updated April 2011).

19. See *Highly Pathogenic Avian Influenza A (HPAI) in People*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/flu/avianflu/h5n1-people.htm> (last updated June 21, 2012).

20. See The Writing Comm. of the World Health Org., *Avian Influenza A (H5N1) Infection in Humans*, 353 NEW ENG. J. MED. 1374, 1375 (2005).

21. See Herfst et al., *supra* note 15, at 1535. See also Imai et al., *supra* note 15, at 420.

22. See Herfst et al., *supra* note 15, at 1535; Imai et al., *supra* note 15, at 420.

23. See Imai et al., *supra* note 15, at 420.

24. See *id.* at 428; Herfst et al., *supra* note 15, at 1541.

25. 42 C.F.R. § 52.5 (2011).

impact on its field,” which “is a function of . . . the importance of the topic,” defined as “the significance and innovation of the research problem — its ability to move the frontier of knowledge forward.”<sup>26</sup>

One of the two studies — the one designed by Yoshihiro Kawaoka, Ph.D. — was conducted at the University of Wisconsin-Madison, and involved recombinant DNA (rDNA) methods.<sup>27</sup> The research team clipped a gene from a H5N1 cell and “stitched” it together with genes from a human H1N1 virus cell.<sup>28</sup> Research, like Dr. Kawaoka’s that uses rDNA techniques, is subject to NIH Guidelines which instruct the research institution not to permit any such research unless it has first been reviewed and approved by an Institutional Biosafety Committee (IBC).<sup>29</sup> An IBC consists of at least five members, including two community members, who collectively have “experience and expertise in recombinant [DNA] technology and the capability to assess the safety of recombinant [DNA] research and to identify any potential risk to public health or the environment.”<sup>30</sup> The University of Wisconsin-Madison’s IBC that reviewed and approved Dr. Kawaoka’s study<sup>31</sup> had 17 members, 15 of whom were employed by the University as faculty or staff.<sup>32</sup>

An IBC’s review determines the level of biosafety laboratory standards that should be applied to proposed research pursuant to NIH’s rDNA Guidelines (Guidelines).<sup>33</sup> These Guidelines specify for IBCs the level of biosafety standards to be employed based on the biological material on which the research is being conducted.<sup>34</sup> When the research involves H5N1 and when it could result in creating a more virulent and less treatable form of influenza, then more stringent biosafety standards might apply than provided for in the Guidelines.<sup>35</sup> In this case, an IBC is instructed to refer the matter as a “major action” to NIH and its Recombinant DNA Advisory

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26. *How Reviewers Score Applications*, NAT’L INST. OF HEALTH, NAT’L INST. OF ALLERGY & INFECTIOUS DISEASES, <http://www.niaid.nih.gov/researchfunding/grant/strategy/Pages/5scoring.aspx> (last updated Aug. 1, 2013).

27. See Imai et al., *supra* note 15, at 427.

28. See Martin Enserink, *Public At Last, H5N1 Study Offers Insight Into Virus’s Possible Path to Pandemic*, 336 SCI. 1494 (2012).

29. See NAT’L INST. OF HEALTH, NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (NIH GUIDELINES) 27 (2013), available at [http://oba.od.nih.gov/rdna/nih\\_guidelines\\_oba.html](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html).

30. See *id.* at 26.

31. See Imai et al., *supra* note 15, at 427.

32. See UNIV. OF WISCONSIN, Institutional Biosafety Committee 2011-2012 Member Roster, <http://www.ehs.wisc.edu/ibc.htm>

33. See generally NAT’L INST. OF HEALTH, *supra* note 29, at 13.

34. See *id.*

35. See *id.* at 21-22.

Committee (RAC).<sup>36</sup> The University of Wisconsin-Madison's IBC reviewed Dr. Kawaoka's study proposal, but the IBC did not refer the proposal to NIH and RAC for federal review, even though the research team proposed creating a new strain of H5N1 that was virulent and much more transmissible among humans than what otherwise occurred in nature.<sup>37</sup> Instead, the University of Wisconsin's IBC approved the study locally and, with that approval, the research began.<sup>38</sup>

In both of the studies, researchers created a new pathogen through genetic manipulation of a naturally occurring H5N1 virus.<sup>39</sup> They then infected laboratory ferrets with the new pathogen.<sup>40</sup> Ferrets are considered to be a good model for human influenza infection because, like humans, ferrets can spread seasonal influenza.<sup>41</sup> The researchers next observed that the genetically modified H5N1 was transmitted to uninfected ferrets.<sup>42</sup> It was through this observation that the researchers concluded it was possible for an avian H5N1 strain that infected a mammal to undergo genetic changes so as to also become easily transmissible among those mammals.<sup>43</sup>

The researchers also discovered that very few genetic changes may be necessary to convert an H5N1 strain capable of leaping the species barrier to infect a human into a strain that is also capable of airborne transmission between humans.<sup>44</sup> Each of the two research teams found only four or five genetic changes between the H5N1 strain with which they started and the modified H5N1 that was easily transmitted between the ferrets.<sup>45</sup> This led the researchers to their final conclusions that avian H5N1 is not incapable of making the genetic changes necessary to become easily transmissible among humans, and that those genetic changes may be so few as to justify the view that an H5N1 pandemic is a real public health threat.<sup>46</sup>

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36. See *id.* at 32.

37. The article describing the Kawaoka Study describes the review and approval it received, and, while it refers to the University of Wisconsin's IBC review and approval, it does not describe any review by NIH or RAC prior to the start of the research. See Imai et al., *supra* note 15, at 427.

38. See Imai et al., *supra* note 15, at 427.

39. See Herfst et al., *supra* note 15, at 1538; Imai et al., *supra* note 15, at 423. See also Martin Enserink, *Controversial Studies Give Deadly Flu Virus Wings*, 334 SCI. 1192, 1192 (2012).

40. See Herfst et al., *supra* note 15, at 1536-37; Imai et al., *supra* note 15, at 423.

41. See Herfst et al., *supra* note 15, at 1536-37; Imai et al., *supra* note 15 at 423. See Nicole M. Bouvier & Anice C. Lowen, *Animal Models for Influenza Virus Pathogenesis and Transmission*, 2 VIRUSES 1530, 1549 (2010).

42. See Herfst et al., *supra* note 15, at 1539; Imai et al., *supra* note 15, at 424.

43. See Herfst et al., *supra* note 15, at 1539; Imai et al., *supra* note 15, at 427.

44. See Herfst et al., *supra* note 15, at 1539, 1541; Imai et al., *supra* note 15, at 427.

45. See *id.* at 1539; Imai et al., *supra* note 15, at 424.

46. See Herfst et al., *supra* note 15, at 1541; Imai et al., *supra* note 15, at 427.

Each of the research teams drafted their experiments, results, and conclusions and submitted their articles for publication. One of the articles was accepted for publication in *Science* and the other in *Nature*.<sup>47</sup> Just before publication, however, the journals' editors became concerned that publication of these studies posed a bioterror risk.<sup>48</sup> The editors sought input from NIH and its National Science Advisory Board for Biosecurity (NSABB) as to whether the publication of the studies created an unacceptable biosecurity risk.<sup>49</sup> The concern was that the publications could provide a blueprint for creating a lethal and transmissible pathogen that could be misused for terrorism.<sup>50</sup> NSABB reviewed the studies and recommended that both journals publish only redacted versions to eliminate the description of how the research teams created the new pathogens they studied.<sup>51</sup>

NSABB's recommendation started a firestorm of controversy.<sup>52</sup> At issue was the value of these research findings to influenza scientists and public health officials who sought to prepare for an influenza pandemic, as compared to the risk that the research posed to national security.<sup>53</sup>

Once it became clear that the new pathogens had not been lethal among the ferrets in either experiment, and that the methods of the experiments were available as a result of earlier published papers and presentations at scientific conferences, NSABB reversed itself.<sup>54</sup> It recommended that both journals publish each of the articles without redaction.<sup>55</sup> The articles were published later in 2012.<sup>56</sup>

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47. See Franz, *supra* note 2, at 11.

48. Robert Roos, *Fouchier Study Reveals Changes Enabling Airborne Spread of H5N1*, UNIV. OF MINNESOTA CTR. FOR INFECTIOUS DISEASE RESEARCH & POLICY (June 21, 2012), <http://www.cidrap.umn.edu/news-perspective/2012/06/fouchier-study-reveals-changes-enabling-airborne-spread-h5n1>.

49. *Id.*

50. See *id.* See also Kenneth I. Berns et al., *Adaptations of Avian Flu Virus Are A Cause For Concern*, 482 NATURE 153, 154 (2012).

51. Franz, *supra* note 2, at 41. Press Release, Nat'l Inst. of Health, Press Statement on the NSABB Review of H5N1 Research (Dec. 20, 2011), available at <http://www.nih.gov/news/health/dec2011/od-20.htm>.

52. See, e.g., Pallab Ghosh, *H5N1 Research Censorship 'Problematic'*, BBC NEWS (May 2, 2012, 1:01 PM), <http://www.bbc.co.uk/news/health-17914706>; Jack Shafer, *Why Are We Censoring Bird Flu Science?* REUTERS (Dec. 22, 2011), <http://blogs.reuters.com/jackshafer/2011/12/22/why-are-we-censoring-bird-flu-science/>; Arthur Caplan, *When Censoring Science Makes Sense*, CNN.COM (Dec. 21, 2011, 7:54 PM), <http://www.cnn.com/2011/12/21/opinion/caplan-flu-science/index.html>; Josh Fischman, *Dangerous Bird-Flu Papers Should Be Partly Censored, Federal Panel Says*, THE CHRON. OF HIGHER EDUC. (Dec. 20, 2011), <http://chronicle.com/article/Dangerous-Bird-Flu-Papers/130140/>.

53. See Fischman, *supra* note 52.

54. See Franz, *supra* note 2, at 42.

55. See *id.*

56. See Herfst et al., *supra* note 15. See Imai et al., *supra* note 15.



B. *The Discovery Imperative and Bias in Science*

To the scientist, “discovery is everything.”<sup>57</sup> That is how Harvard biologist Edward O. Wilson, Ph.D., describes it. Scientists, he says, “know the first rule of the professional game book: Make an important discovery, and you are a successful scientist . . . . You go into the textbooks.”<sup>58</sup> It goes deeper than success and fame, however. Discovery drives the scientist at an emotional level. It is “thrilling,” Dr. Wilson says.<sup>59</sup> “There is no feeling more pleasant, no drug more addictive, than setting foot on virgin soil.”<sup>60</sup> Meanwhile, if, as a scientist, you “[f]ail to discover . . . you are little or nothing in the culture of science, no matter how much you learn and write about science.”<sup>61</sup>

If Dr. Wilson is to be believed, then discovery is an imperative in the professional ethos of science. As such, it demands of researchers a single-minded zeal to add to the body of scientific knowledge. To punctuate his point, Dr. Wilson borrows a quote: “The scientific method is doing your damndest, no holds barred.”<sup>62</sup>

Such “investigative zeal”<sup>63</sup> leads, in turn, to a professional bias toward conducting research and blinding scientists to the risks that an experiment can pose to the public. It is a close kin to what others refer to as a “White Hat Bias” in science; a “bias leading to distortion of information,” which, in the case of DURC, is a protocol’s risks and benefits “in the service of what may be perceived to be righteous ends.”<sup>64</sup> Because it arises from the profession’s imperative to discover, this bias affects not only the scientist who designs and conducts an experiment, but also every other scientist who might have a role in reviewing the experiment for funding or for institutional approval.<sup>65</sup> In short, this bias of the profession travels from one degree to another with each and every scientist no matter the role he or she plays, if any, with respect to a particular experiment.<sup>66</sup>

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57. Edward O. Wilson, *Scientists, Scholars, Knaves and Fools*, 86 AM. SCI. 6, 6 (emphasis added).

58. *Id.* at 7.

59. *Id.*

60. *Id.*

61. *Id.*

62. Wilson, *supra* note 57, at 6 (quoting, without citation, PERCY W. BRIDGMAN, REFLECTIONS OF A PHYSICIST 535 (2d ed. 1955)).

63. I borrow this phrase from Professor Richard Saver. Richard S. Saver, *Is it Really All About the Money? Reconsidering Non-Financial Interests in Medical Research*, 40 J.L. MED. & ETHICS 467, 469 (2012).

64. Mark B. Cope & David B. Allison, *White Hat Bias: A Threat to the Integrity of Scientific Reporting*, 99 ACTA PAEDIATRICA 1615, 1615 (2010).

65. See Saver, *supra* note 63, at 468.

66. See *id.*

In particular, the discovery imperative creates a bias among scientists to overvalue the benefits of an experiment and to undervalue its risks, even among scientists whose roles are limited to participating in the institutional review of an experiment proposed by a colleague. The bias is so pervasive that one experienced chair of an Institutional Review Board (IRB) wrote about it. He observed that researchers on IRBs “share a constantly reinforced bias for experimentation per se,” which, he said, “normally follow[ed] the socialization of scientists.”<sup>67</sup> This professional bias, the author opined, created a real “potential for inappropriate overvaluation of benefits over risks . . . .”<sup>68</sup> Other commentators have found additional anecdotal evidence of such a bias.<sup>69</sup> For example, Professor Richard Saver describes instances in which investigators conducting human subjects research and the IRBs that approved the research have been criticized for allowing the researchers’ “investigative zeal” to result in subjects being exposed to potentially unjustifiable research risks, even in the absence of financial conflicts of interest.<sup>70</sup>

All of the above suggests that the ever-present bias associated with the discovery imperative could have been at work during the design, funding, and institutional approval of the ferret studies. It certainly would explain why there were several lost opportunities prior to the onset of the research to account for the dual use risks of each study and to assure that they were more than offset by research benefits. For example, the discovery imperative can explain why the lead scientists on each of the studies designed their research protocols without expressly completing a dual use risk-benefit analysis. Likewise, it also can explain why the IBC that reviewed and approved Dr. Kawaoka’s study failed to account for the full measure of the biosafety risks of the experiment.<sup>71</sup>

The discovery imperative and its associated biases also explain, at least in part, why a public policy that relies completely on scientists to identify and manage dual use risks is unsustainable. There must be some external check on that bias before we can expect the public to trust researchers and research institutions to manage DURC effectively. This provides one way that regulation generally, and the proposed federal rules for oversight of DURC in particular, play a vital role.

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67. Peter C. Williams, *Success in Spite of Failure: Why IRBs Falter in Reviewing Risks and Benefit*, IRB: ETHICS & HUM. RES., May-June 1984, at 1, 2.

68. *Id.*

69. Saver, *supra* note 64, at 469.

70. *Id.*

71. See Imai et al., *supra* note 15, at 427. See *supra* text accompanying note 37.

C. *Bounded Self-Regulation as a Means for Promoting Public Trust in Scientists*

As I have written elsewhere, regulating for trust is tricky.<sup>72</sup> The law is a powerful vehicle for expressing and enforcing important social norms. It can signal to researchers and research institutions that they are obligated to protect the public from dual use risks that are not clearly justified by the benefits of that research which give rise to those risks.<sup>73</sup> By creating a means to hold science accountable when its practitioners breach that obligation, the law can also provide a basis for the public to trust that science has a strong incentive to live up to its obligation.<sup>74</sup>

For this to work, however, the law must tread somewhat lightly. If, in the hope of gaining greater compliance, the law takes primary control of DURC oversight, the entire effort to promote public trust in the research enterprise could backfire.<sup>75</sup> By taking primary control of DURC oversight, the law would signal that scientists and research institutions cannot be trusted to sufficiently protect public safety.<sup>76</sup> Why else would it be necessary to regulate them so completely?

In the end, promoting public trust in researchers and research institutions to manage dual use risks requires the law to hit a regulatory sweet spot — enough regulation to provide a foundation for the public to believe that scientists have a strong incentive to abide by the norm of protecting public safety, but not so much regulation as to signal that scientists are not sufficiently trustworthy to be given substantial authority to oversee DURC. A model for hitting that sweet spot is bounded self-

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72. See generally Robert Gatter, *Walking the Talk of Trust in Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest*, 52 EMORY L.J. 327 (2003) [hereinafter Gatter, *Walking the Talk of Trust*] (discussing regulating for trust in human subjects research); Robert Gatter, *Faith, Confidence, and Health Care: Fostering Trust in Medicine through Law*, 39 WAKE FOREST L. REV. 395 (2004) [hereinafter Gatter, *Faith, Confidence, and Health Care*] (discussing the promotion of consumer confidence in healthcare) .

73. See Gatter, *Walking the Talk of Trust*, *supra* note 73, at 361-99.

74. See *id.* at 372-73.

75. See *id.* at 391-92.

76. See *id.* at 389, 392. Here is simple example that I shared when making a similar point in earlier writing:

Data from Minnesota reveals that, when regulators announced their intent to audit a larger proportion of taxpayers and increase the penalties for evasion, the incidence of tax evasion rose. Meanwhile, when regulators announced that the voluntary compliance rate was high, compliance increased still more. Thus, taxpayers appear to interpret the law as a signal of the trustworthiness of their fellow taxpayers to voluntarily pay their fair share of tax. Laws increasing audits and penalties signaled that the public cannot be trusted to pay their taxes voluntarily.

Gatter, *Faith, Confidence, and Health Care*, *supra* note 72, at 435.

regulation.<sup>77</sup> Under this model, regulators set boundary procedures and standards by which a target of regulation must abide or suffer some form of legally mandated penalty.<sup>78</sup> Within these boundaries, however, those who are subject to the regulations are permitted to exercise their own judgment about how to apply the boundary standards, and regulators defer to those judgments.<sup>79</sup>

This regulatory technique is particularly useful where the goal of regulation is to signal the trustworthiness of the targets of regulation so as to increase public trust. Accordingly, it has a unique application in health law<sup>80</sup> where trust is viewed as exceptionally important.<sup>81</sup>

The value of promoting trust in the context of scientific research is clear. Society needs the expertise of scientists to advance our collective knowledge about our world, which, of course, requires experimentation. Society might want to assess the risks and benefits of scientists' experiments on a case-by-case basis. Even then, however, it requires the expertise of scientists to identify those risks and benefits; to assess the probability that the risks and benefits actually materialize; and to place those risks, benefits, and probabilities into context for lay people. In short, there is no way to escape

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77. See Gail Agrawal, *Resuscitating Professionalism: Self-Regulation in the Medical Marketplace*, 66 Mo. L. Rev. 341 (2001); Cynthia Estlund, *Rebuilding the Law of the Workplace in an Era of Self-Regulation*, 105 COLUM. L. REV. 319 (2005); and Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, (2000). "Bounded regulation" as I use it here is akin to "audited self-regulation" about which there is a significant literature. See Douglas C. Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171 (1995); and Sunni Yuen, *Exporting Trust with Data: Audited Self-Regulation as a Solution to Cross-Border Data Transfer Protection Concerns in the Offshore Outsourcing Industry*, 9 COLUM. SCI. & TECH. L. REV. 41 (2007-2008). "Audited self-regulation" is defined as "the delegation of power to a nongovernmental entity, by Congress or a federal agency, to implement laws or agency regulations, with powers of review and independent action retained by a federal agency." See Douglas C. Michael, *supra* note 77, at 176-77. Because phrase "audited self-regulation" in the strictest sense involves only a delegation of powers to another "entity" outside of government, I do not use the phrase here. Instead, I use "bounded self-regulation" to capture all of the aspects of delegation by Congress or a federal agency that retains powers of oversight, but also to encompass delegations to individuals, professions, and institutions that are not necessarily organized as a legal entity. For an example of a similar use of law to promote self-regulation, see Agrawal, *Resuscitating Professionalism*, *supra* note 77.

78. DOUGLAS C. MICHAEL, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, FEDERAL AGENCY USE OF AUDITED SELF-REGULATION AS A REGULATORY TECHNIQUE 5-6 (1993), available at <http://archive.org/details/gov.acus.1993.audit>

79. *Id.* at 5, 7.

80. See Agrawal, *supra* note 77, at 55; Gatter, *Walking the Talk of Trust*, *supra* note 73, at 361.

81. See Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463 (2002). See also Gatter, *Faith, Confidence, and Health Care*, *supra* note 73, at 433.

our reliance on scientists to conduct experiments, as well as to help us determine whether the risks of research are worth the benefits. Given the reality of our reliance on the expertise of scientists, society needs a basis for trusting not only in the technical expertise of scientists, but also in their fidelity to our collective interests, which, at times, may mean halting the pursuit of discovery in the name of public safety.

Given the importance of public trust in scientific research, it is not surprising to find the regulatory model of bounded self-regulation already in use. Medical researchers and their institutions have been deputized by federal law to review proposed research involving human research subjects to assure that the benefits of research outweigh the risks, and that human subjects participate on an informed and voluntary basis.<sup>82</sup> Likewise, federal policy deputizes scientists and their institutions to review proposed research involving rDNA techniques to assure that the research will comply with applicable biosafety standards under federal guidelines.<sup>83</sup> In each instance, procedures and standards are set by federal law and the task of administering those standards is delegated to researchers at the research institutions in which proposed research will take place if approved.<sup>84</sup> Research institutions that fail to abide by the boundary procedures and standards are subject to losing their eligibility for federal research funds,<sup>85</sup> which is a powerful incentive for compliance. In this way, these laws fall within the realm of bounded self-regulation because the law signals, through its delegation of authority, that researchers and research institutions are trustworthy, while also providing boundaries for the exercise of discretion and a substantial penalty for violating those boundaries.

Using this model of bounded self-regulation does not guarantee success. Despite employing this model, the regulations both for protecting human subjects and for overseeing rDNA research are rife with flaws. Where the government regulates as a tool to promote public trust, the model of bounded self-regulation gives the government an opportunity to succeed where a command and control model does not.

#### D. *New Federal Policies for DURC Oversight*

In response to the ferret studies, the federal government developed two new policies for the oversight of DURC. The first policy was released on March 29, 2012 (2012 Policy),<sup>86</sup> and it requested that all federal agencies

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82. See generally 45 C.F.R. pt. 46(A) (2009).

83. See NAT'L INST. OF HEALTH, *supra* note 29, at 26.

84. *Id.* at 11.

85. See 45 C.F.R. § 46.122 (2009); NAT'L INST. OF HEALTH, *supra* note 29, at 11.

86. See U.S. DEP'T OF HEALTH & HUMAN SERVS., UNITED STATES GOVERNMENT POLICY FOR OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN 1, 2 (2012), available at

conducting or funding life sciences research review their projects to determine if any involve DURC and to report their findings to the Assistant to the President for Homeland Security and Counterterrorism.<sup>87</sup> Additionally, if an agency finds that it is funding or conducting any DURC, the 2012 Policy provides that the agency should work with the researcher and research institution to develop a plan to mitigate the dual use risks.<sup>88</sup> If those risks cannot be mitigated adequately, then agencies may take more extreme measures, such as classifying the research or terminating its federal funding.<sup>89</sup>

The second policy is a policy in name only. From an administrative law perspective, it is proposed rule-making for which notice was provided and comments requested on February 22, 2013 (2013 Proposed Rules).<sup>90</sup> The 2013 Proposed Rules describe the DURC oversight responsibilities of researchers, research institutions, and federal agencies.<sup>91</sup> Researchers would be obligated to assess whether their proposed research meets the definition of DURC and, if so, to work with the research institution's review board to develop a dual use risk mitigation plan.<sup>92</sup> If finalized, the 2013 Proposed Rules would require research institutions that receive federal funding to establish a board to review research proposals for the purpose of determining if they involve DURC and, if so, develop and enforce dual use risk mitigation plans for the research.<sup>93</sup> The board may be internal or external to the research institution, and it may be a unique committee or an existing committee (such as an IBC) whose charge is expanded to include DURC oversight.<sup>94</sup> The 2013 Proposed Rules do not require a particular make-up of the committee's membership, so long as it has "sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at a given research facility" and has knowledge of dual use issues, federal law, and available risk mitigation alternatives.<sup>95</sup> Additionally, a research institution must notify the agency

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<http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf> [hereinafter 2012 DURC DRAFT POLICY].

87. See *id.* at 3, 4.

88. See *id.* at 3.

89. *Id.* at 3-4.

90. See U.S. DEP'T OF HEALTH & HUMAN SERVS., UNITED STATES GOVERNMENT POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN 11 (2013), <https://www.phe.gov/s3/dualuse/documents/oversight-durc.pdf> [hereinafter 2013 DURC DRAFT POLICY].

91. See *id.* at 4.

92. *Id.* at 8.

93. *Id.* at 10.

94. *Id.* at 11.

95. 2013 DURC DRAFT POLICY, *supra* note 90, at 11.

funding the research, if and when, the institution's review board identifies the funded research as DURC, and it must provide that agency with a copy of the dual use risk mitigation plan developed by the institution.<sup>96</sup> As for funding agencies, the 2013 Proposed Rules incorporate the powers and responsibilities described in the 2012 Policy.<sup>97</sup> Any institution subject to the 2013 Proposed Rules would risk losing its eligibility for federal research funding if it failed to comply.<sup>98</sup>

The 2012 Policy and the 2013 Proposed Rules are positive steps to promoting public trust in scientists and research institutions conducting DURC, because they employ the bounded self-regulation model. Together they set boundary standards and procedures that will add to the accountability of researchers and research institutions with respect to the dual use risks that their research imposes on the public. First, they require researchers and research institutions to be deliberate in assessing whether their proposed research meets the definition of DURC and, if so, to identify the precise dual use risks at issue and then develop a plan of mitigation.<sup>99</sup> This diminishes the likelihood that proposed research will proceed on the assumption that the research does not pose any dual use risks or that dual use risks are simply a price of pursuing discovery. Second, they provide for the funding agency to make a fresh assessment of dual use risks and mitigation plans for DURC that they fund.<sup>100</sup> Moreover, they empower the funding agency to classify research or even refuse to fund research that the agency perceives to have dual use risks that cannot be sufficiently mitigated.<sup>101</sup> In this way, the agency's review is a potentially powerful check on the ability of the researcher and research institution to identify and manage dual use risks effectively. It forces scientists and their institutions either to stand in the shoes of the funding agency when managing DURC, or risk that the funding agency will step in to manage or withhold funding for the research.

At the same time, the 2012 Policy and the 2013 Proposed Rules rely on researchers and research institutions to take the lead in the oversight of DURC.<sup>102</sup> They defer to the researcher and his or her institution to identify DURC and to develop plans for mitigation.<sup>103</sup> Federal regulators override

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96. *Id.* at 10-11.

97. *Id.* at 2, 13.

98. *Id.* at 6.

99. *Id.* at 10-11; 2012 DURC DRAFT POLICY, *supra* note 86, at 3.

100. 2013 DURC DRAFT POLICY, *supra* note 90, at 4.

101. *Id.* at 13; 2012 DURC DRAFT POLICY, *supra* note 86, at 3.

102. 2013 DURC DRAFT POLICY, *supra* note 90, at 6-7; 2012 DURC DRAFT POLICY, *supra* note 86, at 3-4.

103. 2013 DURC DRAFT POLICY, *supra* note 90, at 9; 2012 DURC DRAFT POLICY, *supra* note 86, at 3-4.

the institutional plan to manage DURC only where they find it significantly lacking.<sup>104</sup> This leaves plenty of opportunity and an incentive for science to develop its own norms for protecting the public in the case of DURC.

This is not to say that the 2012 Policy and the 2013 Proposed Rules are perfect. They are not. In particular, the 2013 Proposed Rules should instruct scientists and their institutions to not only assess and mitigate dual use risks, but to articulate why those risks, once mitigated, are justified by the likely benefits of the research. The rules should also identify whether research benefits must merely, clearly, or substantially outweigh dual use risks, and they should require that the institutional review process apply that standard. Finally, the 2013 Proposed Rules should do more than demand life sciences expertise on the institutional committees that review DURC. Those committees should be required to have a sufficient number of institutionally unaffiliated members to act as an additional check on the bias created by the discovery imperative.

In the end, Dr. Franz and I agree that life scientists and their research institutions should not be over-regulated because doing so undermines trust. Yet, fear of over-regulation should not result in closing the door on all regulation. Instead, the answer is finding the right regulatory technique that allows scientists to regulate themselves within legal boundaries that help assure the public that the profession of science has a strong incentive to protect society while pursuing the next discovery.

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104. 2013 DURC DRAFT POLICY, *supra* note 90, at 6-7; 2012 DURC DRAFT POLICY, *supra* note 86, at 3-4.



