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Preparing for the Apocalypse: a Multi-Prong Proposal to Develop Countermeasures for Biological, Chemical, Radiological, and Nuclear Threats

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PREPARING FOR THE APOCALYPSE: A MULTI-PRONG PROPOSAL TO DEVELOP COUNTERMEASURES FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR THREATS

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"Governments will always play a huge part in solving big problems. . . . They also fund basic research, which is a crucial component of the innovation that improves life for everyone."

—Bill Gates[1]

The false alarm of a Hawaiian nuclear attack in January 2018 is an example of the lack of U.S. preparedness for attacks using nuclear and other weapons of mass destruction. To address such threats, this Article proposes the establishment of a nationwide integrated defense of health countermeasures initiative (DHCI). DHCI is a multi-prong program to create a defensive triad comprising government, private

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1 COLLABORATIVE INNOVATION IN DRUG DISCOVERY: STRATEGIES FOR PUBLIC AND PRIVATE PARTNERSHIPS x (Rathnam Chaguturu ed., 2014) (alteration in original) [hereinafter Chaguturu].

industry, and academia to develop countermeasures for health threats posed by chemical, biological, radiological, and nuclear (CBRN) attacks. Key elements of our proposal include the use of the government's Other Transaction Authority to simplify procurement arrangements, the establishment of public-private partnerships with an information commons for the sharing and use of certain information and trusted intermediaries to protect proprietary information pursuant to cooperative research and development agreements, and the creation of a network of incubators sited in ecosystems of excellence. Although our proposal focuses on health countermeasures, it may be applied to other urgent national needs, such as rebuilding U.S. infrastructure.

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INTRODUCTION: TWO MINUTES TO THE APOCALYPSE

On January 13, 2018, the Hawaiian government sent a text to its citizens announcing that a nuclear ballistic missile strike was imminent and instructing residents to seek shelter.[2] It took more than thirty minutes for the government to announce that the notice was sent in error. Several days later, the Japanese government also sent an erroneous notice of an imminent attack, which it corrected several minutes later.[3] Ballistic missile tests by North Korea[4] have triggered memories of the Cuban Missile Crisis in 1962, when the United States and the Soviet Union were on the brink of nuclear war. Had the Hawaii alert been accurate, where exactly were residents to seek shelter? Or are we back to the days of "duck and cover?"

In 2018, the Russian government used a weapons-grade nerve agent in an apparent attempt to assassinate a former spy and his daughter in Britain.[5] In response, the U.K. Minister of Defence announced that the United Kingdom was spending £48 million to set up a chemical weapons defense center and was vaccinating thousands of British troops against anthrax.[6]

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2 Adam Nagourney et al., *Hawaii Panics After Alert About Incoming Missile Is Sent in Error*, N.Y. TIMES (Jan. 13, 2018), https://www.nytimes.com/2018/01/13/us/hawaii-missile.html.

3 *See* Madison Malone Kircher, *Japan Sends False Alert Over Impending North Korean Missile Attack*, INTELLIGENCER (Jan. 16, 2018), http://nymag.com/selectall/2018/01/japan-sends-false-missile-alert-about-north-korea-attack.html [https://perma.cc/THA6-LWPG].

4 *See* Hasani Gittens, *Trump to North Korean Leader Kim: My Nuclear Button 'Is Bigger & More Powerful'*, NBC NEWS (Jan. 2, 2018), https://www.nbcnews.com/politics/donald-trump/trump-north-korean-leader-kim-my-nuclear-button-bigger-more-n834196 [https://perma.cc/L3W7-JUYN]; *see also* Lindsey Bever et al., *The Doomsday Clock is Now Just 2 Minutes to 'Midnight,' the Symbolic Hour of the Apocalypse*, WASH. POST (Jan. 25, 2018), https://www.washingtonpost.com/news/speaking-of-science/wp/2018/01/25/after-a-missile-scare-and-insult-war-with-north-korea-its-time-to-check-the-doomsday-clock/?utm_term=.72758f5758ad [https://perma.cc/6SCK-JG7P].

5 *See Novichok: Murder Inquiry After Dawn Sturgess Dies*, BBC (July 9, 2018), https://www.bbc.com/news/uk-44760875 [https://perma.cc/U8HE-DV56]. Two more Britons were poisoned by the same nerve agent in July 2018, causing at least one death. *Id.*

6 Ewen MacAskill, *UK to Set Up £48m Chemical Weapons Defence Centre*, GUARDIAN (Mar. 14, 2018, 8:01 PM), https://www.theguardian.com/politics/2018/mar/15/uk-set-up-48m-chemical-weapons-defence-centre-gavin-williamson [https://perma.cc/B7JB-4ENF].

Anthrax-laced letters killed five and sickened fifteen Americans in 2001.[7] Syria used sarin gas on its own citizens in 2017 and 2013.[8] If smallpox or other pathogens are weaponized, will we have adequate antidotes and vaccines available? What bacteriological cures or vaccines do we need to fight other weaponized "super bugs" or the spread of Ebola?

The fact is that governments worldwide are woefully unprepared to address threats of chemical, biological, radiological, and nuclear (CBRN) attacks and other emergency events that can cause massive human casualties.[9] Such threats come not only from states at war using traditional military means of delivery, but also from non-state sponsored terrorist groups[10] and naturally occurring diseases such as antibiotic-resistant bacteria and Ebola. Even though CBRN attacks are a

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7 *See* Lawrence O. Gostin et al., *The Model State Emergency Health Powers Act: Planning for and Response to Bioterrorism and Naturally Occurring Infectious Diseases*, 288 J. AM. MED. ASS'N 622 (2002); Larry M. Bush et al., *Index Case of Fatal Inhalational Anthrax Due to Bioterrorism in the United States*, 345 NEW ENG. J. MED. 1607, 1610 (2001), http://www.nejm.org/doi/full/10.1056/NEJMoa012948 [https://perma.cc/K5SU-X24E] ("Coworkers report that the patient had closely examined a suspicious letter containing powder on September 19, approximately eight days before the onset of illness."); John A. Jernigan et al., *Bioterrorism-Related Inhalational Anthrax: The First 10 Cases Reported in the United States*, 7 EMERGING INFECTIOUS DISEASES 933, 933 (2001), https://wwwnc.cdc.gov/eid/article/7/6/pdfs/01-0604.pdf [https://perma.cc/YER5-MMEA] ("Epidemiologic investigation indicated that the outbreak, in the District of Columbia, Florida, New Jersey, and New York, resulted from intentional delivery of *B. anthracis* spores through mailed letters or packages.").

8 *Sarin Gas Used as Weapon in Syria, Says Chemical Weapons Watchdog*, NBC NEWS (June 30, 2017, 5:44 AM), https://www.nbcnews.com/news/world/sarin-gas-used-weapon-syria-says-chemical-weapons-watchdog-n778466 [https://perma.cc/9XJH-BTN6].

9 *See Global Proliferation of Weapons of Mass Destruction: Hearings Before the Permanent Subcomm. on Investigations of the Comm. on Governmental Affairs U.S. S.: Part I*, 104th Cong. (1995); OFFICE OF TECH. ASSESSMENT, OTA-ISC-559, PROLIFERATION OF WEAPONS OF MASS DESTRUCTION: ASSESSING THE RISKS 4–5 (1993).

10 *See Global Proliferation of Weapons of Mass Destruction*, *supra* note 9; PROLIFERATION OF WEAPONS OF MASS DESTRUCTION, *supra* note 9; *see also* David P. Fidler, *Public Health and National Security in the Global Age: Infectious Diseases, Bioterrorism, and Realpolitik*, 35 GEO. WASH. INT'L L. REV. 787, 817 (2003) ("The growth of terrorism as a phenomenon in international relations has presented realism with a dilemma because terrorism's increased prominence suggests that (1) states do not have a monopoly on violence in international politics, and (2) the anarchical structure of the international system is not the only source of conflict and violence."); *Disruptive Technologies Push Bioterrorism to a Whole New Level*, MED. FUTURIST (Sept. 21, 2016), http://medicalfuturist.com/disruptive-technologies-bioterrorism [https://perma.cc/7J9L-BBD7].

recognized national security hazard and public health concern,[11] vaccines and therapeutics are available for only a small number of these threats, leaving large populations in the United States and elsewhere susceptible to such attacks.[12] Successfully addressing this threat will require combining the "rapidly growing" and "complex [governmental] science and technology base"[13] with the more nimble and innovative research and development capabilities of academic and industry scientists to speed up the adoption of the information technology innovations necessary to address CBRN threats.

Also key to developing effective countermeasures is promoting academic entrepreneurship[14] and translational medicine[15] by facilitating

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11 *See* RICHARD A. FALKENRATH ET AL., AMERICA'S ACHILLES' HEEL: NUCLEAR, BIOLOGICAL, AND CHEMICAL TERRORISM AND COVERT ATTACK 221–25, 228–29 (1998) (discussing concerns about nuclear, biological, and chemical terrorist attacks in asymmetrical conflict with the United States).

12 *See* HHS Public Health Emergency Medical Countermeasures Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats, 72 Fed. Reg. 20117 (Apr. 23, 2007); Jason Matheny et al., *Incentives for Biodefense Countermeasure Development*, 5 BIOSECURITY & BIOTERRORISM 228 (2007), http://docs.house.gov/meetings/IF/IF14/20160519/104953/HHRG-114-IF14-20160519-SD006.pdf [https://perma.cc/3XZ8-RQCN] ("[M]edical countermeasures are available for only a fraction of biological threats, including those representing the highest risk, as determined by the Department of Homeland Security's (DHS) threat assessments.").

13 *See generally* NATIONAL INNOVATION SYSTEMS: A COMPARATIVE ANALYSIS 64 n.3 (Richard R. Nelson ed., 1993).

14 Constance E. Bagley & Christina D. Tvarnø, *Promoting "Academic Entrepreneurship" in Europe and the United States: Creating an Intellectual Property Regime to Facilitate the Efficient Transfer of Knowledge from the Lab to the Patient*, 26 DUKE J. COMP. & INT'L L. 1, 3 (2015). On the different types of entrepreneurship, see Anat Alon-Beck, *The Law of Social Entrepreneurship—Creating Shared Value Through the Lens of Sandra Day O'Connor's iCivics*, 20 U. PA. J. BUS. L. (forthcoming), https://ssrn.com/abstract=3064448. *See also* BILL AULET & FIONA MURRAY, MURRAY TR. CENT. FOR MIT ENTREPRENEURSHIP, A TALE OF TWO ENTREPRENEURS: UNDERSTANDING DIFFERENCES IN THE TYPES OF ENTREPRENEURSHIP IN THE ECONOMY 3–4, 7–8 (2013), https://www.kauffman.org/-/media/kauffman_org/research-reports-and-covers/2013/05/a_tale_of_two_entrepreneurs_report.pdf [https://perma.cc/23YA-M5V3].

15 *See* John C. Reed, *NCATS Could Mitigate Pharma Valley of Death*, 31 GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (May 13, 2011), https://www.genengnews.com/gen-articles/ncats-could-mitigate-pharma-valley-of-death/3662/?page=1 [https://perma.cc/S2PP-U4GU]; *see also* Arti K. Rai et al., *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerating Drug Discovery*, 8 YALE J. HEALTH POL'Y L. & ETHICS 1, 4 (2008) (proposing a two-tier regime for promoting "intensive, large-scale collaboration between academics, who possess unique skills in designing assays that can identify promising targets, and pharmaceutical firms that hold libraries of potentially useful small molecules as trade secrets, making them largely off limits to these same academic scientists"). One of the

the movement of medical research and discoveries from "bench to bedside."[16] The pharmaceutical industry is highly concentrated,[17] and

National Institutes of Health (NIH) programs transferred to the National Center for Advancing Translational Sciences (NCATS) is the Molecular Libraries Probe Production Centers Network (MLPCN), "the first federally funded network to facilitate drug discovery by producing early-stage small molecule leads." Reed, *supra*. As Reed explained:

> These centers, most of which reside in universities and nonprofit research institutes across the U.S., provide federally funded researchers and even small biotechnology companies with access to drug discovery capabilities previously found only within large pharmaceutical companies. Those capabilities include large chemical libraries, assay development, ultra high-throughput robotic screening, cheminformatics, medicinal chemistry, project management, and several other drug discovery-related services that typically don't exist in academic labs and departments.

Id. The NCATS Pre-Clinical Research Toolbox includes multiple small molecule libraries containing more than 100,000 small molecules generated by academic researchers. *Compound Management*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCI., https://ncats.nih.gov/preclinical/core/compound [https://perma.cc/66MS-RVGJ] (last updated Sept. 24, 2018). These molecules are available for researchers doing "high-throughput screening (HTS) of small molecule libraries against assays containing target proteins to identify promising compounds that may lead to patentable drugs." Rai, *supra*, at 7.

16 *See* Constance E. Bagley & Christina D. Tvarnø, *Pharmaceutical Public-Private Partnerships: Moving from the Bench to the Bedside*, 4 HARV. BUS. L. REV. 373, 373–74 (2014).

> [G]overnments in the European Union (EU) and the United States have taken bold steps to promote the movement of medical research and discoveries from "bench to bedside," from the university laboratory to the patient. This "translation from the university laboratory to the healthcare sector [is facilitated by] the generation and support of start-ups, spin-offs, university-industry consortia, and other platforms." For example, in 2014, the National Institutes of Health (NIH) in the United States announced the $230 million Accelerating Medicines Partnership, which will bring together scientists from ten large pharmaceutical companies, several research foundations and nonprofit organizations, and the NIH and Food and Drug Administration to collaborate on multi-year, open-source projects. These projects are designed to bridge the gap between (i) cutting-edge genomics, proteomics, imaging and other medical research, and (ii) the new drugs and diagnostics needed to fight type 2 diabetes, Alzheimer's disease, lupus, and rheumatoid arthritis.

Id.; *see also* Editorial, *NIH Tries a New Approach to Speed Drug Development*, WASH. POST (Feb. 8, 2014), https://www.washingtonpost.com/opinions/nih-tries-a-new-approach-to-speed-drug-development/2014/02/08/bf30ba18-8ea1-11e3-b227-12a45d109e03_story.html?utm_term=.d5260b0a243f [https://perma.cc/847S-V6JZ]; *Accelerating Medicines Partnership (AMP)*, NAT'L INSTS. HEALTH, https://www.nih.gov/research-training/accelerating-medicines-partnership-amp [https://perma.cc/3J2T-KEYX] (last visited Sept. 30, 2018); *Budget*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCI., http://www.ncats.nih.gov/about/budget/budget.html [https://perma.cc/25G2-YNN6] (last updated Sept. 10, 2018); *Alliances at NCATS*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCI., https://ncats.nih.gov/alliances/about [https://perma.cc/UTA6-FKFB] (last updated Sept. 10, 2018); *About*, EUR. FED'N FOR

"[t]he development of new pharmaceuticals is both high risk and high cost,[18] with new drugs costing a billion dollars or more to bring to market."[19]

There is a critical need to establish a nationwide integrated public health defense infrastructure, platform, and services initiative (the Defense of Health Countermeasures Initiative, or DHCI) to address such threats. The multi-faceted initiative for addressing the threats of CBRN attacks we introduce in Part IV builds on the successes of the

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PHARMACEUTICAL SCI., http://www.eufeps.org/about [https://perma.cc/4YZS-A4VD] (last visited Sept 30, 2018).

17 "From 2003 to 2007, roughly 80 percent of all pharmaceutical patents granted pursuant to the Patent Cooperation Treaty were issued to firms domiciled in just thirteen developed countries." Bagley & Tvarnø, *supra* note 16, at 377 n.24; *see also* Anand Grover et al., *Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability Under the Right to Health*, 40 J.L. MED. & ETHICS 234, 238 (2012).

18 *See* AMERICA'S BIOPHARMACEUTICAL RESEARCH COS., INFECTIOUS DISEASES: A REPORT ON DISEASES CAUSED BY BACTERIA, VIRUSES, FUNGI AND PARASITES 46 (2013); Matheny et al., *supra* note 12, at 229 tbl.1. (titled *R&D Process for a Typical New Drug*); Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really $802 Million?*, 25 HEALTH AFF. 420 (2006); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003); Ismail Kola & John Landis, *Can the Pharmaceutical Industry Reduce Attrition Rates?*, 3 NATURE REVS. DRUG DISCOVERY 711 (2004).

19 Bagley & Tvarnø, *supra* note 16, at 379 (citing Valerie Gutmann Koch, *Incentivizing the Utilization of Pharmacogenetics in Drug Development*, 15 J. Health Care L. & Pol'y 263, 274 n.89, 276 (2012) (citing data showing that only 1 out of 60,000 compounds created by drug companies are highly successful, roughly 1 out of 6 drugs put into clinical trials are ultimately approved by the Food and Drug Administration (FDA), and more than 3% of drugs approved by the FDA are subsequently withdrawn due to negative side effects); PHARM. RESEARCH & MFRS. OF AM., PHARMACEUTICAL INDUSTRY: 2011 PROFILE 10 (2011); Koch, *supra*, at 274 n.87 (citing Donald W. Light & Rebecca Warburton, *Demythologizing the High Cost of Pharmaceutical Research*, 6 BIO-SCIENCES 34, 36, 38–39 (2011)); ALFONSO GAMBARDELLA, LUIGI ORSENIGO & FABIO PAMMOLLI, GLOBAL COMPETITIVENESS IN PHARMACEUTICALS: A EUROPEAN PERSPECTIVE 11–13 (2000).

> The productivity challenge in the pharmaceutical industry can be explained in part by an increase in R&D costs, reduced output, and depleted pipelines. Innovation losses in developing new drugs are increasing across the industry. Although the number of new, approved molecular entities has remained steady in the past ten years, the cost of new drug development has increased significantly in both the U.S. and the EU. The pharmaceutical industry in both the U.S. and the EU are looking for new ways to sustain pharmaceutical innovation and sell new products. At the same time, pharmaceutical enterprises suffer from inefficient internal processes to perform basic science and to assess the value of "proof of concept" inventions, especially when they involve distant knowledge domains.

Bagley & Tvarnø, *supra* note 16, at 379.

Defense Advanced Research Projects Agency (DARPA) and the Biomedical Advanced Research and Development Authority (BARDA), including their use of the federal government's Other Transaction Authority (discussed in Part III), combined with the use of public-private partnerships[20] of the sort currently used by participants in the European Union's Innovative Medicines Initiative (IMI),[21] the European Commission's Action Plan Against the Rising Threats from

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20 *See* Bagley & Tvarnø, *supra* note 14, at 3; Bagley & Tvarnø, *supra* note 16, at 373–74. *See also* LINDA PARKER, THE ENGINEERING RESEARCH CENTERS (ERC) PROGRAM: AN ASSESSMENT OF BENEFITS AND OUTCOMES i, 1 (1997), https://www.nsf.gov/pubs/1998/nsf9840/nsf9840.pdf [https://perma.cc/KQ58-MR7W] (describing the Engineering Research Centers Program, a government-university-industry partnership the National Science Foundation established in 1985 to enhance the global competitiveness of U.S. firms by creating "long-term collaborations between universities and industry" and "new industry-relevant knowledge at the intersections of the traditional disciplines," as well as by developing "a new generation of engineering leaders who are more capable of engaging successfully in team-based, cross-disciplinary engineering practice").

21 The European Union's Innovative Medicines Initiative (IMI), Europe's largest public-private partnership in the life sciences, was launched in 2008. *See History—the IMI Story So Far*, INNOVATIVE MEDS. INITIATIVE, https://www.imi.europa.eu/about-imi/history-imi-story-so-far [https://perma.cc/46B6-SCFM] (last visited Oct. 22, 2018). It has a budget of €5.3 billion and has funded almost 100 projects. INNOVATIVE MEDS. INITIATIVE, http://www.imi.europa.eu [https://perma.cc/S872-XPGS] (last visited Oct. 22, 2018). As Bagley & Tvarnø explain:

> The public party is the EU, represented by the European Commission ("EC"). The private party is the pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations ("EFPIA") and its members. Among other projects, the IMI supports the European Lead Factory public-private partnership, an international consortium comprising thirty partners that have agreed to pool 500,000 chemical compounds; 300,000 compounds came from AstraZeneca, Bayer Pharma, Merck, Sanofi and three other member companies, and the balance will come from academia and smaller firms.
>
> Each IMI call[] for a project proposal involves open competition for funding as well as multiple stakeholders, including EFPIA, private pharmaceutical and biotechnology enterprises ranging from large to small, universities, hospitals, patient organizations, and public authorities. Thus, universities and firms bid for government and industry funds to support research in areas of high medical need. All IMI contracts are subject to EU regulations, including those pertaining to the ownership of any resulting discoveries . . . .

Bagley & Tvarnø, *supra* note 14, at 16–17. *See* Rogério Gaspar et al., *Towards a European Strategy for Medicines Research (2014–2020): The EUFEPS Position Paper on Horizon 2020*, 47 EUR. J. PHARMACEUTICAL SCI. 979, 980 (2012). For more information on the Innovative Medicines Initiative (IMI), see *How IMI Works,* INNOVATIVE MEDS. INITIATIVE, http://www.imi.europa.eu/about-imi/how-imi-works [https://perma.cc/RDT3-KXRT] (last visited Sept. 30, 2018).

Antimicrobial Resistance,[22] and by certain U.S. entities under the Bayh-Dole Act.[23] Our initiative also includes another component: identifying and generating ecosystems of excellence[24] housing incubators that will bring together all the players and resources needed to support breakthrough multi-disciplinary discoveries. This new model will provide platforms, infrastructure, and services for both accelerating developments in countermeasure and creating a data commons.

The need for speed is very real. On January 25, 2018, the Bulletin of American Scientists moved up the Doomsday Clock thirty seconds to two minutes to midnight, its closest to the midnight apocalypse since 1953 when the Americans and Russians tested the first hydrogen bombs. In a 2018 letter, the Union of the Concerned Atomic Scientists' CEO and President Rachel Bronson stated:

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22 *See generally* ELTA SMITH ET AL., EVALUATION OF THE EC ACTION PLAN AGAINST THE RISING THREATS FROM ANTIMICROBIAL RESISTANCE: FINAL REPORT (2016), https://ec.europa.eu/health/amr/sites/amr/files/amr_final-report_2016_rand.pdf [https://perma.cc/2UDV-PVXS].

23 *See* Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200–12 (2018)). Multiple federal statutes have been enacted to foster innovation, including the Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701–14 (2018)); Small Business Innovation Development Act of 1982, Pub. L. 97-219, 96 Stat. 217 (codified as amended at 15 U.S.C. § 638 (2018)); National Cooperative Research Act of 1984, Pub. L. No. 98-462, 98 Stat. 1815 (codified as amended at 15 U.S.C. §§ 4301–05 (2018)); Small Business Technology Transfer Act of 1992, Pub. L. No. 102-564, § 201, 106 Stat. 4249, 4256–61 (codified as amended at 15 U.S.C. § 631 (2018)); America COMPETES Reauthorization Act of 2010, Pub. L. No. 111-358, § 404, 124 Stat. 3982, 4001 (2011) (codified as amended at 15 U.S.C. § 278k (2018)) (establishing the Manufacturing Extension Partnership); National Defense Authorization Act for Fiscal Years 1992 and 1993, Pub. L. No. 102-190, §§ 2521–26, 105 Stat. 1290, 1426–32 (1991) (Defense Industrial and Technology Base Initiative); High-Performance Computing Act of 1991, Pub. L. No. 102-194, § 102, 105 Stat. 1594, 1598–99 (codified as amended at 15 U.S.C. §§ 5501–28 (2018)); Small Business Research and Development Enhancement Act of 1992, Pub. L. No. 102-564, 106 Stat. 4249 (codified as amended at 15 U.S.C. § 631 (2018)); Department of Commerce Advanced Technology Program (ATP), 15 C.F.R. § 295.1 (2018). For further details on this legislation, see Anat Alon-Beck, *The Coalition Model, a Private-Public Strategic Innovation Policy Model for Encouraging Entrepreneurship and Economic Growth in the Era of New Economic Challenges*, 17 WASH. U. GLOBAL STUD. L. REV. 270, 284 (2018).

24 David J. Teece defines a "business ecosystem" as "a number of firms and other institutions that work together to create and sustain new markets and new products." David J. Teece, *Next-Generation Competition: New Concepts for Understanding How Innovation Shapes Competition and Policy in the Digital Economy*, 9 J.L. ECON. & POL'Y 97, 104 (2012); *see also* JOSH LERNER, BOULEVARD OF BROKEN DREAMS: WHY PUBLIC EFFORTS TO BOOST ENTREPRENEURSHIP AND VENTURE CAPITAL HAVE FAILED—AND WHAT TO DO ABOUT IT (2009).

> In 2017, we saw reckless language in the nuclear realm heat up already dangerous situations and re-learned that minimizing evidence-based assessments regarding climate and other global challenges does not lead to better public policies.
>
> Although the *Bulletin of the Atomic Scientists* focuses on nuclear risk, climate change, and emerging technologies, the nuclear landscape takes center stage in this year's Clock statement. Major nuclear actors are on the cusp of a new arms race, one that will be very expensive and will increase the likelihood of accidents and misperceptions. Across the globe, nuclear weapons are poised to become more rather than less usable because of nations' investments in their nuclear arsenals.[25]

President Trump has called for increasing the U.S. defense budget by 7% to $716 billion for fiscal year 2019,[26] primarily to increase the offensive power of the U.S. military. This Article focuses on the defensive side of the ledger in a world where not only nation states, but also non-state actors or rogue states, like North Korea, can cause mass destruction and panic.[27]

Part I provides a brief summary of the role the federal government has played as a powerful market actor, particularly in the areas of public defense and innovation, including the Defense Advanced Research Projects Agency (formerly known as ARPA), the tremendously successful advanced research initiative that led to groundbreaking innovations, such as computer technology, the internet, and self-driving vehicles.

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25 BULLETIN OF ATOMIC SCIENTISTS, 2018 DOOMSDAY CLOCK STATEMENT 1 (2018), https://thebulletin.org/sites/default/files/2018%20Doomsday%20Clock%20Statement.pdf [https://perma.cc/B3LZ-XPAM] (Statement from Rachel Bronson, President and CEO, Bulletin of the Atomic Scientists); *see also* Lindsey Bever et al., *The Doomsday Clock is Now Just 2 Minutes to 'Midnight,' the Symbolic Hour of the Apocalypse*, WASH. POST (Jan. 25, 2018), https://www.washingtonpost.com/news/speaking-of-science/wp/2018/01/25/after-a-missile-scare-and-insult-war-with-north-korea-its-time-to-check-the-doomsday-clock/?utm_term=.72758f5758ad [https://perma.cc/B4TZ-Y7TU].

26 Anthony Capaccio & Erik Wasson, *Pentagon Wins as Trump Readies a $716 Billion Budget Request*, BLOOMBERG (Jan. 26, 2018, 2:48 PM), https://www.bloomberg.com/news/articles/2018-01-26/trump-is-said-to-seek-716-billion-for-defense-in-2019-budget.

27 *Id.*; *see also* Fidler, *supra* note 10, at 816–19; *Disruptive Technologies Push Bioterrorism to a Whole New Level*, *supra* note 10.

In Part II we discuss several of the most significant government initiatives undertaken after the terrorist attacks on September 11, 2001 (9/11) and their strengths and shortcomings. Lest we repeat the mistakes of the past, Part II explains why many of the federal policies to accelerate the commercial development of countermeasures, especially endeavors to incentivize the biopharmaceutical industry to invest in such developments, had limited success.[28]

In Part III we propose the creation of the Defense of Health Countermeasures Initiative, a multi-prong proposal to create a defensive triad comprising government, private industry, and academia to develop countermeasures for health threats posed by CBRN attacks. Key elements include the use of the government's Other Transaction Authority to simplify procurement arrangements, the establishment of public-private partnerships with trusted intermediaries, and the creation of a network of incubators sited in ecosystems of excellence.

Part IV discusses potential challenges to collaboration and our responses thereto. We conclude with a summary of our proposal and a brief discussion of areas for further research.

I. GOVERNMENT AS MARKET ACTOR

Noble Laureate Robert M. Solow identified technological innovation as a fundamental source for productivity and the only reliable engine that drives change and sustained economic growth.[29] Paul Romer, who shared the Nobel Memorial Prize in Economic Sciences with William D. Nordhaus in 2018, helped confirm that innovation promotes growth, but Romer went on to theorize that the pace at which the market generates new ideas and "the way in which they are translated into growth depend on other factors—such as state

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28 *See* Capaccio & Wasson, *supra* note 26; *see also* Tara O'Toole & Thomas V. Inglesby, Editorial, *Toward Biosecurity*, 1 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, & SCI. 1 (2003); Lynne Gilfillan et al., *Taking the Measure of Countermeasures: Leaders' Views on the Nation's Capacity to Develop Biodefense Countermeasures*, 2 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 320 (2004); Laura DeFrancesco, *Throwing Money at Biodefense*, 22 NATURE BIOTECHNOLOGY 375 (2004).

29 Robert M. Solow, Nobel Prize Laureate, *Prize Lecture: Growth Theory and After* (Dec. 8, 1987), https://www.nobelprize.org/prizes/economics/1987/solow/lecture [https://perma.cc/NG5R-PNDB].

support for research and development or intellectual-property protections."[30]

Throughout U.S. history, governments have played the role of catalyst, venture capitalist, beta tester, and early adopter to promote technological research, development, and commercialization.[31] As demonstrated by the Manhattan Project during World War II, and projects sponsored by the DARPA and the Central Intelligence Agency's In-Q-Tel program (both discussed below), the U.S. government is capable of taking bold steps to foster the development of radically innovative technology to protect the American people from artificial and natural national threats. Further, legislation and regulations, such as transferable vouchers for fast-track FDA review (discussed in Section IV.A), the 21st Century Cures Act[32] (discussed in Section I.C), and the Global Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator initiative (CARB-X) (discussed in detail in Section II.C[33]), can spur commercial efforts to innovate.

A. *The Defense Advanced Research Projects Agency (DARPA)*

DARPA is a prime example of a successful governmental intervention in the market.[34] Created during the 1960s following the Soviet Union's successful and unexpected launch of the first satellite Sputnik,[35] DARPA provided funding to members from the scientific community, public sector, university-based researchers, industry

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30 *The Nobel Prize for Economics Is Awarded for Work on the Climate and Economic Growth*, ECONOMIST (Oct. 8, 2018), https://www.economist.com/finance-and-economics/2018/10/08/the-nobel-prize-for-economics-is-awarded-for-work-on-the-climate-and-economic-growth.

31 LERNER, *supra* note 24, at 6.

32 Pub. L. No. 114-255, 130 Stat. 1033 (2016).

33 *See infra* text accompanying notes 209–13.

34 Richard N. Kuyath, *The Untapped Potential of the Department of Defense's "Other Transaction" Authority*, 24 PUB. CONT. L.J. 521, 526–28 (1995); *see* Fred Block, *Swimming Against the Current: The Rise of a Hidden Developmental State in the United States*, 36 POL. & SOC'Y 169, 175 (2008) ("ARPA's Information Processing Techniques Office (IPTO) was initially established in 1962 and played a central role in the advance of computer technology . . . IPTO provided the resources to create computer science departments at major universities and funded a series of research project[s] that successfully pushed forward advances in human-computer interface.").

35 *See* Block, *supra* note 34, at 175.

syndicates, and private corporations (including start-ups).[36] The agency facilitated cooperation and information exchange among visionary and creative technologists from diverse development and research sites, including helping private firms commercialize new discoveries.[37] DARPA provided venture capital-like services, including mentoring, strategic planning, and technological and business brokering services. Although the technologists were given wide discretion, DARPA helped determine the course of research and served as a catalyst for innovation.[38] According to Erica Fuchs,

> [T]he little-studied key to DARPA's success lies with its program managers. Each program manager, who is temporarily on leave from a permanent position in the academic or industrial research community, is given tremendous autonomy to identify and fund relevant technologies in his or her own field that are relevant to specific military purposes. To carry out their roles, program managers must execute four interrelated tasks: learn about current or forthcoming military challenges; identify emerging technologies that have the potential to address those challenges; grow the community of researchers working on these emerging technologies; and be sure, as this community evolves, to transfer responsibility for the further development and eventual commercialization of these technologies either to the military services or the commercial sector.[39]

To minimize abuse or waste, DARPA staff transferred resources from unproductive groups to more promising, productive, and profitable ones.[40]

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36 *See* Alon-Beck, *supra* note 23, at 283 ("ARPA operated small offices staffed with top engineers and scientists, who were given extensive budget autonomy to sponsor promising ideas."); Block, *supra* note 34 at 175.

37 *See* Alon-Beck, *supra* note 23, at 273, 277, 283–84.

38 *Id.* at 283–84; *see also* Block, *supra* note 34, at 173–75.

39 Erica R. H. Fuchs, *The Road to a New Energy System: Cloning DARPA Successfully*, 26 ISSUES IN SCI. & TECH. 65, 67 (2009).

40 Block, *supra* note 34, at 175 (stating that ARPA employed visionary and creative technologists and gave them the autonomy to grant research funds). Failing contractors or projects are promptly cut from a DARPA program: "No projects or performers are so sacrosanct that poor performance is tolerated. The flip side of this willingness to stop failing efforts is that resources continuously become available to support new and emerging opportunities." NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES ET AL., *Defense Advanced Research Projects Agency Relationships*, *in* GOVERNMENT/INDUSTRY/ACADEMIC RELATIONSHIPS

Through DARPA and other initiatives, the federal government not only established many of the processes that formed the U.S. national innovation system, but also played an active role as a "market-maker."[41] It took a risk-bearing role to create the infrastructure for the high technology world of today.[42] Commercial fruits of government participation include not only computers and the internet, but jet planes, rockets, radar, lasers, civilian nuclear energy, GPS, and biotechnology (or biotech) as well.

More recently, DARPA's driverless car Grand Challenge, initiated in 2004, caused the United States to go "from a car that traveled 7.5 miles in a desert to a car driving itself down the George Washington Parkway in live traffic in 11 years."[43] This was accomplished "at a fraction of the cost and with a far broader set of contributors than a wholly government-driven effort could have supported."[44] DARPA "rewarded a few teams to keep them going but also attracted other teams who used their own resources. It iterated and accepted failures along the way. By providing focus and proofs of concept, it was able to build the critical mass to attract large commercial R&D investments."[45]

FOR TECHNOLOGY DEVELOPMENT: A WORKSHOP REPORT (2005), https://www.nap.edu/read/11206/chapter/4 [https://perma.cc/J2B4-7DPS] [hereinafter NAT'L ACADEMIES OF SCIENCES].

41 *See* Alon-Beck, *supra* note 23, at 271; *see also* Robert C. Hockett & Saule T. Omarova, *"Private" Means to "Public" Ends: Governments as Market Actors*, 15 THEORETICAL INQUIRIES L. 53, 54–57 (2014). Nelson found that the national security concerns of the nations had been central in shaping their innovation systems. NATIONAL INNOVATION SYSTEMS: A COMPARATIVE ANALYSIS, *supra* note 13, at 508; *see also* PETER F. DRUCKER, INNOVATION AND ENTREPRENEURSHIP: PRACTICE AND PRINCIPLES 257 (1985).

42 *See* Alon-Beck, *supra* note 23, at 277; *see also* Hockett & Omarova, *supra* note 41, at 56–57; Marc Berejka, *A Case for Government Promoted Multi-Stakeholderism*, 10 J. TELECOMM. & HIGH TECH. L. 1, 1–2 (2012). For examples of federal legislation promoting innovation, see statutes cited *supra* note 23.

43 Alan Pentz, *Agencies Can Seed Future Success with Creative Investment*, GOV'T EXECUTIVE (Feb. 8, 2016), http://www.govexec.com/excellence/nextgen-strategist/2016/02/agencies-can-seed-future-success-creative-investment/125747 [https://perma.cc/N663-H3FZ].

44 *Id.*

45 *Id.*; *see* NAT'L ACADEMIES OF SCIENCES, *supra* note 40; *see also* Block, *supra* note 34, at 174–75 (stating that following World War II, the Pentagon worked intimately and cooperated with other national security agencies, including the Atomic Energy Commission and the National Aeronautics and Space Agency (NASA), and that such cooperation and funding had a key role in developing these technologies). On the invention of the internet, the personal computer, the laser, and Microsoft Windows, see Erica R.H. Fuchs, *Rethinking the Role of the State in Technology Development: DARPA and the Case for Embedded Network Governance*, 39 RES. POL'Y 1133 (2010). *See also* John Sedgwick, *The Men from DARPA*, PLAYBOY, Aug. 1, 1991, at 108, 122, 154–56.

As discussed further below, DARPA used its "Other Transaction Authority" to remove some of the administrative barriers that previously deterred many commercial companies from participating in the government marketplace.[46] The DARPA model thus spurred innovation and competition by providing incentives to commercial companies "that lack the capabilities or desire to perform government-funded research under standard procurement contracts, grants, or cooperative agreements."[47] Thus, the U.S. government has a proven track record as a powerful market actor.[48]

B. *In-Q-Tel*

Another successful example of the government as a driver of market competition is the first government-funded venture capital firm, In-Q-Tel.[49] Launched in 1999 by the U.S. Central Intelligence Agency

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46 NAT'L ACADEMIES OF SCIENCES, *supra* note 42, at 23 ("[T]he majority of DARPA's large prototype system work was done using the OTA mechanism.").

47 Kuyath, *supra* note 34, at 524; *see also* Richard L. Dunn, *Other Transaction Contracts: Poorly Understood, Little Used*, NAT'L DEFENSE (May 15, 2017), http://www.nationaldefensemagazine.org/articles/2017/5/15/other-transactions-contracts-poorly-understood-little-used [https://perma.cc/E5X9-FK93].

48 *See* Hockett & Omarova, *supra* note 41, at 55–57; LERNER, *supra* note 24, at 179.

49 During the time of In-Q-Tel's establishment, the idea of a government-funded venture capital firm was entirely novel. *See* Steve Henn, *In-Q-Tel: The CIA's Tax-Funded Player in Silicon Valley*, NPR (July 16, 2012, 9:43 AM), http://www.npr.org/blogs/alltechconsidered/2012/07/16/156839153/in-q-tel-the-cias-tax-funded-player-in-silicon-valley ("Whether you have realized it or not, over the past 13 years In-Q-Tel has changed your life. 'Much of the touch-screen technology used now in iPads and other things came out of various companies that In-Q-Tel identified,' [former general counsel of the CIA Jeffrey] Smith says."); Alon-Beck, *supra* note 23, at 29; *see also* LERNER, *supra* note 24, at 176–77 ("For many of the start-ups, which had targeted corporate customers, the challenges of breaking into government procurements were daunting."); John T. Reinert, *In-Q-Tel: The Central Intelligence Agency as Venture Capitalist*, 33 NW. J. INT'L L. & BUS. 677, 679–80, 679 n.7 (2013) (citing *Deals & Deal Makers—Memo to Techies: This Army Wants Your Energy Ideas*, WALL ST. J., May 9, 2003, at C5) (noting that the Army, NASA, the U.S. Postal Service, and other government agencies were interested in investing in technology ventures); Marc Kaufman, *NASA Invests in Its Future with Venture Capital Firm 'Red Planet' Nonprofit to Fund Aerospace Innovation*, WASH. POST, Oct. 31, 2006, at A19; Press Release, NASA, NASA Forms Partnership with Red Planet Capital, Inc. (Sept. 20, 2006), http://www.nasa.gov/home/hqnews/2006/sep/HQ_06317_red_capital.html [https://perma.cc/2CJY-T4PM]; Joe Davidson, *Postal Service Desperate for Good Ideas to End Run of Bad News*, WASH. POST (June 23, 2010), http://www.washingtonpost.com/wp-dyn/content/article/2010/06/22/AR2010062205248.html [https://perma.cc/Q5L6-Q8CE].

(CIA), In-Q-Tel's charge was to "swim in [Silicon] Valley"[50] and invest in emerging technology firms (making small stake investments by utilizing venture-like processes).[51] In-Q-Tel allowed the CIA to invest in high technology firms that had not done business with the government before, serving as a bridge between the government (as a customer for innovative products and services) and emerging growth technology firms.[52]

In-Q-Tel was successful for many reasons, including its geographic proximity[53] to Silicon Valley and its ability to simplify the process of

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50 Then-CIA Director George Tenet said In-Q-Tel was created for this reason. Tim Cooke, *Innovation By and For the Government*, GOV'T EXECUTIVE (Oct. 2, 2017), http://www.govexec.com/excellence/promising-practices/2017/10/innovation-and-government/141433 [https://perma.cc/77SE-E9JK]; *see also* Reinert, *supra* note 49, at 693–94.

51 *See* LERNER, *supra* note 24, at 176 (by presenting new firms and technologies as candidates for acquisition by the CIA, In-Q-Tel served as a bridge linking private and public entities and enhanced the government's role as a new customer for products developed by emerging growth firms); *see also* BUS. EXECS. FOR NAT'L SEC., ACCELERATING THE ACQUISITION AND IMPLEMENTATION OF NEW TECHNOLOGIES FOR INTELLIGENCE: THE REPORT OF THE INDEPENDENT PANEL ON THE CENTRAL INTELLIGENCE AGENCY IN-Q-TEL VENTURE 15–16 (2001) [hereinafter BENS REPORT] (comparing the In-Q-Tel model with the traditional VC model).

52 *See* Alon-Beck, *supra* note 23, at 29 n.177.

53 *Id.* at 37. Geographic proximity is a very important contributor. Personal similarity also matters. *See* Ola Bengtsson & David H. Hsu, How Do Venture Capital Partners Match with Startup Founders? (Mar. 2010) (unpublished working paper), https://ssrn.com/abstract=1568131. According to Bengtsson and Hsu,

> [P]ersonal similarity matters in the [venture capitalist (VC)] matching market. We find that a match between a founder and a VC partner is twice as likely when both share the same ethnic background. A match is also more likely if both attended a top ranked university. As further evidence of the importance of similarity, we show that when the founder and VC partner share an ethnic tie or have both attended a top ranked university the VC's investment represents a larger fraction of its aggregate investments in all portfolio companies. These linkages are significant only for early stage investments in industries with higher levels of intangible assets, for which information costs are likely to be more pronounced. These linkages are also more important when the distance between VC and company is greater. These subsample findings suggest that the economic role of similarity is reduce[d] information costs. We infer that lower information costs associated with similar personal characteristics allow VCs to make larger investments.

Id. at 4; *see also* Lars Ola Bengtsson, Repeated Relationships Between Venture Capitalists and Entrepreneurs 3–5 (2006) (unpublished MBA thesis, University of Chicago) (on file with University of Chicago, Graduate School of Business) (after examining data on roughly 1,500 serial entrepreneurs, Bengtsson found that a failed entrepreneur is twice as likely to repeat VC relationships (as evaluated against a successful entrepreneur)).

federal procurement. The CIA used its Other Transaction Authority (OTA), a flexible contracting vehicle that lowers transaction costs by reducing the disincentives non-traditional government bidders experience when trying to contract with the federal government.[54] We discuss OTA further in Section III.C.

"Unlike a true venture capital model, In-Q-Tel is more aptly described as a 'technology accelerator,' seeking speed and agility in discovering innovative IT solutions for the Agency."[55] Its value proposition centered on obtaining IT solutions, not foremost on return on equity or assets. Deals always resulted in a product or service (e.g., feasibility assessment, test product, or prototype). As with venture capital (VC) funding, the CIA's investments were "smart money," which provided the portfolio companies with not only cash but also "intellectual capital [and] technology-related experience."[56] The CIA also offered "the Agency as a potential test-bed."[57] Consistent with its results-oriented approach, the CIA conducted extensive due diligence before forming a contract comprising an "[i]n-depth investigation into the [potential portfolio] company's structure and financial status as well as the ability of the proposed technology to meet the Agency problem domain."[58]

To encourage recruitment of established managers and staff from the venture capital industry, and to prevent them from leaving In-Q-Tel for more lucrative private positions, the CIA offered a rewarding compensation scheme, which was very unusual compared with typical government jobs.[59] "The [compensation] included a flat salary, a bonus paid based on how well In-Q-Tel met government needs, and an employee investment program, which took a prespecified portion of each employee's salary and invested alongside . . . [the] portfolio."[60]

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54 *See* Kuyath, *supra* note 34, at 524. According to Kuyath, OTA arrangements are in line with the purpose of the Federal Acquisition Streamlining Act of 1994, Pub. L. No. 103-355, 108 Stat. 3243 (codified in scattered sections of 10 and 41 U.S.C.). Kuyath, *supra* note 34, at 524.

55 BENS REPORT, *supra* note 51, at ix; *see About IQT*, IN-Q-TEL, https://www.iqt.org/about-iqt [https://perma.cc/67DB-DB4D] (last visited Oct. 27, 2018).

56 BENS REPORT, *supra* note 51, at ix.

57 *Id.*

58 *Id.*

59 *See* LERNER, *supra* note 24, at 176.

60 *Id.* at 177. For example, in 2012, its CEO Christopher Darby earned roughly $1 million. *See* Henn, *supra* note 49.

C. *21st Century Cures Act: Big Data and Artificial Intelligence*

Acknowledging the urgent need for using big data and artificial intelligence to develop new therapies, President Obama signed the 21st Century Cures Act into law on December 13, 2016.[61] The Act established "Information Commons" initiatives to facilitate broad, open, and responsible sharing of data.[62] Signaling the value of large data sets comprising information garnered from electronic health records (EHRs), pharmaceutical giant Roche agreed in February 2018 to pay $1.9 billion to acquire Flatiron Health, a privately held New York-based healthcare technology company.[63] Flatiron Health collects clinical data on cancer patients and has previously teamed up[64] with public parties, including the Food and Drug Administration (FDA)[65] and the National

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61 *See* Mary A. Majumder et al., *Sharing Data Under the 21st Century Cures Act*, 19 GENETICS MED. 1289 (2017).

62 *See id.* at 1289 ("At the same time, the Act exacerbates or neglects several challenges, for example, increasing complexity by adding a new definition of 'identifiable' and failing to address the financial sustainability of data sharing and the scope of commercialization. In sum, the Act is a positive step, yet there is still much work to be done before the goals of broad data sharing and utilization can be achieved.").

63 *See* Lydia Ramsey, *Pharma Giant Roche is Buying Cancer Tech Startup Flatiron Health for $1.9 Billion*, BUS. INSIDER (Feb. 15, 2018, 3:52 PM), http://www.businessinsider.com/roche-acquires-flatiron-health-for-19-billion-2018-2?r=UK&IR=T [https://perma.cc/4GD8-UM3F]. "Flatiron has raised more than $300 million from investors across the technology and health care investors, including Roche, Allen & Company, GV, First Round Capital and SV Angel." Christina Farr, *Alphabet-Backed Flatiron Health Is Being Acquired by Roche*, CNBC (Feb. 15, 2018, 3:02 PM), https://www.cnbc.com/2018/02/15/roche-buying-flatiron-health-backed-by-alphabet.html [https://perma.cc/9A2G-6R2J].

64 On Flatiron's partnerships and milestones, see Nat Turner, *Flatiron's Next Phase*, FLATIRON HEALTH (Feb. 15, 2018), https://flatiron.com/blog/roche [https://perma.cc/UP7U-JCM2].

65 *See* Nick Paul Taylor, *FDA Teams with Flatiron for Real-World Cancer Data Analytics Project*, FIERCEBIOTECH (May 27, 2016, 8:04 AM), https://www.fiercebiotech.com/it/fda-teams-flatiron-for-real-world-cancer-data-analytics-project [https://perma.cc/CZL4-J9KM]; *see also* Michael Mezher, *Woodcock: Drug Safety Surveillance System Ready for Full Operation*, REG. AFF. PROFS. SOC'Y (Feb. 3, 2016), https://www.raps.org/news-articles/news-articles/2016/2/woodcock-drug-safety-surveillance-system-ready-for-full-operation [https://perma.cc/8UHZ-5CXA] ("Launched in 2008, the Sentinel initiative encompasses FDA's effort to meet obligations set by Congress in the 2007 *Food and Drug Administration Amendments Act (FDAAA)* to develop a system for active postmarket risk identification and analysis for medical products.").

Cancer Institute, academic medical centers,[66] and private parties such as independent community oncology practices,[67] life sciences oncology companies, and others.

D. *Need for Additional Government Intervention for CBRN Countermeasures*

Notwithstanding existing public support for innovation and new therapies, the U.S. federal government is losing its place as a world leader in generating innovation, technology, and economic growth.[68] To successfully compete in tomorrow's marketplace, promote growth, and protect its citizens, as well as to increase productivity and expand economic and social value,[69] U.S. policymakers must institute sweeping innovation policies to modernize the U.S. innovation infrastructure.

In the past, most of the U.S. research and development (R&D) spending, which contributes to innovation, came from the Department of Defense (DoD). For example, according to the Government Accountability Office (GAO), 40% of R&D spending in the United

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66 *See* Nick Paul Taylor, *Roche Pens $1.9B Deal to Buy Oncology Data Firm Flatiron*, FIERCEBIOTECH (Feb. 16, 2018, 7:25 AM), https://www.fiercebiotech.com/biotech/roche-pens-1-9b-deal-to-buy-oncology-data-firm-flatiron [https://perma.cc/LTX4-R2B8].

67 Flatiron Health

> expanded partnerships with some of the nation's largest independent community oncology practices using the first EHR-embedded technology solution for the Center for Medicare & Medicaid Innovation's (CMMI) Oncology Care Model (OCM). Approximately one-third of all OCM practices use Flatiron's technology to adapt to the rapidly-changing requirements of value-based care programs for which practices commit to providing enhanced services to patients, such as care coordination, navigation and the use of national treatment guidelines.

Press Release, Flatiron Health, Flatiron Health Expands Technology Partnerships with Oncology Care Model Practices (June 13, 2017), https://flatiron.com/press/press-release/flatiron-health-expands-technology-partnerships-with-oncology-care-model-practices [https://perma.cc/9NPR-F3WA].

68 JOHN KAO, INNOVATION NATION: HOW AMERICA IS LOSING ITS INNOVATION EDGE, WHY IT MATTERS, AND WHAT WE CAN DO TO GET IT BACK 3 (2007) ("In tomorrow's world, even more than today's, innovation will be the engine of progress. So unless we move to rectify this dismal situation, the United States cannot hope to remain a leader. What's at stake is nothing less than the future prosperity and security of our nation.").

69 *See* Michael E. Porter & Mark R. Kramer, *Creating Shared Value: How to Reinvent Capitalism—and Unleash a Wave of Innovation and Growth*, HARV. BUS. REV., Jan.–Feb. 2011, at 1, 5.

States came from the DoD in 1987. By 2013, the DoD provided less than 20% of the U.S. R&D, whereas commercial R&D increased its spending by 200% between 1987 and 2013.[70] Today, however, the military and commercial demands in the United States have diverged drastically,[71] resulting in declining civilian-military technology spillovers.[72] For example, the U.S. military market no longer plays a strategic role in the computer and semiconductor industries (as compared with its position in the 1960s).[73]

Government is once again needed to drive the innovation necessary to even begin to seriously address today's CBRN threats. The need is particularly acute given the closing of major private R&D institutions, such as Bell Labs and General Electric's R&D enterprise. By investing in knowledge, human capital, and innovation, governments promote knowledge spillovers,[74] and thereby encourage the formation (and survival) of new entrepreneurial firms and new lines of business in existing firms.[75]

The government is not a profit-maximizing entity,[76] and is therefore in a better position than private investors to deal with

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70 Cooke, *supra* note 50.

71 *See* Kenneth Flamm & Thomas L. McNaugher, *Rationalizing Technology Investments*, *in* RESTRUCTURING AMERICAN FOREIGN POLICY 119 (John D. Steinbruner ed., 1989) (citing declines in the share of basic research in DoD research and development spending, as well as increases in the congressional demand for military research and development programs to yield near-term applications in weapons systems).

72 *Id.* An exception is the DoD funding of the Small Business Innovation Research program, on which it spends approximately $1 billion in grants annually. SMALL BUS. INNOVATION RES. & SMALL BUS. TECH. TRANSFER PROGRAM INTERAGENCY POLICY COMM., SBIR/STTR INTERAGENCY POLICY COMMITTEE REPORT TO CONGRESS: AWARD SIZE FLEXIBILITY 9 (2014), http://www.sbir.gov/sites/default/files/3_award_size-ipc_report.pdf [https://perma.cc/LZG3-DZUW].

73 *See* DAVID C. MOWERY & NATHAN ROSENBERG, PATHS OF INNOVATION: TECHNOLOGICAL CHANGE IN 20TH-CENTURY AMERICA 44–45 (1998).

74 *See* DAVID B. AUDRETSCH, ENTREPRENEURSHIP: A SURVEY OF THE LITERATURE 9–10 (2003), http://ec.europa.eu/DocsRoom/documents/2977/attachments/1/translations/en/renditions/pdf (discussing "knowledge spillover" and how "small firms account for a disproportional share of new product innovations given their low R&D expenditures").

75 LERNER, *supra* note 24, at 10.

76 *See* DAVID A. LEWIS, ELSIE HARPER-ANDERSON & LAWRENCE A. MOLNAR, INCUBATING SUCCESS: INCUBATION BEST PRACTICES THAT LEAD TO SUCCESSFUL NEW VENTURES 8 (2011). This study found:

> Most high-achieving incubators are not-for-profit models. All but one of the top-performing incubators in this study were nonprofits, as were 93% of the respondent population. This finding suggests that incubation programs focused on earning

situations of great uncertainty that require long-term investments in radical innovation.[77] Government actors are often not as efficient as private firms,[78] but they can alleviate market inefficiencies and failures by addressing the tragedy of the commons,[79] monitoring economic progress and market trends, and guiding local systems and intra-industrial innovation to meet social and military needs.[80] By promoting long-term development strategies, governments can serve as "bridge builders" between the public sector and private businesses and innovative industries.[81] Joint collaboration gives government scientists an opportunity to learn from industry and vice versa. Ideally, government participation complements, and does not replace, private efforts to build emerging growth firms.

Public-private partnerships use various methods of collaboration designed to combine the government's forward-looking policies and funds with the private sector's innovative efforts. Such efforts often include support from for-profit private intermediaries and nonprofit organizations, such as private disease foundations. There are several financing models of incubators, ranging from public non-profit to quasi-public to private non-profit.[82] This Article centers on public-private and quasi-public–private partnerships, given the need for the government to fund basic research and seed companies, in an industry

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> profits are not strongly correlated to client success. Instead, the most important goals of top-performing incubation programs are creating jobs and fostering the entrepreneurial climate in the community, followed by diversifying the local economy, building or accelerating new industries and businesses, and attracting or retaining businesses to the host region.

Id.

77 *See id.*

78 *Id.* at 9.

79 *See* Hockett & Omarova, *supra* note 41, at 57, 64–66 (explaining the "market-making" role of the government whereby the government assumes certain risks that private actors are unwilling or unable to assume in order to either "(a) make a publicly beneficial market possible, or (b) facilitate an incipient such market's growth to critical mass").

80 *Id.* at 67.

81 *See* KAO, *supra* note 68, at 198 ("They also would serve as bridge-builders between creative industries and the business mainstream, following models pioneered by such organizations as the Learning Lab in Denmark and Arts & Business in the United Kingdom. Above all, they would be mechanisms for linking federal, regional, and urban development strategies.").

82 For example, ten large pharmaceutical companies formed TransCelerate BioPharma "based on a nonprofit precompetitive model, to speed drug development by broad participation and collaboration across the global R&D community." Chaguturu, *supra* note 1, at xx.

in which the "average time between the 'key enabling discovery' and the introduction of a drug is 12–15 years."[83]

But governments and industries cannot fill the countermeasure pipeline alone. Institutes of higher learning (and national systems of innovation[84]) play critical roles in today's knowledge economy.[85] The "standard" growth theory in economics tends to concentrate on the roles of the business firms (including the constraints and incentives that are provided by competition in a market setting), and it is often blind to a wide range of other institutions that have played key roles in stimulating growth and driving innovation.[86] In the case of drug discovery, "[p]ublicly funded research, occurring at universities and the National Institutes of Health, over the years has produced a great majority of the key enabling discoveries underlying nearly 80% of the important drugs."[87] Typically, "the academic laboratory . . . identifies the interesting molecular targets that are important enzymes and proteins in various biochemical and physiological processes."[88] The U.S. government funded and made publicly available the sequencing of the human genome, but it took academic researchers to convert the basic science into innovative discoveries, including "the biomarkers of disease identified in genomics, proteomics, and biochemical studies" and the "identification of new messenger molecules and their receptors."[89] For example, the University of California and Stanford University were instrumental in developing the gene sequencing techniques, which biotech companies like Genentech commercialized.[90]

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83 *Id.* at xix; *see also* Filippo Belloc, *Innovation in State-Owned Enterprises: Reconsidering the Conventional Wisdom*, 48 J. ECON. ISSUES 821, 823–25 (2014).

84 In this context, the term "systems" means a "set of institutional actors that, together, play[] the major role in influencing innovation performance." NATIONAL INNOVATION SYSTEMS: A COMPARATIVE ANALYSIS, *supra* note 13, at 4.

85 *Id.* at 4–5. *See also* Philippe Laredo & Philippe Mustar, *Public Sector Research: A Growing Role in Innovation Systems*, 42 MINERVA 11 (2004).

86 Laredo & Mustar, *supra* note 85, at 11–12.

87 Chaguturu, *supra* note 1, at xix–xx.

88 *Id.*

89 Ferid Murad, *Foreword*, *in* Chaguturu, *supra* note 1, at xvi.

90 *See* Mark Edwards, Fiona Murray & Robert Yu, *Value Creation and Sharing Among Universities, Biotechnology and Pharma*, 21 NATURE BIOTECHNOLOGY 618 (2003), https://ssrn.com/abstract=904260. As Edwards et al. explain:

> Scientific institutions have always made a contribution to medical progress, but their traditional role was to educate and to publish advances in basic science—creating the intellectual foundation upon which others have built more commercial discoveries.

To develop new treatments, vaccines, and protective devices, government agencies need to collaborate with academia and private industry to identify the specific challenges not being adequately addressed by the private or governmental sectors. The government must then be willing to help fund the cutting-edge public and private research, innovation, development, and commercialization[91] necessary to show proof of concept and feasibility.[92] Accordingly, the Defense of

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> In recent times, however, universities have become active participants in the commercialization of scientific ideas through patenting and the establishment of active technology licensing as a legitimate and increasingly important part of academic life.
>
> This is especially true with respect to university and medical center patenting in biotechnology. For example, before 1989 the top recipient of biotechnology patents was Merck (Whitehouse Station, NJ, USA); however, a decade later, in 1999, the combined campuses of the University of California held that spot. In fact, twelve academic institutions were among the top 40 biotechnology patent-generating entities over this past decade, including Stanford University (Palo Alto, CA, USA), the Massachusetts Institute of Technology (MIT; Cambridge, MA, USA), the Massachusetts General Hospital (MGH; Boston, MA) and The Scripps Research Institute (La Jolla, CA, USA).

Id. at 618.

91 As Charles Wessner, Director of the Program on Technology, Innovation, and Entrepreneurship at the National Academy of Sciences, cautioned in 2008:

> There is great complacency in Washington about the US position in the world. There is relatively limited understanding in the policy community about the scale and scope of foreign investments in new technologies, including new institutions, such as ASTAR in Singapore or the large and apparently effective Chinese S&T Parks, or the highly successful Microelectronics center, called IMEC, in Flanders. . . . [Although] in the US we do not need to do exactly what others are doing . . . we do need to greatly strengthen the interaction between the government, the universities, and the private sector by providing a wide variety of incentives for cooperation on the new technologies that will be the basis of future industries.

Quoted in Philipp Marxgut, *Innovation Policy in the US—An Interview with Charles Wessner*, OFF. SCI. & TECH. AUSTRIA: BRIDGES (Oct. 19, 2008), http://ostaustria.org/bridges-magazine/volume-19-october-16-2008/item/3585-innovation-policy-in-the-us-an-interview-with-charles-wessner [https://perma.cc/Q87Q-7QDG].

92 The United States is already in competition with China for preeminence in the field of artificial intelligence (AI). Like the space race between the United States and the former Soviet Union, the AI race is likely to have a major impact on the next generation of innovation. While China is actively funding start-ups, the United States has lagged in providing public funding, relying instead on private actors like Google. *See, e.g.*, Jackie Snow, *The Defense Department Is Taking on ISIS with Google's Open-Source AI Software*, MIT TECH. REV.: THE DOWNLOAD (Mar. 6, 2018, 2:31 PM), https://www.technologyreview.com/the-download/610429/the-

Health Countermeasures Initiative we propose in Part III is designed to allow the government to make direct equity investments in seed projects through the DHCI Incubators and national platforms for networks of innovation hubs. At the same time, our proposed DHCI encourages private actors to help finance such projects and makes it possible for universities and academic scientists to share in the economic proceeds through the Bayh-Dole Act and the glory through the right to publish novel findings. This defensive triad, comprising government, academia, and industry, should promote effectiveness and, more importantly, reduce political capture (discussed further in Section IV.D) and other distortions.

II. EXISTING MEASURES TO DEAL WITH THE THREAT OF CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR ATTACKS

Following the terror events of 9/11, including the anthrax attacks, the federal government and certain states took various measures to protect U.S. civilians from potential CBRN terrorism and other emergency outbreaks. These included financial incentives to mobilize the biotechnology and pharmaceutical industries to pursue the R&D of medical countermeasures, such as diagnostic tests, drugs, vaccines, and other treatments, that can minimize the impact of a CBRN attack.[93]

Despite these efforts, the current pipeline of new countermeasures is not robust. Many start-up companies continue to find themselves trapped in the "Valley of Death," populated by firms at the early stage of development that are caught, as in amber, in the "time between a basic science discovery (usually in academic labs) and the decision to commit resources to develop the idea into a drug (almost always by industry)."[94]

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defense-department-is-taking-on-isis-with-googles-open-source-ai-software [https://perma.cc/D7AK-7GUT].

93 *See* CONG. RESEARCH SERV., R44786, SCIENCE AND TECHNOLOGY ISSUES IN THE 115TH CONGRESS 28 (2018) ("Policymakers identified a lack of such countermeasures as a challenge to responding to the CBRN threat. To address this gap, the federal government created several programs to encourage private sector development of new CBRN medical countermeasures.").

94 *Moving Drug Discoveries Beyond 'The Valley of Death'*, ABBVIE (Feb. 15, 2016), https://stories.abbvie.com/stories/moving-drug-discoveries-beyond-the-valley-of-death.htm [https://perma.cc/Y8DB-9GUZ]. The so-called "'valley of death' . . . separates 'upstream research on promising genes, proteins, and biological pathways' by government-funded academic researchers from 'downstream drug candidates' outside firms fund in hopes of commercializing the researchers' discoveries." CONSTANCE E. BAGLEY & CRAIG E. DAUCHY, THE

A. *The Public Health Security and Bioterrorism Preparedness and Response Act of 2002*

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PHSBPRA) specifically authorizes the Secretary of Health and Human Services to "prevent, prepare for, and respond to bioterrorism and other public health emergencies"[95] by coordinating the activities of federal, state, and local governments. In accordance with this mandate, the Centers for Disease Control and Prevention (CDC) launched three programs in 2003: (1) the BioSense program, "a nationwide integrated public health surveillance system for early detection and assessment of potential bioterrorism-related illness";[96] (2)

ENTREPRENEUR'S GUIDE TO LAW AND STRATEGY 155 (5th ed. 2018) (quoting Arti K. Rai et al., *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, 8 YALE J. HEALTH POL'Y L. & ETHICS 1, 4 (2008)); *see* LEWIS M. BRANSCOMB & PHILLIP E. AUERSWALD, NAT'L INST. OF STANDARDS & TECH, NIST GCR 02-841, BETWEEN INVENTION AND INNOVATION: AN ANALYSIS OF FUNDING FOR EARLY-STAGE TECHNOLOGY DEVELOPMENT 1–2, 4–5 (2002), https://www.nist.gov/sites/default/files/documents/2017/05/09/gcr02-841.pdf [https://perma.cc/RF7G-492R]; GEORGE S. FORD ET AL., AN ECONOMIC INVESTIGATION OF THE VALLEY OF DEATH IN THE INNOVATION SEQUENCE 2–3 (2007), http://www.osec.doc.gov/Report-Valley%20of%20Death%20Funding%20Gap.pdf [https://perma.cc/9TUV-CMBM]; *see also* PHILIP E. AUERSWALD ET AL., NAT'L INST. OF STANDARDS & TECH, NIST GCR 02-841A, UNDERSTANDING PRIVATE-SECTOR DECISION MAKING FOR EARLY-STAGE TECHNOLOGY DEVELOPMENT: A "BETWEEN INVENTION AND INNOVATION PROJECT" REPORT (2005), http://www.nist.gov/tpo/sbir/upload/gcr02-841a.pdf [https://perma.cc/C3P6-6M8B]; Ederyn Williams, *Crossing the Valley of Death*, INGENIA, Nov.–Dec. 2004, at 23, http://www2.warwick.ac.uk/services/ventures/valley.pdf [https://perma.cc/5ABB-MH3Q] (discussing valley of death in the United Kingdom); Philipp Marxgut, *supra* note 91.

95 Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

96 Deborah W. Gould et al., *The Evolution of BioSense: Lessons Learned and Future Directions*, 132 PUB. HEALTH REP. 7S–11S (2017).

> The initial BioSense program had 4 goals: (1) improve the nation's capabilities for conducting near–real-time biosurveillance and health situational awareness; (2) advance analytics for prediagnostic and diagnostic data; (3) increase sharing of approaches and technology among federal, state, and local public health agencies; and (4) promote national system standards and specifications to ensure integration with other public health systems.

Id.; *see also* Colleen A. Bradley et al., *BioSense: Implementation of a National Early Event Detection and Situational Awareness System*, 54 MORBIDITY & MORTALITY WKLY. REP. S11 (2005); Jerome I. Tokars et al., *Summary of Data Reported to CDC's National Automated Biosurveillance System, 2008*, 10 BMC MED. INFORMATICS & DECISION MAKING 1, 11–12 (2010); Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub.

the BioShield program, which is charged with accelerating "the research, development, acquisition, and availability of medical countermeasures to improve the government's preparedness for and ability to counter chemical, biological, radiological, and nuclear threat agents;[97] and (3)

L. No. 107-188, 116 Stat. 594; John W. Loonsk, *BioSense—A National Initiative for Early Detection and Quantification of Public Health Emergencies*, 53 MORBIDITY & MORTALITY WKLY. REP. 53 (2004).

> A major component of the BioSense system was the infrastructure that CDC developed to receive and securely manage health care-sourced data and to host the BioSense application for analyzing and visualizing data reported to BioSense. The infrastructure included (1) data management processes to receive and process inbound clinical care and related data, (2) analytic processes to bin records into syndrome categories and analyze trends for suspect signals, and (3) a user interface that allowed CDC and state and local staff members to access patient-level data to investigate results, report on notifications, and coordinate responses. Data from different sources were added to the BioSense system over time, including data from US Department of Veterans Affairs and US Department of Defense hospitals and ambulatory care clinics (2003), test orders from the Laboratory Corporation of America (2004), data from nonfederal hospitals directly reporting to CDC (2005), data from state health departments' syndromic surveillance systems (2006), anti-infective prescription data from Relay Health outpatient pharmacies (2007), and test orders from Quest Diagnostics (2007). By 2008, the primary data sources for BioSense included 333 Department of Defense and 770 Veterans Affairs hospitals and ambulatory clinics and 532 civilian hospital emergency departments (EDs).

Gould et al., *supra*, at 7S.

97 Philip K. Russell, *Project BioShield: What It Is, Why It Is Needed, and Its Accomplishments So Far*, 45 CLINICAL INFECTIOUS DISEASES S68 (2007).

> The legislation authorizes use of the Special Reserve Fund, which makes available $5.6 billion over 10 years for the advanced development and purchase of medical countermeasures. This appropriation is intended to provide an economic incentive to the pharmaceutical industry to develop medical countermeasures for which the government is the only significant market. Acquisitions under Project BioShield are restricted to products in development that are potentially licensable within 8 years from the time of contract award. In exercising the procurement authorities under Project BioShield, HHS has launched acquisition programs to address each of the 4 threat agents, including *Bacillus anthracis* (anthrax), smallpox virus, botulinum toxins, and radiological/nuclear agents, originally deemed by the Department of Homeland Security to be threats to the US population sufficient to affect national security. At the time of writing [2007], 7 contracts have been awarded: (1) recombinant protective antigen anthrax vaccine, the next-generation anthrax vaccine (contract terminated in December 2006 for default); (2) anthrax vaccine adsorbed, the currently licensed anthrax vaccine; (3) anthrax therapeutics (monoclonal); (4) anthrax therapeutics (human immune globulin); (5) the pediatric formulation of potassium iodide; (6) Ca- and Zn-diethylenetriaminepentaacetate (DTPA), chelating

BioWatch, a program "designed to sample the air in major metropolitan areas for pathogens that terrorists might use."[98]

B. *BioShield*

Of the three programs authorized by the PHSBPRA, this Article will focus on the BioShield initiative. This federal program is designed to address the CBRN threat gap by encouraging private sector development of new CBRN medical countermeasures. Project BioShield established a direct procurement mechanism whereby the federal government can buy a countermeasure up to eight years before the product is likely to be fully developed.[99] Although Project BioShield was designed to remove barriers to procurement and to address the market uncertainty faced by countermeasure developers, initial implementation of Project BioShield 1 was not very successful.[100]

The disappointing results of BioShield 1 were due in part to the lack of adequate monetary incentives[101] to motivate private pharmaceutical companies to invest the hundreds of millions of dollars in R&D necessary to successfully produce a new medical countermeasure.[102] The following are the five broad stages in the

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> agents to treat ingestion of certain radiological particles; and (7) botulinum antitoxins. Additional acquisition contracts [were] expected to be awarded in 2007.

Id.

98 Gould et al., *supra* note 96, at 7S.

99 Russell, *supra* note 97, at S68.

100 *See* SCIENCE AND TECHNOLOGY ISSUES IN THE 115TH CONGRESS, *supra* note 93, at 28 ("Despite these efforts, the federal government still lacks medical countermeasures for many CBRN threats, including Ebola."). Since the publication of Peter K. Russell's Article in 2007, Russell, *supra* note 97, BARDA and Merck & Co. have developed an Ebola vaccine that BARDA is seeking to license and perhaps add to the Strategic National Stockpile. Steve Brozak, *An Unlikely Biotech Investor: The Government*, FORBES (June 8, 2018, 9:14 AM), https://www.forbes.com/sites/stephenbrozak/2018/06/08/merck-and-achaogen-two-companies-working-with-barda-to-fight-emerging-health-threats/#686518984fd0 [https://perma.cc/H4DZ-LNHE].

101 FRANK GOTTRON, CONG. RESEARCH SERV., R43607, THE PROJECT BIOSHIELD ACT: ISSUES FOR THE 113TH CONGRESS 1 n.1 (2014) ("Representatives of the pharmaceutical industry attributed the paucity of CBRN agent countermeasures to the lack of a significant commercial market.") (citing Alan Pemberton, Pharm. Research & Mfrs. of Am., Testimony before the U.S. H. Select Comm. on Homeland Security (May 15, 2003)).

102 *See id.* Joseph Larsen, former Deputy Director of BARDA, stressed the importance of incentives, stating that both push and pull government incentives are often required to get

innovation process, as well as the financial sources that are usually available at each stage.[103] First is the stage of basic research, for which funding is usually available to entrepreneurs from government sources, such as the National Science Foundation (NSF), National Institutes of Health (NIH), the Small Business Innovation Research (SBIR) phase I (Feasibility and Proof of Concept),[104] and from private corporate resources, such as the funds large corporations allocate to R&D. Second is the proof of concept or invention stage, for which financing sources usually include private angel investors, corporate R&D funds, and government funding from SBIR phase II (Research/Research and Development)[105] and technology labs. Third is the early-stage technology development stage, which is often termed the Valley of

major pharmaceutical companies to participate. Telephone interview with Joseph Larsen, Senior Vice President of Life Scis., Strategic Mktg. Innovations, Inc. (June 4, 2018). When the U.S. government set up the dedicated fund to finance the development for anthrax cures and vaccines as part of BioShield (a "pull" initiative), only small, inexperienced biotech companies applied to participate. *Id.*

103 Except as noted otherwise, the balance of this paragraph is drawn from Alon-Beck, *supra* note 23, at 296.

104 The SBIR program was founded in 1982. It was intended to encourage small businesses to develop new products and processes as well as present valuable research for the nation's research and development efforts. The program requires the eleven federal agencies with extramural research budgets in excess of $100 million to allocate a certain percentage of their total extramural research and development budgets for grants or contracts to small businesses conducting research and development that have commercialization potential and meet the needs of the U.S. government. *See* CHARLES W. WESSNER, SBIR AND THE PHASE III CHALLENGE OF COMMERCIALIZATION: REPORT OF A SYMPOSIUM 3–5, 9 (2007). According to Wessner:

> Commercializing SBIR-funded technologies though federal procurement is no less challenging for innovative small companies. Finding private sources of funding to further develop even successful SBIR Phase II projects—those innovations that have demonstrated technical and commercial feasibility—is often difficult because the eventual "market" for products is unlikely to be large enough to attract private venture funding. As Mark Redding of Impact Technologies noted at the conference, venture capitalists tend to avoid funding firms focused on government contracts citing higher costs, regulatory burdens, and limited markets associated with government contracting.

Id. at 9; *see also About SBIR*, SBIR, http://www.sbir.gov/about/about-sbir [https://perma.cc/WS3J-CDEX] (last visited Oct. 2, 2018) (listing the program's objectives as: "Stimulate technological innovation. Meet Federal research and development needs. Foster and encourage participation in innovation and entrepreneurship by women and socially or economically disadvantaged persons. Increase private-sector commercialization of innovations derived from Federal research and development funding.").

105 *See About SBIR*, *supra* note 104.

Death because of the entrepreneur's difficulty in obtaining financing for this stage.[106] Fourth is product development, the stage at which private venture capital firms traditionally invest in start-up firms. Fifth, and last, is the production or marketing stage, for which financing sources include private venture capitalists, corporate venture capital, private equity, or commercial debt.

PHSBPRA provided inadequate R&D funding to get private actors across the Valley of Death.[107] Even if a private firm was successful developing a new treatment, there tended to be no continuous commercial market for the product. "There is little incentive for publicly-traded drug companies to make products with low profit margins, infrequent use and a high likelihood of liability lawsuits, such as vaccines."[108]

Second, the government was unwilling to guarantee that the pharmaceutical companies' patent and other intellectual property rights would not be compromised if a public crisis required large scale dissemination of their drugs.[109] After the anthrax attacks in 2001, the

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106 *See* Bagley & Tvarnø, *supra* note 16, at 375; *see* also Alon-Beck, *supra* note 23, at 270–71.

107 *See* Alon-Beck, *supra* note 23, at 295–96.

108 *See* Janet Temko, The Project BioShield Act of 2004: An Innovative Failure 10 (May 2006) (unpublished third-year student paper, Harvard University), http://nrs.harvard.edu/urn-3:HUL.InstRepos:8944670 (citing Scott Hensley & Bernard Wysocki Jr., *Missing Medicine—Shots in the Dark: As Industry Profits Elsewhere, U.S. Lacks Vaccines, Antibiotics; Incentives Are Low to Develop Some Public-Health Drugs; New Moves in Washington; A $200 Million Legal Fight*, WALL ST. J., Nov. 8, 2005, at A.1). As Temko pointed out, "drugs that treat a disease are more lucrative than vaccines to prevent it partly because people are more inclined to pay for a medicine that treats a condition they already have." *Id. See also id.* at 9 n.44 ("when you're dealing with a product for which there is no guarantee of a return, or for which the market is tenuous, these companies clearly need some assurances that there will ultimately be a return for their investment. Without such assurances, they will simply pursue the development of other products.") (quoting *Project BioShield: Contracting for the Health and Security of the American Public: Hearings Before the Comm. On Gov't Reform*, 108th Cong. 16, 10 n.44 (2003) (statement of Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases)).

109 *See* Temko, *supra* note 108, at 9. Regarding the authority of ARPA to use OTA, Kuyath explained:

> In support of its position on the Bayh-Dole Act, ARPA relied on the legislative history of two defense authorization acts. First, the conference report of the House and Senate Armed Services Committees on the National Defense Authorization Act for Fiscal Year 1992 stated:
>
> > The conferees also recognize that the regulations applicable to the allocation of patent and data rights under the procurement statutes may not be appropriate to partnership arrangements in certain cases. The conferees believe that the option

government forced Bayer to lower the already discounted price of the Cipro drug by threatening "to force compulsory licensing of the patent on Cipro in order to enable generic companies to enter the market."[110] The PHSBPRA failed to address this issue.

Third, the PHSBPRA lacked adequate indemnification provisions that would shield pharmaceutical companies from liability for new

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> to support partnerships pursuant to section 2371 of title 10, United States Code, provides adequate flexibility for the Defense Department and other partnership participants to agree to allocations of intellectual property rights in a manner that will meet the needs of all parties involved in a transaction.

Additionally, the House Armed Services Committee report on the 1995 National Defense Authorization bill noted:

> . . . TRP policy provides that the Federal Government should avoid acquiring rights if that will impede commercialization. Foreign access to technology is scrutinized and, if deemed necessary, restricted. Broad exposure of the technology among partnerships participants is encouraged. The Advanced Research Projects Agency (ARPA) can fully effectuate these policies because it has great flexibility to tailor patent and other intellectual property rights provisions under its "other transactions" authority.

. . . The Bayh-Dole Act sets forth the Government's policy regarding allocation of patent rights to inventions conceived or first actually reduced to practice under contracts, grants, and cooperative agreements with small business firms and educational and other nonprofit organizations (subject inventions). This patent policy also has been extended to large businesses. The contractor (or recipient, in the case of grants and cooperative agreements) is permitted to retain title to subject inventions and the Government receives a nonexclusive, nontransferable, irrevocable, worldwide, paid-up license to practice or have practiced subject inventions on behalf of the United States throughout the world.

Kuyath, *supra* note 34, at 531–32, 536–37.

110 *See* Temko, *supra* note 108, at 10 n.43 (citing Gregory M. Lamb, *New Buffer for Bioterror's Tempest*, CHRISTIAN SCI. MONITOR (July 1, 2004), https://www.csmonitor.com/2004/0701/p14s02-stct.html ("After the anthrax letters scare, Tommy Thompson, the HHS secretary, demanded that Bayer lower its prices on Cipro, an anthrax drug, or risk losing its patent—sending a chilling signal to drugmakers."); *Roundtable Discussion: When Terror Strikes—Preparing an Effective and Immediate Public Health Response: Hearing of the Comm. On Health, Educ., Labor, & Pensions*, 109th Cong. 47–48 (2005) (response to questions of the committee by Chuck Ludlam) (They say, "Look what happened to Bayer," which was subject to virtual expropriation of its antibiotic, Cipro, by HHS following the 2001 anthrax attack. In fact, the outrageous actions of HHS in that case have plagued our ability to engage this industry in this research. We must have credible Administration officials state categorically that these Mafioso tactics will never ever be seen again against a company that develops countermeasures for infectious pathogens. The companies must be rewarded, not vilified.)). *See also* Cynthia M. Ho, *Inoculation Inventions: The Interplay of Infringement and Immunity in the Development of Biodefense Vaccines*, 8 J. HEALTH CARE L. & POL'Y 111, 113 (2005).

drugs and vaccines. Wyeth spent millions defending lawsuits related to its smallpox vaccines.[111] The fact that vaccines require animal testing and cannot be ethically tested on humans make such concerns particularly acute.[112] Fourth, the PHSBPRA did not reduce the lengthy FDA approval process (which can take ten to fifteen years).[113] Fifth, the failure of the procurement contract, whereby the small biotechnology firm VaxGen agreed to provide millions of doses of an unproven anthrax vaccine, deterred other small (and large) private companies from collaborating with the government.[114]

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111 *See* Temko, *supra* note 108, at 10–11 ("Wyeth started making smallpox vaccine in 1885 and was a principle [sic] supplier of childhood vaccines in the United States for most of the 20th Century. But beginning in the 1980s, it became the target of lawsuits linking vaccines to a wide range of illnesses without obvious causes, such as epilepsy and attention deficit disorder. Wyeth estimates the industry has spent more than $200 million defending itself against hundreds of lawsuits alleging that a preservative in some vaccines called thimerosal causes autism and other diseases.").

112 *See id.* at 11–13; *see also* James T. O'Reilly, *Bombing Bureaucratic Complacency: Effects of Counter-Terrorism Pressure upon Medical Product Approvals*, 60 N.Y.U. ANN. SURV. AM. L. 329, 336 n.33 (2004) ("This uncertainty is inherent in the antidote research effort, but it makes the investor less willing to support the development costs and it expands the company's liability concerns.").

113 *See* Temko, *supra* note 108, at 12–13; PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW, CASES AND MATERIALS 514 (2d ed. 1991); Janene Boyce, *Disclosure of Clinical Trial Data: Why Exemption 4 of the Freedom of Information Act Should Be Restored*, 2005 DUKE L. & TECH. REV. 3, 8. *See also* James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLA. J. INT'L L. 261, 340 (2002) ("The foregoing process of drug approval takes at least seven years."); *Crossing the Valley of Death: Bringing Promising Medical Countermeasures to BioShield: Hearing before the Subcomm. on Bioterrorism and Pub. Health Preparedness of the Comm. on Health, Educ., Labor & Pensions*, 109th Cong. 17 (2005) ("[F]ewer than one in one hundred candidate drugs will receive approval by the FDA for Investigational New Drug (IND) status, and of those, only about one in four will receive approval by the FDA. Second, once a product receives IND approval, it may take 8–10 years and $500–$800 million or more to support the clinical trials and development manufacturing processes to bring a product to market. This does not include the research investment to develop candidate products.") (prepared statement of Colonel Joseph Palma, M.D., USAF). As discussed *infra* note 294, there is precedent for providing expedited review for orphan drugs and drugs for neglected diseases through the use of tradeable vouchers.

114 *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-88, PROJECT BIOSHIELD: ACTIONS NEEDED TO AVOID REPEATING PAST PROBLEMS WITH PROCURING NEW ANTHRAX VACCINE AND MANAGING THE STOCKPILE OF LICENSED VACCINE (2007), https://www.gao.gov/assets/270/268295.pdf [https://perma.cc/W7DG-L4VA]. According to the U.S. Government Accountability Office:

> Three major factors contributed to the failure of the first Project BioShield procurement effort for an rPA anthrax vaccine. First, HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) awarded the procurement contract

Sixth, the PHSBPRA did not reduce the bureaucratic governmental red tape private firms had to cut through to finalize the government procurement contracts. Indeed, private executives complained that government officials were changing the requirements and delaying contracts.[115] Seventh, the PHSBPRA failed to establish an effective delivery system for the distribution of drugs and vaccines in a large-scale crisis even if it had an adequate supply stockpiled.[116] Finally, Eliah Zerhouni and Anthony Fauci, the directors of the NIH and National Institute of Allergy and Infectious Diseases (NIAID), were criticized for putting too much emphasis on government research.

C. *BARDA and OTA*

To address the shortfalls of the BioShield program and further encourage the development and procurement of CBRN medical countermeasures, Congress passed the Pandemic and All-Hazards Preparedness Act (PAHPA) in 2006. PAHPA created the Biomedical Advanced Research and Development Authority (BARDA) and established the position of Assistant Secretary for Preparedness and Response in the Department of Health and Human Services (HHS).

> to VaxGen, a small biotechnology firm, while VaxGen was still in the early stages of developing a vaccine and had not addressed many critical manufacturing issues. This award preempted critical development work on the vaccine. Also, the contract required VaxGen to deliver 25 million doses of the vaccine in 2 years, which would have been unrealistic even for a larger manufacturer. Second, VaxGen took unrealistic risks in accepting the contract terms. VaxGen officials told GAO that they accepted the contract despite significant risks due to (1) the aggressive delivery time line for the vaccine, (2) VaxGen's lack of in-house technical expertise—a condition exacerbated by the attrition of key company staff as the contract progressed—and (3) VaxGen's limited options for securing any additional funding needed. Third, important Food and Drug Administration (FDA) requirements regarding the type of data and testing required for the rPA anthrax vaccine to be eligible for use in an emergency were not known at the outset of the procurement contract. In addition, ASPR's anticipated use of the rPA anthrax vaccine was not articulated to all parties clearly enough and evolved over time. Finally, according to VaxGen, the purchase of BioThrax for the stockpile as a stopgap measure raised the bar for the VaxGen vaccine. All these factors created confusion over the acceptance criteria for VaxGen's product and significantly diminished VaxGen's ability to meet contract time lines.
>
> *Id.*

115 *See* Temko, *supra* note 108, at 34–35.

116 *See id.* at 39.

Since then, BARDA has made substantial progress closing the innovation gap by stimulating R&D through public-private partnerships with various stakeholders, including industry.

1. Other Transaction Authority

Since 2013, BARDA has provided non-dilutive funding and technical advisory support to its partners pursuant to a flexible government contracting vehicle, the OTA.[117] OTA collaborators are not required to comply with the typical lengthy and time-consuming procurement requirements or to change their standard business practices.[118] Given the flexibility inherent in collaborations governed by OTA, the federal government can also accommodate the various licensing (and collaboration) terms and conditions that a company may already have in place with its partners, including licensors' account rights.[119]

When using its OTA, BARDA is not required to comply with the multitude of laws, regulations, and other requirements that normally apply to standard procurement contracts, grants, and cooperative agreements. As a result, the turnaround time is shorter, "with less internal paperwork than normally would be the case."[120] Thus, used correctly, OTA contracts can attract leading-edge, biotech and pharmaceutical companies and academics to collaborate with federal funding agencies to participate in BARDA-funded R&D programs in situations where they otherwise would not do so.

OTA arrangements permit BARDA to take the "portfolio approach" that industry and venture capitalists use to fund R&D by diversifying investments, funding multiple rounds dependent upon success,[121] and not trying to pick a national champion.[122] BARDA is

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117 *See* Kuyath, *supra* note 34, at 522–24.

118 *Id.* at 536.

119 *See id.* at 523.

120 *See id.* at 524; *see also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-209, FEDERAL ACQUISITIONS: USE OF 'OTHER TRANSACTION' AGREEMENTS LIMITED AND MOSTLY FOR RESEARCH AND DEVELOPMENT ACTIVITIES (2016), https://www.gao.gov/assets/680/674534.pdf [https://perma.cc/PP5A-K4Y2] ("[A]gencies told GAO the authority allowed them to develop customized agreements . . . . This flexibility allowed agencies to address concerns regarding intellectual property and cost accounting provisions . . . .").

121 *See* BAGLEY & DAUCHY, *supra* note 94, at 438–95.

accordingly able to support a "company's [and the government's] effort to simultaneously and in parallel develop multiple drug candidates."[123]

2. Use of OTA to Form Public-Private Partnerships

Both DARPA and BARDA have used OTA to establish public-private partnerships to deal with technological challenges. Public-private partnerships are "contractual agreements between a public agency or public-sector authority and a private-sector entity that allow for greater private participation in the delivery of public services, or in developing an environment that improves the quality of life for the general public."[124] In order to develop a public-private partnership,[125] the conventional community of stakeholders is expanded to include the private sector (emerging and established firms); management; academia and research communities; industry and economic development organizations; federal, state, regional, and local governments; and the financial sector, including investment banks, angel groups, and venture capital groups. This is in addition to the traditional stakeholder groups, which include customers, employees, creditors, suppliers, and shareholders.

Agreements reached through the use of a government agency's OTA have formed the basis for pharmaceutical public-private partnerships with large pharmaceutical companies, such as GlaxoSmithKline (2013), AstraZeneca (2015), the Medicines Company

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122 *See* Christopher Houchens & Joseph Larsen, *The Role of the Biomedical Advanced Research and Development Authority (BARDA) in Promoting Innovation in Antibacterial Product Development*, AMR CONTROL (Aug. 2, 2017), http://resistancecontrol.info/2017/the-role-of-the-biomedical-advanced-research-and-development-authority-barda-in-promoting-innovation-in-antibacterial-product-development [https://perma.cc/C535-H38N].

123 *Id.* ("Such portfolio-based funding is also more consistent with industry practice and reduces technical risk by allowing for the reallocation of resources across activities and among drug candidates if technical or business risks materialize, thereby increasing the probability of bringing a successful drug to market.").

124 Louis Witters et al., *The Role of Public-Private Partnerships in Driving Innovation*, *in* THE GLOBAL INNOVATION INDEX 2012: STRONGER INNOVATION LINKAGES FOR GLOBAL GROWTH 81 (Soumitra Dutta ed., 2012), https://www.globalinnovationindex.org/userfiles/file/GII-2012-Report.pdf [https://perma.cc/NN2E-MRWE].

125 Anat Alon-Beck developed the Coalition Model in her dissertation. *See* Alon-Beck, *supra* note 23.

and Hoffmann-La Roche (both 2016), and Pfizer (2017).[126] OTAs have also been used to enter into international collaborations with other funding agencies, such as the European Union's IMI (to co-fund the development of one of AstraZeneca's lead antibacterial candidates), and to jointly support other product development.[127] Finally, OTA contracts have made it possible for the U.S. government and its contractors to enter into consortiums.[128]

For example, as discussed further below,[129] BARDA and the NIH's NIAID used OTA to create the Global Combating Antibiotic Resistant

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126 *See* Michael J. Eichberg, *Public Funding of Clinical-Stage Antibiotic Development in the United States and European Union*, 13 HEALTH SECURITY 156 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4486734/pdf/hs.2014.0081.pdf [https://perma.cc/6TTH-QN6Y]; *see* Houchens & Larsen, *supra* note 122.

127 As Bagley & Tvarnø explain:

> The IMI acts as a neutral third party supporting open-source, public-private research projects in the EU involving large biopharmaceutical companies that are members of the EFPIA, small and medium enterprises, patients' organizations, universities, other research organizations, hospitals, and regulatory agencies with the aim of improving drug development. The IMI is governed by Council Regulation (EC) No. 73/2008 on the establishment of the IMI Joint Undertaking (IMI-JU), the IMIJU financial rules, as well as other European Community and European Union law. The IMI grant agreement of 2011 comprises eleven articles and several appendices concerning the parties, research management, the scope and duration of the project, reports, budget and financial contribution, communication, applicable law and the competent court of jurisdiction. The grant agreement allows introduction of special clauses but does not itself include clauses promoting joint utility.

Bagley & Tvarnø, *supra* note 16, at 400. *See, e.g.*, Council Regulation 73/2008, Setting Up the Joint Undertaking for the Implementation of the Joint Technology Initiative on Innovative Medicines, 2008 O.J. (L 30) 38 (EC); *IMI Joint Undertaking Model* Grant Agreement *Core* 3–4, https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi1/IMI_Grant_Agreement_rev2011_Core.pdf [https://perma.cc/U2A8-MFD2]. On joint support of other product development, see Houchens & Larsen, *supra* note 122.

128 *See, e.g.*, *DoD Seeks to Establish Consortium for CBRN Countermeasures, Diagnostics*, GLOBAL BIODEFENSE (May 20, 2015), https://globalbiodefense.com/2015/05/20/dod-seeks-to-establish-consortium-for-cbrn-countermeasures-diagnostics [https://perma.cc/UYR6-B4T8] ("The DoD's Joint Project Manager for Medical Countermeasure Systems (JPM-MCS), part of the Joint Program Executive Office for Chemical and Biological Defense, is seeking to establish a consortium for advanced development efforts to support defense medical pharmaceutical and diagnostic requirements."); *see also Special Operations Forces Countering Weapons of Mass Destruction OTA*, CBRNE CENT. (Aug. 30, 2017), https://cbrnecentral.com/special-operations-forces-countering-weapons-mass-destruction-ota/10789 [https://perma.cc/SVC2-W4X8] ("The U.S. Army has released a competitive solicitation to establish an agreement with a single new or established consortium to develop and mature technologies which support Countering Weapons of Mass Destruction (CWMD).").

129 *See infra* text accompanying notes 210–13.

Bacteria Biopharmaceutical Accelerator (CARB-X).[130] In another effort "to accelerate research, development, and availability of transformative countermeasures to protect Americans," BARDA announced the creation of the Division of Research, Innovation, and Ventures (DRIVe) in June 2018.[131] According to Steve Brozak:

> Unlike the current funding mechanisms the government uses, it seems that DRIVe will act more like a strategic investor in private and public companies in addition to being a grant maker. This means that the new division may be able to make direct investments into companies BARDA would like to partner with and derive value by holding equity or equity-like instruments in the venture. Investing in opportunities in this manner offers a pathway to renew funds to reinvest into other ventures deemed essential to the national interest.[132]

Notwithstanding the promise of initiatives like CARB-X and DRIVe, the federal government's policies in effect since 2001[133] have not provided sufficient incentives for private biotechnology and pharmaceutical companies to engage in the development of countermeasures, with few companies advancing "candidates through clinical trials, and fewer still . . . likely to market products."[134]

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130 *Gates Foundation, UK Commit Nearly $52 Million to Fight Superbugs*, PHILANTHROPY NEWS DIG. (May 23, 2018), http://philanthropynewsdigest.org/news/gates-foundation-uk-commit-nearly-52-million-to-fight-superbugs [https://perma.cc/RZ6J-PJN4] [hereinafter *Gates Foundation*].

131 Steve Brozak, *An Unlikely Biotech Investor: The Government*, FORBES (June 8, 2018, 9:14 AM), https://www.forbes.com/sites/stephenbrozak/2018/06/08/merck-and-achaogen-two-companies-working-with-barda-to-fight-emerging-health-threats/#686518984fd0 [https://perma.cc/H4DZ-LNHE].

132 *Id.*

133 *See* Matheny et al., *supra* note 12, at 228–31; *see also* Clarence Lam et al., *Billions for Biodefense: Federal Agency Biodefense Funding, FY2006–FY2007*, 4 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 113 (2006).

134 *See* Matheny et al., *supra* note 12, at 228 ("Out of 11 requests for proposals issued by the Department of Health and Human Services (HHS) for biodefense countermeasures, only six products have been procured—none from a large pharmaceutical firm."); *see also id.* tbl.2; Melanie C. Trull et al., *Turning Biodefense Dollars into Products*, 25 NATURE BIOTECHNOLOGY 179, 180 (2007); U.S. DEP'T OF HEALTH & HUMAN SERVS., PROJECT BIOSHIELD ANNUAL REPORT TO CONGRESS: AUGUST 2006–JULY 2007 5 (2007).

D. *The Model State Emergency Health Powers Act*

Following the events of 9/11, the Center for Law and the Public's Health at Georgetown University and Johns Hopkins University prepared and published a Model State Emergency Health Powers Act (MSEHPA).[135] As a result of public criticism,[136] they subsequently introduced a second draft.[137] As of July 1, 2004, thirty-four states and the District of Columbia had enacted some form of the MSEHPA, and it was under consideration by another nine states.[138] As with the first version, various civil rights groups criticized the second draft for providing excessive powers to state governors at the expense of individual rights, and for allocating primary responsibility for responding to a bioterrorism attack to underfunded and undertrained individual state health departments ill-equipped to manage the after-effects of such an attack.[139] We agree that a national response regime is necessary.

III. DEFENSE OF HEALTH COUNTERMEASURES INITIATIVE

We call on the U.S. government to build on the success of DARPA and BARDA and the effective use of OTA to establish the Defense of Health Countermeasures Initiative. The DHCI builds on the concept that the government needs to be a key risk-taker and invest in

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135 MODEL STATE EMERGENCY HEALTH POWERS ACT (THE CTR. FOR LAW & THE PUB.'S HEALTH AT GEORGETOWN & JOHNS HOPKINS UNIVS., Proposed Draft Oct. 23, 2001), https://biotech.law.lsu.edu/blaw/bt/MSEHPA.pdf [https://perma.cc/K6KN-EMXW].

136 *See Model State Emergency Health Powers Act*, AM. C.L. UNION, https://www.aclu.org/other/model-state-emergency-health-powers-act [https://perma.cc/BJW9-UMM4] (last visited Oct. 4, 2018); *Model State Emergency Health Powers Act (MSEHPA)*, NAT'L VACCINE INFO. CTR., https://www.nvic.org/Vaccine-Laws/model-state-emergency-health-powers-act.aspx [https://perma.cc/5RBA-F545](last visited Oct. 4, 2018).

137 MODEL STATE EMERGENCY HEALTH POWERS ACT (THE CTR. FOR LAW & THE PUB.'S HEALTH AT GEORGETOWN & JOHNS HOPKINS UNIVS., Discussion Draft Dec. 21, 2001), http://www.aapsonline.org/legis/msehpa2.pdf [https://perma.cc/NHW4-RKB5].

138 Matthew E. Brown, *Reconsidering the Model State Emergency Health Powers Act: Toward State Regionalization in Bioterrorism Response*, 14 ANNALS HEALTH L. 95, 97 (2005), https://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1204&context=annals [https://perma.cc/GW28-5AK2].

139 *Id.*

knowledge, human capital, and innovation to encourage knowledge spillovers.[140]

The DHCI includes the creation of a public-private network of "ecosystems of excellence,"[141] comprising triads of universities and other research institutions, private pharmaceutical and biotechnology firms and private investors, and government actors, to form incubators for the development of effective CBRN countermeasures (Incubators or DHCIIs). The DHCI is designed to complement, and not to replace, the private market efforts in financing and growing emerging growth firms, new technology, and applications. It allows the government to make direct equity investments in seed projects (ideas that are promising bases for a new company or expansion of an existing firm) within a short period of time (usually within two but sometimes within up to five years), while also encouraging private intermediaries to participate in the financing and management of the funded companies.

Precedents include the National Science Foundation's University-Industry Demonstration Partnership and the NIH's Roadmap Initiatives, which have been "integral to engaging academia in drug discovery research and have been effectively leveraged to help bridge the chasm between basic research activities and the commercialization of a drug."[142] More recently, in 2012, the Obama Administration created Partnerships to Accelerate Therapeutics "to identify and resolve bottlenecks and speed the development of life-saving medicines through synergistic alliances involving industry, academia, government, and disease foundations."[143]

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140 *See* AUDRETSCH, *supra* note 74, at 9–10; LERNER, *supra* note 24, at 13, 71.

141 *See* Teece, *supra* note 24, at 104; *see also* Mike Alvarez Cohen, *Strategies for Developing University Innovation Ecosystems: An Analysis, Segmentation and Frame-Work Based on Somewhat Non-Intuitive and Slightly Controversial Findings*, 51 LES NOUVELLES 184 (2016) (defining "university innovation ecosystems" as "applied research, entrepreneurship education, technology transfer, idea incubators, startup accelerators, new venture competitions, mentor networks, industry collaborations, and venture capital resources"). Cohen found that "the top ecosystems have strong pools of innovative and entrepreneurial students, faculty and staff" and "relatively decentralized entrepreneurship-related activities, not top-down centralized control of activities." *Id.* at 185. For a discussion of the cybersecurity ecosystem of excellence in San Diego, California, see *infra* note 277.

142 Chaguturu, *supra* note 1, at xxi.

143 *Id.* at xx.

A. *Technology Innovation and Business Incubators: In General*

A key element of the DHCI is the use of technology innovation and business incubators to encourage innovation by serving the needs of entrepreneurs (and seed stage companies) and by providing them with access to the resources required to successfully grow their ideas.[144] Joseph Mancuso established the first U.S. business incubator, the Batavia Industrial Center in Batavia, New York, in 1959.[145] For the purpose of this Article, the term "business incubator program" is taken from the working definition provided by David A. Lewis, Elsie Harper-Anderson, and Lawrence A. Molnar, to mean the following:

> Business incubation programs are designed to accelerate the successful development of entrepreneurial companies through an array of business support resources and services, developed or orchestrated by the incubator manager, and offered both in the incubator and through its network of contacts. A business incubation program's main goal is to produce successful firms that will leave the program financially viable and freestanding. Critical to the definition of an incubator is the provision of management guidance, technical assistance, and consulting tailored to the needs of new enterprises.[146]

As of 2014, there were an estimated 7,000 incubators worldwide.[147]

There are different forms of technology and business incubators, which can generally be divided into four types, ranging from "virtual incubators"[148] (with no walls), "incubators with walls,"[149] and

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144 The use of the "technology business incubators" as a strategic development tool in the United States became popular in the mid-1980s.

145 *See* LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 76, at 13 ("The first U.S. business incubator opened in 1959, when Joseph Mancuso started the Batavia Industrial Center in Batavia, New York. Since that time, business incubation programs have emerged as successful economic development tools throughout the country and around the world. As of October 2006, approximately 1,400 business incubators operated in North America, including 1,115 in the U.S.").

146 *Id.* at 5.

147 Bjørn Petter Bjercke, Business Incubators as a Resource Provider 1 (July 2015) (unpublished thesis, Norwegian University of Science and Technology), https://brage.bibsys.no/xmlui/bitstream/handle/11250/2364869/13128_FULLTEXT.pdf?sequence=1 [https://perma.cc/PFG4-CGVA].

148 *See* LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 76, at 15. The terms "virtual incubators" and "[i]ncubators without walls" are synonymous. These incubators are:

"accelerators,"[150] to "international incubators."[151] For the reasons set forth in Section III.C below, we recommend incubators with walls, that is, incubators with shared-use facilities.

> [B]usiness incubators that do not offer on-site space for clients, although they may have a central office to coordinate services, house the management staff, meet with clients, and perhaps even provide conference rooms for clients. Virtual incubators may or may not be located in the same geographic area as their client companies, since a virtual presence is what defines an incubator without walls. Virtual incubation programs tend to be less expensive to operate than traditional business incubators that have additional expenses related to the operation and management of a physical plant. In rural areas—where the client base is often spread out over large areas, making commutes difficult—virtual incubation may be a good alternative. Also, some entrepreneurs prefer not to locate in an incubator facility because they already have established offices elsewhere or need access to specialized equipment or facilities not present in the incubator. For these firms, virtual incubation or participation in an affiliate program at an incubation program with walls is a better option. One significant challenge of virtual incubation is encouraging networking among clients. Having strong networks provides an environment that facilitates peer-to-peer learning, mutual support, and potential collaboration, as well as camaraderie—all of which are critical to client success. In addition, having clients located in close proximity within the incubator facility makes it easier for the incubator staff to deliver entrepreneurial support services. Some have compared virtual incubation with well-operated Small Business Development Centers. As with incubators with walls, virtual business incubation programs also face significant funding challenges.

Id.

149 *See id.* ("An incubator with walls is a business incubation program with a multitenant business incubator facility and on-site management. Although an incubator with walls offers entrepreneurs space in which to operate their businesses, the focus of the program remains on the business assistance services provided to the start-ups, not on the building itself.").

150 *See id.* at 16 (stating that there is no definitive definition of business accelerator in the literature). The term may be generally defined

> either as: (1) a late-stage incubation program, assisting entrepreneurial firms that are more mature and ready for external financing; or (2) a facility that houses a modified business incubation program designed for incubator graduates as they ease into the market. A third definition—which is both more expansive and less measurable—is similar to the virtual incubator model. Finally, some industry professionals use the terms business incubator and business accelerator interchangeably.

Id. In this Article, we use the definition provided by Cohen, Bingham, and Hallen: accelerators, such as Y Combinator (Silicon Valley) and Techstars (Boston, Boulder, London, and Seattle), are "short-term, limited duration, cohort-based educational programs for nascent ventures" that provide intense and quick mentoring for entrepreneurs who start and end the program together. Susan L. Cohen, Christopher B. Bingham & Benjamin L. Hallen, *The Role of Accelerator Designs in Mitigating Bounded Rationality in New Ventures*, ADMIN. SCI. Q. (July 2018), at 1, 3, 5–6, http://journals.sagepub.com/doi/pdf/10.1177/0001839218782131 [https://

For example, the University of Connecticut's Technology Incubation Program (TIP) operates two of the largest incubators in the United States, one in Farmington, Connecticut, next to its medical, nursing, and dental schools, specializing in life sciences, and a second near its main campus in Storrs, Connecticut, specializing in computer science and related high technology. TIP offers:

> [1] Incubator facilities featuring wet labs and access to instrumentation
>
> [2] Collaboration with Scientific Experts
>
> [3] Technically trained employees, fellows, interns and graduates
>
> [4] The university's world-class library resources [and]
>
> [5] Customized business planning and mentoring.[152]

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perma.cc/ZM86-2WPA]. An accelerator can have cohorts ranging from 6 to 125 start-ups. *Id.* at 6. Typically, the accelerator receives 6–8% of the equity of each participant in exchange for a $15,000 to $20,000 cash investment. *Id.* Since the first accelerator in the United States was created in 2005, approximately 6,000 start-ups nurtured in 650 accelerators have collectively raised more than $30 billion in capital. *Id.* at 5–6.

151 There appears to be no clear and generally accepted definition of the terms "international business incubator" or "international accelerator" in the literature. Additionally, there is scant empirical research or evaluation of these models. LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 76, at 16. As Lewis, Harper-Anderson, and Molnar explain, an international form of business incubation program has recently emerged to help foreign firms to enter the U.S. market:

> [I]nternational business incubators provide the same set of entrepreneurial services as a typical incubator, but they concentrate on providing a "soft landing" for international firms that want to access U.S. markets, partner with U.S. firms, or access other resources. Some specialized services offered by international incubators that are above and beyond typical business incubation services include translation services, language training, help obtaining business and driver's licenses, cultural training, immigration and visa assistance, and housing assistance. Immigration services are often extended to trailing spouses and children, making it easier for foreign entrepreneurs to settle into their new location.

Id. at 16–17.

152 *Wet Labs & Offices*, UNIVERSITY OF CONNECTICUT: OFFICE OF THE VICE PRESIDENT FOR RESEARCH, https://tip.uconn.edu/availablespace [https://perma.cc/3DW8-8B9Q] (last visited Oct. 4, 2018). There are also resident entrepreneurs and legal counsel available to assist the startups. Telephone Interview by Constance E. Bagley with Mostafa Analoui, Executive Director, Venture Development at the University of Connecticut's Technology Incubation Program (April 9, 2018).

B. *The Israeli Technology Incubator Program*

The Israeli government, acting through the Israeli Office of the Chief Scientist (OCS), established the Technology Incubator Program whereby it created twenty-eight technology incubators with shared-use facilities between the years of 1991 and 1993.[153] Designed to help build successful firms that could leave the incubator in relatively short order in a financially and organizationally self-sustained and viable state,[154] the program spurred the innovation and cross-fertilization necessary to develop Israel's high technology industry.[155] It also provided employment for the engineers and scientists who had immigrated to Israel from the former Soviet Union,[156] as well as laid-off engineers from the military sector.[157] By providing shared-use facilities and short-term financial and other support to individuals and early-stage companies with a promising idea,[158] the incubators "transformed" engineers into technological entrepreneurs.[159] Finally, the program forged links and

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153 *See* Frenkel et al., *infra* note 155, at 189.

154 Manuel Trajtenberg, *R&D Policy in Israel: An Overview and Reassessment* 10 (Nat'l Bureau of Econ. Research, Working Paper No. 7930, 2000). As Trajtenberg explained:

> [The] premise is that the technological incubator would significantly enhance the entrepreneur's prospects of raising further capital, finding strategic partners, and emerging from the incubator with businesses that can stand on their own. Of course, this initial stage is the riskiest, and certainly in the early 1990s there were virtually no other sources of finance in Israel for such ventures.

Id.

155 *See* Amnon Frenkel et al., *Public Versus Private Technological Incubator Programmes: Privatizing the Technological Incubators in Israel*, 16 EUR. PLAN. STUD. 189 (2005).

156 *See id.* According to Trajtenberg:

> Many of these immigrants were scientists and skilled professionals that came to Israel with highly valuable human capital as well as with plenty of ideas for innovative products. However, they were lacking in virtually all other dimensions required for commercial success, from knowledge of the relevant languages (e.g. Hebrew and English) and of commercial practices in western economies, to managerial skills and access to capital. Even though it targeted new immigrants, the program is open to all.

Trajtenberg, *supra* note 154, at 10.

157 *See* DANIEL SHEFER & AMNON FRENKEL, AN EVALUATION OF THE ISRAELI TECHNOLOGICAL INCUBATOR PROGRAM AND ITS PROJECTS 2–3 (2002), http://ifise.unipv.it/Download/final-draft3.pdf [https://perma.cc/KW4V-2QX5].

158 In Israel, incubators usually provide seed capital to entrepreneurs, whereas venture-capital funds provide start-up capital to an existing firm. *Id.* at 3.

159 *See id.* at 2–3.

promoted cooperation among entrepreneurs, academic institutions, private industry, and government procurement officials.[160] The incubators had no industrial sector designation or limitation, and any university or research institution, local municipality, or large private firm could sponsor a project.[161] Their geographic locations ranged from metropolitan areas to more remote regions.[162]

Each incubator's manager, often with the assistance of a group of professional advisors, was responsible for selecting eight to twelve projects from multiple applicants who were subject to a rigorous screening process.[163] To be accepted, the idea underlying the project had to be based on innovative R&D that was capable of being commercialized and exported to an appropriate market within a reasonable period of time.[164]

1. Governance

Initially, the Israeli technology incubators were organized as not-for-profit quasi-governmental entities.[165] They were governed by an incubator manager, as well as by public actors, such as government officials, municipalities, research institutions, and universities.[166]

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160 The academic peer review of the research underlying the applicants' proposals helped the incubator's managers gauge whether the idea or project in question could be commercialized in a timely manner, thereby strengthening the relationship between academic research and private industry.

161 *See* SHEFER & FRENKEL, *supra* note 157, at 3.

162 *See id.* at 4. As Frenkel et al. explain:

> The aim of the technological incubator programme, as a development programme "from below", is to foster entrepreneurial activities from the very beginning of a project's initiation. Therefore, the incubator has the advantages and drawbacks typical of this kind of programme. It can help to create a healthy entrepreneurial culture by empowering local people and encouraging them to develop their own firms locally. A technological incubator located in a remote region may be able to provide a number of functions that are seldom found in peripheral areas, such as VC supply, business and legal consultation, and the filtering of valuable ideas. Obviously, however, it cannot help in increasing the supply of skilled labour.

Frenkel et al., *supra* note 155, at 192–93.

163 *See* SHEFER & FRENKEL, *supra* note 157, at 3.

164 *See id.* at 11.

165 Catarina Wylie, *Vision in Venture: Israel's High-Tech Incubator Program*, 10 CELL CYCLE 855 (2011).

166 *See* SHEFER & FRENKEL, *supra* note 157, at 3–4.

Following the selection process, the incubator's manager and its professional advisors were responsible for working with the entrepreneur[167] to draft a "project folder," which was then submitted to the incubator's steering committee for approval.[168] The steering committee was typically chaired by the incubator's manager and usually comprised members from the following stakeholder groups: research institutions and academia, industry representatives, and community leaders.[169]

2. Financing Mechanisms and Services Provided

The Israeli government provided financial support both to the incubator's management, as well as to the program's participants. Annual grants to the incubator's management of up to $175,000 per year were available.[170] The government also provided grants of up to $150,000 per year, for a maximum of two years, to each seed company participating in the program.[171]

Subject to that upper limit of $150,000, the Israeli government limited the grants it allocated to each seed company to not more than 85% of that company's approved project budget.[172] As a result, the entrepreneur was responsible for obtaining non-government financing for the remaining 15% of the project budget, termed the "complementary financing."[173] The entrepreneur could (1) contribute that amount directly to the project, (2) raise that amount from a non-government party, or (3) provide some combination of self-funding and non-governmental financing.[174] Research in 2003 showed that founders

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167 The entrepreneur seeking approval of a project to commercialize a promising idea often will not have formed a separate entity, such as a corporation, before being accepted by the incubator. *Id.* at 3–4. When able to afford to pay the organizational costs, the entrepreneur may form a start-up firm with minimal capital before applying to the incubator. In this Article, we use the terms "entrepreneur," "founder," "seed company," "fledgling company," and "start-up" interchangeably unless the context clearly requires otherwise.

168 *Id.* at 3.

169 *Id.*

170 *Id.*

171 *Id.*

172 *See* Frenkel et al., *supra* note 155, at 193.

173 *Id.*

174 *Id.* ("From a small annual budget of $2 million at the beginning in 1991, the technological incubator programme increased its annual budget to $32 million in 2002. As of

had successfully obtained non-government financing for their incubator projects from private investors in exchange for a share of the equity in the project and by collecting fees from "royalties, sale of shares and dividends, and strategic partnerships."[175]

If the "incubated" firm was successful in commercializing its project, then it was obligated to repay the government "priming" grant by paying royalties to the Israeli government. If a new venture failed, however, then neither the entrepreneur nor the entity formed to pursue the project was required to repay the money the government had contributed to the project.[176]

3. Annual Evaluations and Possibility of Additional Governmental Support in Rare Cases

Each of the projects accepted into the incubator program was evaluated on a yearly basis. As noted above, government funding and other support were almost always limited to not more than two years after the venture commenced operations.[177] In limited circumstances, mainly when the evaluators concluded that the project was well-managed but was in a field like the biotech that required a longer

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2003, total government grants to the programme amounted to $285 million . . . . At the end of 2003, more than 200 projects were in operation in incubators, which employed more than 2,000 workers. One third of the initiatives were based on ideas brought by new immigrants, all of whom had an academic education (most with a Master's or PhD degree).").

175 *See* SHEFER & FRENKEL, *supra* note 157, at 55. Shefer and Frenkel assessed the successes of the Israeli technological incubator Program in 2003, which was ten years following its establishment. *See* Frenkel et al., *supra* note 155, at 193. They concluded that generally the program had fulfilled its purpose, because approximately 86.4% of the projects (during the years 1999–2001) had graduated from the program, and 78% of these projects were able to secure immediate financial support. *Id.* According to Frenkel, Shefer, and Miller, these statistics indicated that the programs were successful. *Id.* It should be noted, however, that incubators located in geographic areas considered to be the periphery experienced lower levels and rates of success than programs located in more central regions. *Id.* According to Frenkel, Shefer, and Miller, these findings suggested that vast government support was still needed in the initial stages of incubator programs. *Id.* However, government support in the programs can be gradually reduced over time, especially once private financing sources are available. *Id.* Yet, there is a caveat, as it appears that technological incubators located in peripheral regions require more public support for a longer period of time than incubators located in central regions of the country. *Id.*

176 *See* SHEFER & FRENKEL, *supra* note 157, at 15, 55.

177 *See id.* at 3–4.

incubation period, then a third year of government support might be granted.[178]

4. Privatization in 2002

The Israeli technological incubator program initiated in 1991 was privatized in 2002 and converted into public-private partnerships, which were organized in the form of incubator joint companies.[179] Once the private sector was able to provide adequate private capital for the incubators on reasonable terms, policy makers concluded that government funding was no longer necessary.[180]

The incubator joint company reduced its percentage of equity shares (which were not tradable) by increasing capital from external investment.[181] Wholly privately-owned incubator models then started to emerge in Israel.[182]

After the privatization, there was a dramatic rise in the success rates of entrepreneurial firms that participated in the private or quasi-public technology incubator programs.[183] Success rates were measured by the ability of entrepreneurial firms, after graduation from the incubator program, to obtain subsequent funding as well as to continue growing their operations.[184] Following graduation, many companies were able to create more jobs and attract international venture capital funds.[185]

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178 *Id.*

179 *See* Frenkel et al., *supra* note 155, at 194.

180 *See id.* According to Frenkel et al.:

> Privatization means a reduction in the government's role in producing goods and services, as well as limiting its control and regulation of the economy. . . . It is commonly understood that government usually does not manage its resources efficiently. Therefore, public companies will be less efficient than private companies. Thus, turning public companies into private enterprises could increase their efficiency and, thereby, the efficiency of the whole economic system . . . . Results have shown, though, that privatization increases efficiency and innovation if it is done in a wise manner.

Id.

181 *See id.*

182 *Id.*

183 *Id.*

184 *Id.*

185 *Id.*

The Israeli government further privatized the programs by establishing a franchise system, whereby the government licensed the public and quasi-public incubators to experienced equity investment firms.[186] Such firms extensively invested in the incubator start-up projects, providing both capital and management support.[187] Since 2002, the franchise model used a new repayment mechanism.[188] Originally, the Israeli government provided funding for projects directly to the public technological incubator program.[189] In that way, the program was the agent in charge of transferring the government funding to the individual companies. Moreover, the program, not the start-up firm, was accountable for repaying the grant, usually within a four-year period from the date in which the start-up firm graduated from the program.[190] To guarantee that the money would be repaid, the Israeli government held shares in each of the funded start-up firms. If the incubator did not repay the grant on time, the government had the right to decide whether or not to sell its stake in the start-up. According to Yossi Smoler, Director of the Technological Incubators Program, the repayment mechanism was "too complex and wasn't something in which the government wanted to be involved."[191] Today, the government allocates funds directly to the start-up company, and the company pays off the amount via royalties and interest (usually 3–5% of revenues plus a market rate of interest).[192]

5. Results

The Israeli technology incubator programs exceeded the initial goals of their founders, facilitating the development of a world-class, high-tech industry in Israel. The execution of the mission of the Office of Chief Scientist (OCS) to encourage cross-regional cooperation on innovation was and continues to be extremely successful. The OCS continues to expand its R&D initiatives with international partners (via

186 Wylie, *supra* note 165, at 855–56 (quoting Yossi Smoler, Director of Israel's Technological Incubators Program).

187 *Id.*

188 *Id.*

189 *Id.* at 855–56.

190 *Id.* at 856.

191 *Id.* at 856.

192 *Id.*

bilateral or multilateral cooperation) and contribute to the expansion of global innovative markets. Among these expanding markets are the United States, China, and India.[193]

C. *Proposed Structure of DHCI Incubators*

Each of the DHCI Incubators (DCHIIs) will have its own differentiating characteristics, which will depend on its regional and historical influences, as well as its stakeholders and purpose.[194] At a minimum, as stated by Ferid Murad, Nobel Laureate in Physiology and Medicine, "the collaborating parties must plan carefully, take the project seriously, define who does what, and honor their commitments in a timely fashion."[195] Although no single incubator structure or practice guarantees favorable results, we believe that, based on the Israeli experience and others studied by a variety of academics,[196] the DHCIIs should include the following features.

1. Shared Use Facilities

The DHCIIs should typically be part of a shared-use facility, where multiple founders of new ventures are physically located. Shared physical space promotes networking, collaboration, and the transfer of both information and tacit knowledge.[197]

Many entrepreneurs lack the accumulated knowledge, deep networks, and industry peer groups available to seasoned managers of established firms.[198] To handle the uncertainties and complexities

193 The Israel Innovation Authority (formerly called "Matimop"), the Israeli Industry Center for R&D, operates international R&D agreements on behalf of the OCS with Italy, Belgium, Ireland, Germany, Holland, Spain, Portugal, Finland, France, Sweden, Denmark, India, Turkey, Brazil, Argentina, Uruguay, Greece, China, Russia, the Czech Republic, Hungary, Ontario (Canada), Maryland (U.S.), and Victoria (Australia). *United States*, ISR. INNOVATION AUTHORITY, http://www.matimop.org.il/usa.html [https://perma.cc/F4VW-PB3T] (last visited Oct. 4, 2018).

194 For more suggestions, see KAO, *supra* note 68.

195 Ferid Murad, *Foreword*, *in* Chaguturu, *supra* note 1, at xvii–xviii.

196 Including, especially, the survey and analysis by Lewis, Harper-Anderson, and Molnar of the top performing incubation programs in the United States. LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 76.

197 BJERCKE, *supra* note 147, at vi.

198 Cohen et al., *supra* note 150, at 4.

inherent in many new ventures, entrepreneurs may overuse bounded rationality, be too quick to reject alternative courses of action, and "settle" for what seems like a "good enough" outcome; they may also suffer from confirmation and other cognitive biases.[199] Cohen, Bingham, and Hallen found, in a comparative study of accelerators, that by front-loading and concentrating the provision of expert advice, mentoring, and meetings with customers at the beginning of the program, by promoting transparency and information sharing among peer ventures in a cluster of innovation, and by standardizing focus, mentor meetings, peer gatherings, and other activities, the designers of accelerators were able to mitigate the adverse effects of oversized reliance on bounded rationality.[200] We would expect a similar dynamic to occur with incubators.[201]

Consider, for example, LabCentral, in Cambridge, Massachusetts—a shared-use, affordable, move-in-ready laboratory facility suitable for early-stage biotech research. Its founding sponsors include Triumvirate Environmental and Johnson & Johnson Innovation. It is a 70,000 square-foot facility in the heart of the Kendall Square, Cambridge, biotech innovation hub—near Harvard University and the Massachusetts Institute of Technology (MIT)—and was designed as a launchpad for high-potential life sciences and biotech start-ups. It offers fully permitted laboratory and office space for as many as sixty start-ups, comprising approximately 200 scientists and entrepreneurs. It is a private, nonprofit institution, funded in part by two $5 million grants from the Massachusetts Life Sciences Center, with support from its real estate partner, MIT.[202]

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199 *Id.* at 3–4. For a more detailed discussion of bounded rationality and the "satisficing" and cognitive biases that can accompany it, see Herbert A. Simon, *A Behavioral Model of Rational Choice*, 69 Q.J. ECON. 99 (1955); Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCI. 1124 (1974).

200 Cohen et al., *supra* note 150.

201 Bjercke found that co-location does not guarantee collaboration among incubatees in part because collaboration requires mutual trust. BJERCKE, *supra* note 147, at vi. However, co-location, when coupled with "proactive and continuous coaching" and the promotion by the incubator sponsor of knowledge sharing and collaboration among incubatees, resulted in greater access to resources. *Id.*

202 This entire paragraph is drawn from *What Is LabCentral?*, LABCENTRAL https://labcentral.org/about/what-is-labcentral [https://perma.cc/6XKF-MTZZ] (last visited Nov. 11, 2018).

To quote Douglas Crawford, the associate director of a LabCentral affiliate QB3@953:

> Once [biotech entrepreneurs] are convinced that they should try to bring their work to market, either with or without bridging-the-gap funding, they are often astounded by the next mental adjustment: the amount [of] effort required to turn their attractive innovation into a useful product . . . .
>
> Besides securing intellectual property and developing a business plan, the budding entrepreneur must find a place[,] . . . supporting services, and access to needed resources.[203]

2. Sponsors: DARPA and the Proposed Central Health Incubators Bureau

The DHCI requires a federal government agency tasked with spearheading the Initiative and setting up the Incubators in various geographic regions across the United States. We recommend that Congress authorize DARPA, with input from BARDA, the FDA, and the NIH, to create the Central Health Incubators Bureau (CHIB).[204] CHIB will be in charge of heading the Initiative and making the final decisions on the projects to be selected to participate in the various Incubators. CHIB should include experts from the private and public sectors, as well as nongovernmental organizations such as the American Civil Liberties Union, the World Health Organization, and the Red Cross. To avoid undue political interference, the members of CHIB should be granted the sort of independent authority given to the civilians chosen to determine which military bases should be closed after Congress decided that the United States no longer needed as many bases as it had during the Cold War.[205] Otherwise, each government official would find it politically very difficult to vote to close the base in that official's own geographic district regardless of its importance to the strategic defense of the United States.

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203 Kenneth D. Harrison et al., *Building a Life Sciences Innovation Ecosystem*, 4 SCI. TRANSLATIONAL MED. 1, 1–2 (2012).

204 This term is taken from the Israeli experience described *supra* in the text accompanying notes 153–93.

205 Jim Garamone, *Why Civilian Control of the Military?*, U.S. DEP'T DEFENSE (May 2, 2001), http://archive.defense.gov/news/newsarticle.aspx?id=45870 [https://perma.cc/PV84-WXWP].

3. Stakeholder Engagement

The shared facilities should be designed to encourage cooperation among not only the participating entrepreneurs but also between entrepreneurs and various stakeholder groups in ecosystems of excellence.[206] For the purpose of the Initiative, the term "stakeholders" refers to the following groups of public and private partners that will have a role in forming and operating the Incubator: management, the private sector, academia, industry, government, the financial sector, and other traditional stakeholders.[207] Accordingly, preferably, each Incubator will be located near established pharmaceutical and biotech firms, as well as research universities and other academic institutions with strong life sciences, engineering, and business departments, and will have access to military experts. As Robert Urban, Global Head of Johnson & Johnson Innovation, explains, "success requires density and proximity."[208]

For example, CARB-X, created pursuant to the Combating Antibiotic Resistant Bacteria (CARB) plan President Obama released in

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206 For a discussion of the Cyber Center of Excellence ecosystem in San Diego, California, see *infra* note 277.

207 In 2009–2010, the U.S. Small Business Administration launched and provided $14.7 million in funding for a pilot program of ten contract-based innovation clusters in various states. They ranged from agriculture innovation and autonomous systems and cybersecurity in California to smart grid and efficient energy in Illinois to geospatial technology in Mississippi. U.S. SMALL BUS. ADMIN., OVERVIEW: SBA INNOVATION CLUSTERS (Nov. 12, 2013), http://www.clustermapping.us/sites/default/files/files/page/Overview%20-%20SBA%20Innovation%20Clusters.pdf [https://perma.cc/5GXF-A8GV]. In just two years, participants in the ten clusters grew employment by 18%; increased revenues by 23%; raised more than $66 million in outside financing from venture capitalists, angel investors, and lenders; and secured more than $14 million in SBIR and STTR early-development awards. *Id.* at 5. In that same two-year period, small businesses in the ten clusters won contracts and subcontracts worth more than $807 million. *Id.* By 2013, the SBA and other agencies (including the Economic Development Agency, the Employment and Training Agency, the U.S. Department of Energy, the Environmental Protection Agency, the National Institute of Standards and Technology, and the U.S. Department of Agriculture) had allocated a total of $214.6 million to fund fifty-six clusters (including the ten pilot clusters) ranging from the Advanced Manufacturing Jobs Accelerator to the Rural Jobs Accelerator. *Id.* at 2.

208 Telephone interview by Constance E. Bagley with Robert Urban, Global Head, Johnson & Johnson Innovation, on February 26, 2018. For more information about Johnson & Johnson Innovation and its incubators and partnerships, see *About Us*, JOHNSON & JOHNSON INNOVATION, https://www.jnjinnovation.com/about-us [https://perma.cc/9LX7-LXER] (last visited Oct. 4, 2018).

2015,[209] "brings together leaders in industry, philanthropy, government, and academia with the aim of rejuvenating the antimicrobial pipeline for the next 25 years."[210] Its participants include:

> (1) BARDA and the NIH's NIAID are the U.S.-sponsoring governmental agencies.
>
> (2) Kevin Outterson, a leading health law researcher at Boston University who has collaborated in global projects to address antibiotic resistance, is the Executive Director.
>
> (3) The executive team "includes experts with decades of experience in antibiotic drug development, including John Rex, Senior Vice President at AstraZeneca," and Barry Eisenstein from Merck.
>
> (4) NIAID "will provide in-kind services, including preclinical services, to projects that CARB-X supports. NIAID also is providing technical support for CARB-X from their internal subject matter experts in early stage antibiotic drug discovery and product development."
>
> (5) MassBio and the California Life Sciences Institute "will provide world-class business support and mentoring services to innovative product developers selected for funding. The two accelerators will also share best practices with the Wellcome Trust and AMR Centre."
>
> (6) The Broad Institute of MIT and Harvard University "will host a new inter-disciplinary Collaborative Hub for Early Antibiotic Discovery. This hub, aimed at early drug discovery, will work with multiple academic programs to advance promising antibiotic candidates that the CARB-X initiative can pursue."
>
> (7) RTI International "will provide technical and regulatory support services to product developers in the partner

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209 Press Release, Office of the Press Sec'y, FACT SHEET: Obama Administration Releases National Action Plan to Combat Antibiotic-Resistant Bacteria (Mar. 27, 2015), https://obamawhitehouse.archives.gov/the-press-office/2015/03/27/fact-sheet-obama-administration-releases-national-action-plan-combat-ant [https://perma.cc/DFS2-G7PA]; *see also HSS Highlights Recent Progress Against Antibiotic Resistance*, HEALIO (Nov. 17, 2017), https://www.healio.com/infectious-disease/antimicrobials/news/online/%7B49c58212-a24a-467f-872b-2ec69dafdfc8%7D/hss-highlights-recent-pro [https://perma.cc/3DZA-EPV9].

210 *CARB-X Global Partnership*, B.U. SCH. LAW, www.bu.edu/law/faculty-scholarship/carb-x [https://perma.cc/8BV4-WUL3] (last visited Oct. 4, 2018).

> accelerators as well as build and run the computing systems to identify, track, and monitor all research programs, including a real-time dashboard management information systems. RTI will evaluate all CARB-X operations to identify and share best practices across all partners and supporting continuous quality improvement."[211] Two nongovernmental organizations—the Bill and Melinda Gates Foundation and the Wellcome Trust—will provide funding and other support.[212]

CARB-X has raised more than $500 million in funding and has more than thirty-three projects underway.[213]

4. Structure of Incubators

The DHCIIs should be largely autonomous organizations, usually structured as not-for-profit corporations, B corporations, or limited liability companies with (1) limits on the transfer of equity ownership and on the transfer or licensing of assets; and (2) the right to buy back equity or reacquire assets and licensed rights at cost. Such ventures are able to "lock in" their assets by protecting their stakeholders from the risk of shareholders attempting to withdraw assets.[214]

It should be noted that an incubator for life sciences will be different from, say, a computer software incubator, both because the time from invention to commercialization is much longer and because the incubator will require academic peer review of marketable research to gauge the safety and efficacy of an idea or a project. As a result, it should reinforce the connection between academia and industry while ensuring that funds are distributed to research projects that are deemed worthy by scientists, not just business people seeking short-term profits.[215]

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211 CARB-X, https://carb-x.org [https://perma.cc/8GG5-LTBR] (last visited Oct. 2, 2018).

212 *Id.*; *Gates Foundation*, *supra* note 130.

213 *Gates Foundation*, *supra* note 130. For more information about CARB-X, see CARB-X, *supra* note 211.

214 *See* Lynn A. Stout, *The Corporation as Time Machine: Intergenerational Equity, Intergenerational Efficiency, and the Corporate Form*, 38 SEATTLE U. L. REV. 685, 688–90 (2015). Stout's theory is discussed further *infra* in text accompanying notes 280–81.

215 *See* Block, *supra* note 34, at 175, 177 (according to Block, the NIH officials and policy makers rely heavily on the peer review model, in which funds are distributed to research

5. Financing

The DoD, the NIH, the CHIB, and other government agencies will provide seed funding for projects accepted by a DHCI in response to requests for proposals. Such grants will typically be limited to not more than two years.[216] Because these projects are from the biotech field, a third year of government support could be granted under special circumstances and after due assessment.[217] In contrast, projects supported by an accelerator would usually be funded for five months or less.[218]

Building on the Israeli incubator model, the funds should be invested in the portfolio companies in the Incubator and not given to the manager of the Incubator. However, in most cases, it will be the new venture, and not the government, that will own the technology with certain residual rights belonging to the academic institution and a portion of the royalties being payable to the inventors in accordance with the Bayh-Dole Act. The incubated firm will be required to repay the government grant once successful, perhaps (if one follows the Israeli model) with royalties equal to 3–5% of revenues plus market rate interest.[219] If the new venture fails, however, then the government will not require repayment of the grants.[220] Both the public and private participants should understand and acknowledge that it is very likely that entrepreneurs and start-up firms will fail several times before they reach a successful outcome in the biotech industry.

It will usually be necessary to raise additional funding from various local and regional stakeholder groups (such as colleges or universities, other government agencies, economic development groups, private industry, angel investors, venture capital and hedge funds, and any other potential sponsors of the Incubator). According to a study by Lewis, Harper-Anderson, and Molnar, public sector support contributes

projects that were deemed worthy by scientists); *see also* NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES, AN ASSESSMENT OF THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM AT THE NATIONAL INSTITUTES OF HEALTH (Charles W. Wessner ed., 2009), http://www.ncbi.nlm.nih.gov/books/NBK11455.

216 See Israeli example discussed in SHEFER & FRENKEL, *supra* note 157, at 3.

217 *See id.* at 3–4. In theory, a fourth or fifth year of support might be provided.

218 Cohen et al., *supra* note 150, at 8.

219 See Israeli Incubator example in Wylie, *supra* note 165, at 856.

220 *Id.*

to the success of projects nurtured in an incubator.[221] Moreover, incubators that enjoy larger budgets (in terms of both revenues and expenditures) outperform incubators that have to deal with budget constraints.[222]

Accordingly, the top managers of each Incubator should be expected to work with the entrepreneurs to line up investments from other private and public sources representing roughly 15% of each portfolio company's approved budget.[223] Getting private capital to supplement the government investment will increase the total capital introduced into the market, as well as provide networking opportunities for the portfolio companies, which may result in follow-on investments in the companies from such sources. As discussed below, the project managers of the firms in the incubators should also be expected to contribute funds, property, or sweat equity.

6. Other Governmental Actors and their Roles

Governmental actors can perform various tasks. Regional, state, and federal governments can generally be expected to provide R&D grants and other funding. Various agencies, such as the DoD, Department of Commerce (DOC), HHS, and Department of Labor, may be called upon to oversee and help carry out initiatives and projects

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221 *See* LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 76, at 8 ("[T]his research suggests that some level of public sector investment contributes to greater incubator outcomes in terms of job creation, graduation rates, etc.").

222 According to Lewis, Harper-Anderson, and Molnar:

> Programs with more financial resources have more capacity to deliver critical client services and are more stable. However, the sources of incubation program revenues and the ways the incubator uses these resources also are important. This study found that incubators receiving a larger portion of revenues from rent and service fees perform better than other programs. On the expenditure side, the more programs invest in staffing and program delivery—relative to building maintenance or debt servicing—the higher the probability of improved client outcomes.

Id. at 9.

223 "ARPA almost always requires 50 percent cost-matching for 'other transactions.'" Kuyath, *supra* note 34, at 533. "[T]he 50 percent cost-matching requirement can be a deterrent to companies participating in government-funded research, particularly if the company is a nonprofit or small business concern and lacks the financial resources to match costs." *Id.* Accordingly, we recommend the lower percentage successfully required by the Israeli incubator model.

funded by regional, state, or federal governments whereas economic development companies will usually represent the local government. Any government entity may serve as a future client or supplier for portfolio firms in the Incubator at prices tied to fair market value.

The following are four additional significant roles that government can play, as suggested by economists Muro and Katz.[224] First, federal policymakers can provide Incubator stakeholders around the nation with information and foundational resources.[225] This implies that the managers of the Incubators should recruit the involvement of federal agencies, and, in particular, the following: DOC (particularly, the National Institute of Standards and Technology); DoD; Education (ED); Energy (DOE); NASA; and the National Science Foundation (NSF).

Second, at the state level, policymakers should strategically invest resources in life science clusters and encourage regional collaboration.[226] Regional clusters are defined as "geographic concentrations of interconnected companies and institutions in a particular field," which include "governmental and other institutions."[227] The state government

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224 MARK MURO & BRUCE KATZ, THE NEW "CLUSTER MOMENT": HOW REGIONAL INNOVATION CLUSTERS CAN FOSTER THE NEXT ECONOMY 5 (2010), https://www.brookings.edu/wp-content/uploads/2016/06/0921_clusters_muro_katz.pdf [https://perma.cc/7DB5-2G53] ("[S]trong clusters foster innovation through dense knowledge flows and spillovers"). The different government stakeholders should align their efforts horizontally in addition to "vertically":

> The cluster paradigm can—and should—be used to organize the disconnected policy offerings of any one level of government in service of clusters' needs in a region, but it also provides a framework for coordinating them up and down the tiers of federalism to avoid policy conflict, redundancy, or missed opportunities for synergy.

Id. at 7.

225 *Id.* at 7–8 ("Going forward, the federal government should move aggressively to build the information base necessary for cluster activity and policymaking; create effective forums for best practice sharing; enhance the capacity of regional cluster intermediaries with planning and other assistance; employ cluster paradigms on major national challenges; coordinate disparate cluster-relevant programs; and ensure the overarching cluster effort is visibly prominent").

226 *Id.* at 8 ("States can make clusters a central component of economic development planning; target investments strategically to clusters of state significance; and adjust metropolitan governance to ease regional collaboration").

227 Michael E. Porter, *Clusters and the New Economics of Competition*, HARV. BUS. REV., Nov.–Dec. 1998, at 77, https://hbr.org/1998/11/clusters-and-the-new-economics-of-competition; *see also* MICHAEL E. PORTER, THE COMPETITIVE ADVANTAGE OF NATIONS (1990); Hal Wolman & Diana Hincapie, *Clusters and Cluster-Based Development: A Literature Review and Policy Discussion* 2–3 (Dec. 17, 2010) (unpublished working paper), https://gwipp.gwu.edu/

should encourage university-industry partnerships to leverage federal and academic research funds, to build a technically educated workforce, and to ease regulations to create a more fertile ground for technology.

Third, regional leaders should coordinate all the cluster participants and identify the various challenges facing clusters in that region.[228] Finally, local policymakers will need to implement the strategic cluster-oriented economic development policy, as well as help gauge the clusters' effectiveness and their possible expansion.[229] By working together, federal, regional, and local governments can foster the creation of ecosystems of excellence.[230]

7. Management

The DHCI requires two sets of managers—a top program manager (or top management team)[231] for each Incubator and a project manager (or project management team) for each portfolio company. Both the top program managers and the top project managers would report to the steering committee (discussed in the next Section).

a. Selecting the Top Program Managers for the Incubators

The Incubators could be managed in one of two ways—by internal executive managers hired to manage the program or by external trusted partners or intermediaries that contract to perform the top management function. Regardless of the selection process, the top program managers of the incubators would be tasked with facilitating the collaboration and coordination efforts essential for a successful Incubator.

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sites/g/files/zaxdzs2181/f/downloads/Working_Paper_042_Clusters.pdf [https://perma.cc/8M2V-ZJQ6].

228 MURO & KATZ, *supra* note 224, at 8 ("Regional intermediaries should work to identify and describe local clusters, identify their binding constraints, and facilitate regional joint action to implement needed exchanges and initiatives.").

229 *Id.* (recommending that local policy makers "should manage zoning and permitting issues to benefit the physical infrastructure in which clusters exist, and they should keep an eye out for the broader demographic and social context in which new industry clusters might form and to which existing ones must adjust").

230 *See* text *infra* accompanying notes 277–87.

231 In this Section we use the terms "top manager," "executive manager," and "top management team" interchangeably unless the context indicates otherwise.

i. Selecting Internal Executive Program Managers

The CHIB or an existing agency, such as DARPA, could hire internal executive program managers for each Incubator. Prospective executive managers would be required to compete for the right to participate in the DHCIIs.[232] To the extent that such matters have not otherwise been specified by the relevant government agency in its request for OTA proposals, applicants for the position of top program manager would be expected to address the following in their bids.

First, they should state which industry sectors they believe should be represented and identify the incubator's potential clients (that is, the entrepreneurs and firms that are likely to want to participate in the program). They should describe the potential clients' level of development[233] and evaluate their level of management skills.

Second, they should specify the region they believe is best suited to physically house the incubator and explain their selection criteria. Factors to be considered include whether the proposed region is a technology or non-technology-oriented region; whether it is considered a central or peripheral geographic area; and what is the industrial capacity of the region.[234] It is further proposed that the Incubators

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232 *See* Fannie Chen, Note, *Structuring Public-Private Partnerships: Implications from the "Public-Private Investment Program for Legacy Securities"*, 46 COLUM. J.L. & SOC. PROBS. 509 (2013) ("[B]uilding a process whereby private parties compete for participation in a [private-public partnership] through an auction-like mechanism can help government actors to accurately gauge the level of private sector risk-aversion ex ante and calibrate the optimal amount of financial incentive needed to attract private sector participation.").

233 *See About SBIR*, *supra* note 104 (the SBIR guidelines, Phase I definition, and eligibility for funding provide: "The objective of Phase I is to establish the technical merit, feasibility, and commercial potential of the proposed R/R&D efforts and to determine the quality of performance of the small business awardee organization prior to providing further Federal support in Phase II. SBIR Phase I awards normally do not exceed $150,000 total costs for 6 months.").

234 *See* LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 76. Lewis et al. found:

> Incubator management practices are better predictors of incubator performance than the size or growth of the region's employment or GDP. Only the aggregate host region employment in 2007 was a strong predictor of any incubator outcome—change in *affiliate* firm FTE from 2003 to 2008. . . . Compared with incubator quality variables, regional capacity variables have less predictive power. Among the regional capacity measures studied, only the proxies for urbanization, work force skills, availability of locally controlled capital, and higher educational attainment have moderate influence on incubator client outcomes.

Id. at 9.

should be sited in ecosystems of excellence that offer affordable and comfortable housing in order to attract talent.

Third, the applicants should identify the various stakeholders and potential sponsors (and partners) in the region and explain how they vary in terms of resources, missions, and requirements.

When selecting the program managers for the Incubators, the CHIB (or other government agency) should consider the reputation and experience of the managerial candidates, particularly with regard to the region in question; the industries (or research) that the agency would like to promote; the applicant's experience with seed investments, developing entrepreneurs and helping them convert their ideas into viable firms; and the applicant's ability to marshal additional investments and resources from local and regional stakeholders. The vetting and bidding process could also take into account the maximum amount of capital that the proposed executive program manager (or management group) would be willing to invest in the Incubator's portfolio companies and the equity or executive compensation expected in return, as well as the size of Incubator that the applicant seeks to establish.

The program managers will be paid a base salary for the managerial services that they provide, in addition to a certain equity stake in the portfolio companies (as equity compensation, in return for a cash investment in the portfolio company, or both).[235] The percentage of equity will be determined by the steering committee and will take into account private industry practice (not public government practice or wage standards), the region, and the fields of R&D. The Incubators' program managers will also be subject to the oversight of the private market, because if the portfolio firms are successful in the future and complete an acquisition or an initial public offering, then the managers will be compensated when the value of their equity stake increases.

ii. Selecting Trusted Partners or Intermediaries to Serve as Top Program Managers

Alternatively, the federal government could use the relevant agency's OTA to contract with trusted partners and third-party intermediaries. Many of the criteria used for selecting trusted partners and intermediaries are similar to those applicable to candidates for an

235 *See* sources cited *infra* note 264.

internal executive position. They include expertise vetting potential projects and ensuring that the cooperation, coordination, exchange of information, incentives, operational pieces, quality controls, and ethics and compliance systems necessary for a successful incubator are in place. Trusted partners and intermediaries will, like internal candidates, be expected to respond to a request for proposals, but their applications will not be nearly as extensive as what applicants for internal executive positions are required to submit. In addition, trusted partners and intermediaries will not be required to invest any of their own funds. They would, however, have the option of acquiring an equity stake in a specific portfolio company on terms acceptable to the project manager and the steering committee unless such an investment would create conflicts of interest.

b. Selection of Project Managers of Portfolio Companies

The process for selecting the project manager for a proposed portfolio company is extremely important.[236] When entrepreneurs are applying to join an Incubator, they will be required to provide a detailed account of their management experience and their perceived need for hiring others to serve on the top management team for the firm created to undertake the proposed project. The program manager of the Incubator for which an entrepreneur is applying will take this information into account when deciding whether to accept a project. Under certain circumstances, approval may be conditioned on a different project manager or an augmented project management team.

c. Business Plans for the Incubators and Portfolio Company Operations

Subject to approval by the CHIB (or other authorized government agency) acting pursuant to its OTA, the top program managers of the Incubators will be expected to set forth in a business plan or similar document clear (and well-defined) mission statements, investment processes, and goals for the Incubator, including a robust schedule of the fees that will be payable by the portfolio companies for the rental of

236 *See* LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 76, at 9 ("The findings provide empirical evidence that business incubation best practices are positively correlated to incubator success. Specifically, practices related to the composition of advisory boards, hiring qualified staffs that spend sufficient time with clients, and tracking incubator outcomes result in more successful incubation programs, clients, and graduates.").

facilities and equipment and the provision of other services, such as hazardous waste removal. The plan should also address the items required in the applications for executive program managers discussed above. Ultimately, the Incubator program manager will be expected to work with the most promising project applicants to help them craft a brief business plan (or pitch deck) for their proposed project. That business plan should meld the Incubator's program plan and the proposed project description in the participating entrepreneur's application into project specifications acceptable to the governing agency and the steering committee.

Once the government agency and the steering committee approve the project specifications, it is critical for the Incubator managers to ensure that the portfolio companies have project managers who are largely autonomous, as is the case with DARPA projects. Subject to approval by the steering committee, the top managers of the firms in the Incubators should have the authority to set goals, supervise staff, and take other appropriate steps to limit and mitigate the dangers of political pressures and abuse.[237]

The Incubators' program managers should, however, encourage the project managers and other stakeholders to promote collaboration between academic and industry researchers and scientists, given the key roles institutions of higher learning and research institutes play in a knowledge economy.[238] These include doing the basic and applied research necessary to understand various natural and technical phenomena and thereby contributing to the development of innovative commercial solutions. Academic partners can also provide guidance to the businesses fostered by the Incubator and help provide the tacit knowledge often necessary for successful commercialization. In addition, academic institutions are often well-suited to addressing the particular needs of the core industries in the region where the academic

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237 *See* Sean Silverthorne, *Government's Positive Role in Kick-Starting Entrepreneurship*, HARV. BUS. SCH. (Dec. 7, 2009), http://hbswk.hbs.edu/item/6318.html [https://perma.cc/S7RS-9SKF].

238 *See* NATIONAL INNOVATION SYSTEMS: A COMPARATIVE ANALYSIS, *supra* note 13, at 47–48; NATIONAL SYSTEMS OF INNOVATION: TOWARD A THEORY OF INNOVATION AND INTERACTIVE LEARNING 1–2 (Bengt-Åke Lundvall ed., 2010) (discussing the knowledge economy and noting that a national system of innovation is social and dynamic); SYSTEMS OF INNOVATION: TECHNOLOGIES, INSTITUTIONS AND ORGANIZATIONS (Charles Edquist ed., 1997); *see also* Laredo & Mustar, *supra* note 85.

laboratories and other facilities are located. The Incubators' managers should also encourage open innovation,[239] shared-use facilities, and technology transfer from the participating research institutions to firms capable of converting basic and applied science into marketable products and services or manufacturing processes.

8. Steering Committee

Each Incubator will have a steering committee which, according to the Israeli experience, would typically be chaired by the executive manager of the Incubator's management group.[240] The steering committee should include a technology transfer specialist; an executive from an incubator graduate firm;[241] accounting, intellectual property (patent assistance), and general legal experts;[242] representatives from research institutions and academia; industry representatives; local government and economic development agency officials;[243] and representatives from any other stakeholders involved with the incubator.[244]

9. Key Elements of the Public-Private Partnership Management Contract

The relationship among the various participants in an Incubator will typically be memorialized in a public-private partnership agreement. To increase the likelihood of success, all parties should do their best to couple a mutual relationship of trust predicated on honesty,

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239 Henry Chesbrough, adjunct professor and faculty director of the Center for Corporate Innovation at the University of California's Haas School of Business, coined the term "open innovation." HENRY CHESBROUGH, OPEN INNOVATION: THE NEW IMPERATIVE FOR CREATING AND PROFITING FROM TECHNOLOGY xxiv (2005). According to Chesbrough, "Open Innovation is a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as the firms look to advance their technology." *Id.*

240 SHEFER & FRENKEL, *supra* note 157, at 3.

241 LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 76, at 7–8.

242 *Id.*

243 *See id.* at 8 (stating that local government and economic development officials "play key roles in enhanced client firm performance, as their presence ensures that the incubator is embedded in the community, which is necessary for its success. . . . [They] also help educate critical funding sources about the incubation program and its successes.").

244 SHEFER & FRENKEL, *supra* note 157, at 3.

integrity, transparency, and fair dealing with a long-form contract that ensures that the proper incentives are in place.[245] Commons theory posits that private arrangements can be effective to govern shared resources such as information and data.[246] In this respect, our proposal incorporates aspects of the work of Nobel Laureate Elinor Ostrom on a commons framework whereby consortia can share certain data pursuant to contracts that structure their interactions by taking into account the knowledge and information resources that they create and exploit.[247] Unlike the nongovernmental governance structure for commons contemplated by Ostrom, however, our proposal includes aspects of the Information Commons contemplated by the 21st Century Cures Act, and it contemplates that the government will be one of the contracting parties and confer economically efficient intellectual property rights.[248]

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245 *See* Bagley & Tvarnø, *supra* note 16, at 396 ("The prisoners' dilemma shows that the parties, acting alone, will self-optimize. A well-crafted and fully enforceable [public-private partnership] contract can help prevent self-optimization and instead promote joint optimization and efficient allocation of added value.").

246 *See* Katherine J. Strandburg et al., *Knowledge Commons and the Road to Medical Commons*, *in* GOVERNING MEDICAL KNOWLEDGE COMMONS 1 (Katherine J. Strandburg, Brett M. Frischmann & Michael J. Madison eds., 2017).

247 Nobel Laureate Elinor Ostrom is known for "her analysis of economic governance." Kelsey Sharpe, *UCLA Alumna Elinor Ostrom Wins 2009 Nobel Prize in Economics*, UCLA (Oct. 12, 2009), http://newsroom.ucla.edu/stories/ucla-alumna-elinor-ostrom-wins-111209 [https://perma.cc/S7ZE-4YD2]. She demonstrated how common property (such as forests, fisheries, or oil fields) can be successfully managed by the groups using it, without government intervention. *See* ELINOR OSTROM, GOVERNING THE COMMONS: THE EVOLUTION OF INSTITUTIONS FOR COLLECTIVE ACTION (1990); *see also* Elinor Ostrom & Charlotte Hess, *A Framework for Analyzing the Knowledge Commons*, *in* UNDERSTANDING KNOWLEDGE AS A COMMONS: FROM THEORY TO PRACTICE 41 (Charlotte Hess & Elinor Ostrom eds., 2007). For more on commons approach, see Michael J. Madison, Brett M. Frischmann & Katherine J. Strandburg, *Constructing Commons in the Cultural Environment*, 95 CORNELL L. REV. 657 (2010); Robert P. Merges, *Individual Creators in the Cultural Commons*, 95 CORNELL L. REV. 793 (2010). *See also* Elinor Ostrom, *The Institutional Analysis and Development Framework and the Commons*, 95 CORNELL L. REV. 807 (2010); Strandburg et al., *Knowledge Commons and the Road to Medical Commons*, *supra* note 246.

248 As Nobel Laureate Paul Romer explained:

> If we had a field, a pasture, and we let everybody use it for free, we know what happens. You get the tragedy of the common pasture. It gets overused. You get congestion. You get waste[.] But there's no tragedy of the intellectual commons. There's no overuse or congestion from having everybody use an idea once it's discovered.

Tiffany Jeung, *Paul Romer: How the Economics Nobel Prize Winner Unlocked World Innovation*, INVERSE (Oct. 8, 2018), https://www.inverse.com/article/49702-paul-romer-

To promote trust and cooperation and reduce the risk of defection, the contract should include clauses to the following effect:

> (1) The parties shall together pursue a strategic alliance by joint initiatives and optimization for the benefit of the project. The parties recognize that achieving joint optimization requires specific legal clauses.
>
> (2) The parties agree to fulfill their obligations in accordance with the agreed binding clauses setting forth the common goals and the value added by joint optimization.
>
> (3) The parties agree to work and conduct research together in the spirit of the project with openness, trust, and collaboration.
>
> (4) A copy of the contract shall remain on the table in the lab. The parties shall use the contract on a daily basis and educate the involved staff, researchers, and legal back office in a joint optimization spirit. The parties acknowledge that the contract is a necessary tool to create added value.
>
> (5) The parties shall take the steps necessary to optimize the value of the project. Accordingly, all parties have the obligation to warn each other of any error, omission, or discrepancy of which they become aware and shall immediately propose solutions designed to jointly optimize the successful completion of the project.
>
> (6) It is a requirement that all relevant information be made available to all parties because it generates transparency, trust, and confidence. Accordingly, all parties shall open up their books and calculations concerning the project.

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economics-nobel [https://perma.cc/R6QB-DLS3] (quoting a 2007 interview to EconTalk). Indeed, "'[t]he more we know, the easier it gets to discover.'" Hilary Brueck, *Economist Paul Romer Just Won the Nobel Prize in Economics—and His Ideas Sound Like the Backbone of Bill Gates' Philanthropy Playbook*, BUS. INSIDER (Oct. 8, 2018, 5:42 PM), https://www.businessinsider.com/paul-romer-nobel-prize-in-economics-endogenous-growth-theory-2018-10 [https://perma.cc/GZQ5-Z7RA]. Because a "society never runs out of ideas," others "will inevitably leapfrog over the sitting king [holding the patent on an idea], pushing the boundaries of technology forward while resetting the monopoly. So with more money invested and more frogs preparing to jump, discovery and economic progress quickens." Jeung, *supra*.

> (7) The parties must ensure each other a healthy business case and optimal research conditions and recognize that they have different economic yields from the project.
> (8) Due to the above clauses, the parties shall establish, develop, and implement a strategic alliance relationship in the lab and other shared facilities with the objectives of achieving:
>
> (a) Mutual cooperation, openness, and trust
> (b) Joint research
> (c) Common goals
> (d) An understanding of each other's values and the joint value of the project
> (e) Innovation
> (f) Improved efficiency and optimization of the project
>
> (9) Delivery in accordance with Key Performance Indicators (KPIs) and timetables. Any research, added value, risk, pain, and gain identified by the parties shall be subject to incentive payments.
> (10) The parties shall investigate all possible positive incentives to fulfill the value-added transaction. The parties shall be awarded for and encouraged to maximize their effort for the benefit of the project and to allocate the added value in accordance with the key factors in paragraphs (8) and (9).
> (11) Any dispute shall be resolved as soon as possible and the parties shall apply the following specific strategic alliance guideline: When a problem arises, the first responsible director shall gather the parties and, based on the objectives set forth in the contract, launch a procedure to solve the problem. If the problem persists, the next director in the hierarchy shall be given responsibility for the problem; then, if necessary, a mediator and finally an arbitrator shall be appointed. At every stage, the above points shall be observed. All parties recognize that even when they experience conflict, common goals and optimization lead to added value for the project.[249]

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[249] Bagley & Tvarnø, *supra* note 16, at 396–97 (with minor changes in wording).

10. Selection and Evaluation of Projects and Portfolio Companies

The Incubator's management team, including the executive director and other professional advisors, will propose to the steering committee one or more (depending on the size and capital of the Incubator) projects or portfolio companies to participate in the Incubator.[250] Once the steering committee has approved a project or portfolio company, the CHIB will be responsible for making the final decision on which projects and companies will participate in the program and receive funding. Before making its final determination, the CHIB will, absent exigent circumstances, be expected to obtain peer review of the proposals, as happens now with both NIH and IMI grants, and to request additional advice from independent experts, depending on the industry and research objectives.[251] To ensure that only truly innovative projects are approved, regardless of the publishing history or established reputation of the inventor, we advocate following the process developed by Thomas Sinkjær, whereby each member of the review committee is given a "golden ticket" that can be used to green-light a project even if it is not approved by the other members of the review committee.[252]

To be accepted into the program, the project (business, technical, or scientific idea) must be innovative, based on sound R&D, and capable of being commercialized and exported to the appropriate market. The industry scope is the core activity or common denominator that links

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> Certain "add-on" contract clauses promote long-term, Pareto optimal collaborations between pharmaceutical companies and universities in the research discovery phase, the stage in the value chain at which a strategic alliance can create benefits for both the university and the pharmaceutical business. For example, positive incentive clauses ensure that both parties have an incentive to add value for each other. They create a bigger pie and a more efficient allocation of the slices through the articulation of common goals, shared value creation, and joint optimization.

Id. at 396; *see also* Strandburg et al., *Knowledge Commons and the Road to Medical Commons*, *supra* note 246; Strandburg et al., *The Knowledge Commons Framework*, *supra* note 246.

250 For a discussion of the Israeli Incubator Model, see SHEFER & FRENKEL, *supra* note 157.

251 *See id.* at 3.

252 Thomas Sinkjær, *Fund Ideas, Not Pedigree, to Find Fresh Insight*, 555 NATURE 143, 143 (2018) ("Anonymous applications free scientists to make bold proposals, and 'golden tickets' free reviewers to bet on them.").

the participating actors.[253] An Incubator may concentrate on a specific sector, such as biotechnology or defense needs, but under certain circumstances the managers might be encouraged to go beyond the industry scope and support different projects from various industries.

A general objective of the DHCI is to encourage the adoption of the stakeholder approach to strategic management,[254] which is intended to give managers a framework within which to deal with constant changes in the environment, society, technology, and industry.[255] Accordingly, the Incubator managers will be able to actively design a new direction for the Incubator,[256] as needed to take into account how the Incubator can affect the environment, in addition to how the environment may affect the Incubator,[257] subject to the approval of the steering committee and CHIB.

The managers should be free to select projects that might take a long time to produce results because they will not be subject to the threat of losing their jobs if the projects do not produce short-term results and profits.[258] Such emphasis on investment in long-term R&D

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253 *See generally* THOMAS ANDERSSON ET AL., THE CLUSTER POLICIES WHITEBOOK (2004), http://www.tci-network.org/uploads/media/CKC/0001/03/245afe2fcf683b3b2fcaf803cabc80795f2ff0fe.pdf [https://perma.cc/Q53D-2J6Y].

254 *See* R. Edward Freeman & John McVea, *A Stakeholder Approach to Strategic Management* (Darden Graduate Sch. of Bus. Admin., Univ. of Va., Working Paper No. 01-02, 2001), http://faculty.wwu.edu/dunnc3/rprnts.stakeholderapproach.pdf [https://perma.cc/D5NQ-AG6L].

> The impetus behind stakeholder management was to try and build a framework that was responsive to the concerns of managers who were being buffeted by unprecedented levels of environmental turbulence and change. Traditional strategy frameworks were neither helping managers develop new strategic directions nor were they helping them understand how to create new opportunities in the midst of so much change. As Freeman observed "[O]ur current theories are inconsistent with both the quantity and kinds of change that are occurring in the business environment of the [1980s] . . . . A new conceptual framework is needed." A stakeholder approach was a response to this challenge.

Id.

255 *See id.* ("The purpose of stakeholder management was to devise methods to manage the myriad groups and relationships that resulted in a strategic fashion.").

256 SHEFER & FRENKEL, *supra* note 157.

257 *See* Freeman & McVea, *supra* note 254.

258 *See* LYNN STOUT, THE SHAREHOLDER VALUE MYTH: HOW PUTTING SHAREHOLDERS FIRST HARMS INVESTORS, CORPORATIONS, AND THE PUBLIC 72 (2012).

will provide current and future generations with the ability to enjoy the wealth generated from the innovative projects.[259]

Each of the projects in the Incubator program should be evaluated on a yearly basis.[260] If a project is running over budget or behind schedule or otherwise not meeting expectations, then the program manager should give the portfolio company management a reasonable time to get it back on track. If the program manager or CHIB is still not satisfied after the portfolio company's management has been given an opportunity to meet expectations then either the program manager or CHIB should have the power to terminate the project, with all intellectual property rights not already licensed to third parties reverting to the portfolio company.

11. Management Incentives to Prevent Adverse Selection, Conflicts of Interest, Shirking, and Political Capture

To avoid "waste" (i.e., management getting paid by the government no matter how well the projects do) and political capture (i.e., management being pressured by local stakeholders to accept friends, relatives, or political allies into programs or to otherwise take actions not in the best interests of the Incubator),[261] the following incentives are

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259 *See* Stout, *supra* note 214, at 707–08. Stout gave examples of the ways in which the results of research and development by large public corporations have benefited current and future generations:

> IBM and AT&T likely incurred very high levels of "wasteful" agency costs while operating their Big Blue and Bell Labs research divisions during the 1950s and 1960s. Nevertheless, those costs have been repaid many times over by the gains to multiple generations of shareholders (and others) from developing the computer and the transistor. Similarly, multiple future generations may benefit enormously from current corporate projects to develop self-driving cars, commercial space transport, and algal biofuels.

Id.

260 *See generally* SHEFER & FRENKEL, *supra* note 157, at 3.

261 *See* Andrei Shleifer, *State Versus Private Ownership*, 12 J. ECON. PERSPS. 133, 141 (1998) (arguing that "[g]overnments throughout the world have long directed benefits to their political supporters, whether in the form of jobs at above-market wages or outright transfers").

designed to encourage the management to be diligent in selecting the companies that will join the Incubator portfolio.[262]

First, the management of the Incubator must be autonomous so it can set clear and well-defined strategic long-term goals for running the Incubator. Its duties will include supervising the funding from the various stakeholder groups, and providing accelerator- and venture capital-like support services to the portfolio companies, such as assisting in the development of the R&D and commercialization strategy; helping to prepare the business plan and the pitch deck; introducing the entrepreneurs to members of the Incubator management's network, including potential mentors, investors, collaborators, and customers; and providing clerical services, organizational analysis, and legal and accounting guidance.[263] Additionally, to accelerate the formation and growth of the seed companies, the management will need to integrate education and workforce training functions into the Incubator's operations, which is where academia and the research community can also play important roles.

Second, based on lessons learned from the Israeli experience and following the recent successful market trend of the accelerator model, the management of the Incubator should be expected to invest a certain amount of their own capital in the portfolio companies, in cash or as sweat equity, in return for an equity stake in the companies.[264] Managers who have invested their own capital in the portfolio Incubator companies will have a stake in making sure that they do not pick

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262 Capture problems can be reduced by "passing the funds onto intermediaries such as venture capital funds that make the real investment decisions. By keeping individual awards relatively modest, they limit efforts to misdirect these funds." Silverthorne, *supra* note 237.

263 For an excellent description of the types of support accelerators typically provide and their effect on start-ups' success, see Cohen et al., *supra* note 150. *See also* MURO & KATZ, *supra* note 224, at 7 ("Clustering is a dynamic of the private economy in the presence of public goods. Cluster strategy should be pursued with humility as a matter of supporting, connecting, filling gaps, and removing obstacles to private enterprise while making sure certain public and quasi-public goods are available.").

264 For example, the accelerator program AlphaLab, a nationally-ranked start-up accelerator program based in Pittsburgh, Pennsylvania, receives 4% common stock in the companies it invests in, in return for a $25,000 investment in each company from Innovation Works (AlphaLab's parent organization), plus space and services. *FAQ*, ALPHALAB, http://alphalab.org/faq (last visited Oct. 6, 2018); *see also* Cohen et al., *supra* note 150, at 6 (accelerators typically invest $15,000 to $20,000 in exchange for 6–8% of the new venture's equity).

"lemons."[265] Having an equity stake also reduces the dangers of management shirking[266] and not acting in the best interests of the companies and their investors.[267] It may also lessen the effects of political pressures from the government agencies involved.

12. Open Innovation and the Creation and Governance of a Commons

The DHCI is based on the "open-innovation"[268] and "commons"[269] paradigms, which enable the participating early-stage firms in the Incubator to use internal and external ideas to develop their biotechnology, product, or process, as well as to take advantage of the shared-use facilities. Firms using open innovation are able to leverage the basic research that was done by other firms while exploiting both external and internal sources of innovation,[270] thereby reducing the cost of carrying out R&D[271] and increasing the likelihood of developing products or services that would otherwise not exist or would remain

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265 *See* George A. Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism*, 84 Q.J. ECONOMICS 488, 493 (1970) (discussing the "adverse selection" problem, as well as firms' offerings of equity that may be associated with the "lemons" problem); *see also* Manuel A. Utset, *Reciprocal Fairness, Strategic Behavior & Venture Survival: A Theory of Venture Capital-Financed Firms*, 2002 WIS. L. REV. 45, 56; PAUL A. GOMPERS & JOSH LERNER, THE VENTURE CAPITAL CYCLE 159 (2d ed. 2004).

266 *See* Michael C. Jensen & William H. Meckling, *Theory of the Firm: Managerial Behavior, Agency Costs and Ownership Structure*, 3 J. FIN. ECON. 305, 309 (1976) ("The problem of inducing an 'agent' to behave as if he were maximizing the 'principal's' welfare is quite general. It exists in all organizations and in all cooperative efforts—at every level of management in firms, in universities, in mutual companies, in cooperatives, in governmental authorities and bureaus, in unions, and in relationships normally classified as agency relationships such as are common in the performing arts and the market for real estate.").

267 *See* LERNER, *supra* note 24, at 7.

268 *See* CHESBROUGH, *supra* note 239.

269 *See generally* Strandburg et al., *supra* note 246.

270 *See* Joel West & Scott Gallagher, *Patterns of Open Innovation in Open Source Software*, *in* OPEN INNOVATION: RESEARCHING A NEW PARADIGM 82 (Henry Chesbrough, Wim Vanhaverbeke & Joel West eds., 2006) (arguing firms produce internal innovations (from internal knowledge), and various models have been developed in order to try and explain how firms can also exploit external knowledge). West and Gallagher state there are four sources of external knowledge: first, supplier and customer; second, university, government, and private laboratories; third, competitors; and fourth, other nations. *Id.* at 6 (citing ERIC VON HIPPEL, THE SOURCES OF INNOVATION (1988)).

271 *See* CHESBROUGH, *supra* note 239, at xxiv.

untapped in the economy.[272] Both open innovation and the creation of an information commons encourage knowledge spillovers and collaboration among the participating firms and stakeholders. They can also facilitate the early incorporation of customers in the development process[273] and boost the accuracy of customer targeting and market research. Finally, they increase the potential for viral marketing.[274] Firms that have successfully used open innovation include Intel, Cisco, and Microsoft.[275]

If, however, there is proprietary information that a private firm will eventually want to patent or otherwise protect, then a trusted intermediary may be used to match up promising discoveries and needs without disclosing the proprietary information to a rival firm or institution. This is already being done with a high throughput program whereby promising small molecules or biologics owned by pharmaceutical and biotech firms are matched against pathogens and pathways or genes identified by academic scientists pursuant to cooperative R&D agreements. Alternatively, the OTA contract could specify that the government is the sole owner of the technology and has the sole right to use it. If, for example, the government decided to offer a $1 billion prize to the first firm to successfully develop an antibiotic effective against "superbugs," the government would want to keep it as a drug of last resort to prevent the development of antibiotic-resistant

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272 *See also* Yoram Margalioth, *Not a Panacea for Economic Growth: The Case of Accelerated Depreciation*, 26 VA. TAX REV. 493, 495 (2007); Charles I. Jones, *Growth and Ideas*, *in* 1B HANDBOOK OF ECONOMIC GROWTH 1063, 1065–66 (Philippe Aghion & Steven Durlauf eds., 2005).

273 According to Marais and Schutte, firms are struggling to find efficient ways to identify the wants and needs of their target market. Therefore, they should use practical and "realistic" product testing or prototypes. *See* STEPHAN MARAIS & CORNE SCHUTTE, THE DEVELOPMENT OF OPEN INNOVATION MODELS TO ASSIST THE INNOVATION PROCESS 96 (2009).

274 *See id.* at 105–06; *see also* Stephan Marais, The Definition and Development of Open Innovation Models to Assist the Innovation Process 67 (March 2010) (unpublished MScEng thesis, University of Stellenbosch), http://scholar.sun.ac.za/handle/10019.1/2891 [https://perma.cc/ARV8-QGLC] ("Idea Bounty puts a lot of emphasis on marketing, not only to retain existing community members, but also to attract new members. As is the nature of the service offering, all marketing efforts are done through the use of Web 2.0 technologies—blogs, micro-blogs and social networking sites.").

275 *See* CHESBROUGH, *supra* note 239, at xxiv.

strains. In such a case, the drug might be manufactured by a large pharmaceutical firm but the government would be the sole customer.[276]

13. Ecosystems of Excellence

If our initiative is properly implemented, it should lead to the formation of "ecosystems of excellence,"[277] sometimes called "clusters,"[278] with the following positive results. First, it can foster geographic connections between the various regions where the Incubators are located.[279] Second, it can boost new enterprise formation[280] and help firms survive the Valley of Death[281] by stimulating

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276 Thanks to Jo Handelsman, the Howard Hughes Medical Institute Professor and the Frederick Phineas Rose Professor of Molecular, Cellular, and Developmental Biology at Yale University, and the former Associate Director for Science, the White House Office of Science and Technology Policy during the Obama administration, for this example.

277 *See* Teece, *supra* note 24, at 104; *see also* Cohen, *supra* note 141; *supra* note 141 and accompanying text. An example of an ecosystem of excellence is the Cyber Center of Excellence in San Diego, California. It is "a non-profit dedicated to accelerating the region's cyber economy and positioning it as a global hub of cyber innovation." CYBER CTR. OF EXCELLENCE, ANNUAL REPORT: 2017 (2018), https://sdccoe.org/wp-content/uploads/2018/02/CCOE_2017-Annual-Report_DIGITAL.pdf [https://perma.cc/4QQ5-CMHK]. "The ecosystem includes incubators, financiers, experienced service providers and non-profits that support more than *100* firms focused exclusively on cybersecurity. In addition, the proximity of research and development facilities to Northern Mexico's manufacturing hub allows for the development of quick-to-market products." CYBER CTR. OF EXCELLENCE, ACCELERATING THE CYBER INNOVATION ECONOMY 2 (2016), https://sdccoe.org/wp-content/uploads/2016/09/CCOE_Brochure_v5.2.pdf [https://perma.cc/7P6Y -7MKB]. Multiple universities and colleges in the region engage in cutting-edge research in cybersecurity and train students for careers in cybersecurity, computer science, and engineering. *Id.* The Navy's Space & Naval Warfare Systems Command is based in San Diego, and it awards more than $1.1 billion in private-industry contracts annually to companies in the San Diego region, making its presence "a huge contributing factor for many companies to locate and stay in the region." *Id. See generally* CYBER CTR. EXCELLENCE, https://sdccoe.org [https://perma.cc/KMB8-KANZ] (last visited Oct. 4, 2018).

278 PORTER, *supra* note 227 (approximately twenty years ago, Michael Porter, a Harvard Business School professor, introduced and popularized the concept of "clusters"); s*ee also supra* text accompanying notes 248–53.

279 *See generally* PAUL R. KRUGMAN, GEOGRAPHY AND TRADE (1993) (discussing the significance of geographical economics).

280 PORTER, *supra* note 227.

281 *Id. See* discussion on Valley of Death *supra* Part II. These small and young firms are often more open to a commons framework whereby consortia can share certain data pursuant to contracts that structure their interactions by taking into account the knowledge and information resources that they create and exploit. These new ideas also tend to have a greater

low-cost collaboration between early-stage companies and various stakeholders, including customers, employees, creditors, suppliers, and other non-shareholder groups, which will supply the enterprise with resources (such as funding, labor, expertise, infrastructure, and the like).[282] Third, it can foster innovation and commercialization through dense knowledge flows and spillovers, including networking, data gathering, and sharing.[283] Finally, it can foster competition and encourage firms to innovate.[284]

CHIB should be in charge of developing platforms that will allow the various Incubator program managers to meet; share their progress, difficulty, and achievements; and share their resources, so that they can create a public-private "National Network for Innovation Incubation" to successfully deal with natural or terror events in the future. During previous events of this sort, there were deficiencies in both the local public health response and the federal government's ability to manage it.[285] For example, in 2001, respondents complained that "they did not have all the necessary agreements in place to put the plans into operation rapidly," ran into trouble reaching clinicians to provide them with guidance, and had not anticipated the number of entities with which they would have to communicate.[286]

We note that there is controversy concerning the issue of whether foreign companies or entrepreneurs should be able to participate in programs funded by American taxpayers. However, in today's global

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chance of making their way into practice due to the greater flexibility and more direct exchange of ideas among the various levels of the managerial hierarchy in smaller firms. Therefore, our initiative incorporates aspects of the work of Nobel Laureate Elinor Ostrom on the commons.

282 *See* Stout, *supra* note 214, at 692 (definition of "stakeholders").

283 *See* MURO & KATZ, *supra* note 224, at 5. Because cluster entities share an industrial focus, they tend to be in an excellent position to make use of knowledge and innovation relevant to an industry. PORTER, *supra* note 227. Absent the cluster, individual companies would lack access to certain information, such as market research and supply chain analysis. *Id.*

284 *See* MURO & KATZ, *supra* note 224, at 5; PORTER, *supra* note 227; *see also* Harald Bathelt et al., *Clusters and Knowledge: Local Buzz, Global Pipelines and the Process of Knowledge Creation*, 28 PROGRESS HUM. GEOGRAPHY 31, 36–37 (2004) (clusters strongly encourage and pressure companies to innovate both to stay competitive and to increase profitability).

285 *See* Temko, *supra* note 108, at 2–3, 6. For past example of failure to deal with the Anthrax incidents of 2001, see U.S. GOV'T ACCOUNTABILITY OFF., GAO-04-152, BIOTERRORISM: PUBLIC HEALTH RESPONSE TO ANTHRAX INCIDENTS OF 2001 (2003) [hereinafter BIOTERRORISM: PUBLIC HEALTH RESPONSE TO ANTHRAX INCIDENTS OF 2001].

286 BIOTERRORISM: PUBLIC HEALTH RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 285, at 1.

economy, such collaborations are necessary and even inevitable.[287] Therefore, international firms should be able to participate (as partners of American firms) unless their involvement would pose a threat to national security.

IV. CHALLENGES AND SOLUTIONS

There are many challenges associated with introducing change into an existing organization, especially a massive bureaucratic organization like the U.S. government or a complex system such as the patchwork of physicians, nurses, researchers, hospitals, clinics, insurers, and others responsible for the provision of healthcare in the United States.[288]

A. *Reluctance to Deal with the Government*

Individuals and companies in the private sector are often reluctant to sell to and collaborate with the government.[289] Reasons include the federal government's inflexible fight for control over intellectual property rights and software warranties;[290] unreasonable, time-consuming, and very costly delays in funding due to such things as shifts in government priorities and changing strategies and procurement needs;[291] complex cost accounting requirements; and the "long, onerous and costly federal acquisition process."[292] According to one GAO report that compared the process of submitting proposals for sale to the government with submitting bids to private parties, it took one company twenty-five full-time employees, twelve months, and millions of dollars to prepare a bid for the government.[293] In contrast, it took only three part-time employees, two months, and thousands of dollars to prepare the same bid for a private firm.

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287 *See* discussion *supra* Section III.B.5 (discussing cross-regional collaboration with respect to the Israeli Incubator programs.

288 *See* Dorothy Leonard-Barton & William A. Kraus, *Implementing New Technology*, HARV. BUS. REV., Nov. 1985, at 102.

289 *See* Cooke, *supra* note 50.

290 *Id.*

291 *Id.*

292 *Id.*

293 *Id.*

There are also cultural differences between the private industry, business, and government in general and with respect to public health in particular. There is a lack of familiarity with one another's values, metrics, resources, constraints, lines of accountability, management styles, lingo, and modes of operation. Private parties often view government management styles as inefficient and wasteful. Entrepreneurs and business leaders are concerned about the need to follow misinformed or opaque government regulations. Public leaders in the public health area may see their role as constraining businesses from promoting unhealthy products, harming the environment, or threatening the health of workers and patients—not as taking risks to find new therapies or finding ways to fund all the compounds and biologics that never find their way to a patient.

But there is precedent for the public-private partnerships we propose, including the Manhattan Project and DARPA. The surprise attack by the Japanese on Pearl Harbor, Hawaii, gave birth to the field of operations research as the country scrambled to arm and clothe its soldiers and build fleets of ships, submarines, tanks, and aircraft. Given the threats posed by CBRN attacks and diseases like influenza, we call on President Trump to order a review by operations research experts of how the FDA assesses and approves new drugs and medical devices. Queuing theory suggests that backlogs can be reduced by incremental increases in resources. The markets have already signaled what expedited FDA approval is worth; major pharmaceutical firms, which are often seeking approval of a "me-too drug" (one that is only slightly different from other drugs on the market), have paid hundreds of millions of dollars to acquire the transferable fast-track vouchers provided to the developers of cures for orphan diseases.[294]

We applaud the FDA's willingness to consider accepting aggregated patient data, of the sort gathered by Flatiron Health, based on electronic health records to be used in lieu of expensive and time-consuming clinical trials.[295] This may be particularly appropriate when a

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294 Ana Santos Rutschman, *The Priority Review Voucher Program at the FDA: From Neglected Tropical Diseases to the 21st Century Cures Act*, 26 ANNALS HEALTH L. 71 (2017). Government prizes can also spur otherwise unprofitable private-sector innovation. *See generally* Michael J. Burstein & Fiona E. Murray, *Innovation Prizes in Practice and Theory*, 29 HARV. J.L. & TECH. 401 (2016).

295 Lydia Ramsey, *The FDA and a $1.2 Billion Startup Are Analyzing How Drugs Are Used After Approval—and it Could One Day Change How We Treat Cancer*, BUS. INSIDER (June 2,

drug already approved for one clinical use is being considered for another (so-called repurposing).

B. *Lack of a Unified Healthcare Infrastructure*

Some (including certain members of Congress) maintain that the first BioShield initiative failed because the enabling act did not address the United States' healthcare infrastructure problems. Our DCHI ameliorates this by calling for centralized collaboration and coordination between and among local, state, and federal authorities, universities and research institutes, public and private hospitals and medical centers, private industry, and nongovernmental organizations for the purpose of defending U.S. residents from CBRN attacks and naturally occurring diseases like antibiotic-resistant bacteria. Given the gravity and widespread nature of such threats, our hope is that our modest proposal will be able to withstand the partisan politics that have resulted in the partial dismemberment of the Affordable Care Act.[296]

C. *Uncertainty, High-Risk, and Asymmetric Information Barriers*

Uncertainty, high-risk, and asymmetric information barriers are associated with investing in early-stage pharmaceutical, medical device, and biotech firms.[297] The markets for allocating risk capital to early stage ventures are inefficient.[298] Private investors often cannot obtain adequate information about which inventions and companies are likely to succeed. It is particularly difficult to quantify market uncertainties when an innovation is radical and technologies and markets are constantly evolving, changing, and becoming ever more complex. Even venture capital investors, who are special financial intermediaries that have found a way to address at least some of these information challenges, have abandoned early-stage biotech investments in favor of

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2017, 10:24 AM), http://www.businessinsider.com/flatiron-health-collaboration-with-fda-data-at-asco-2017-6 [https://perma.cc/63MG-7TPM].

296 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

297 *See* BRANSCOMB & AUERSWALD, *supra* note 94, at 5–6.

298 *See id.*

later stage investments,[299] in part because they cannot capture the full benefits of such technologies.[300] Additionally, many large public firms are closing or relocating their R&D labs to sites outside of the United States, and are shying away from "Moon Shot" investments in R&D initiatives with uncertain returns.[301]

The DHCI is designed to address many of these challenges by having the government intervene in the market, as it did after the Soviet Union launched Sputnik, by creating DARPA and giving it OTA to harness the power of the private sector and the university research community. Providing seed capital for public-private incubators that together form an ecosystem of excellence reduces at least some of the financial inefficiencies and helps bridge information gaps associated with investment in R&D. Perhaps, most importantly, it will serve as a catalyst for encouraging and stimulating the private development of innovative solutions (including funding early-stage companies) as happened with the Israeli Technology Incubator program.

D. *Political Capture of Business Objectives*

A primary argument for the privatization of state-owned firms or state-financed ventures has been the political capture of business purposes and objectives. Politicians concerned with being re-elected have a strong personal interest in making their constituents happy. Therefore, they have a tendency to push for more recruitment than

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299 Joseph A. McCahery et al., *Corporate Venture Capital: From Venturing to Partnering*, *in* THE OXFORD HANDBOOK OF VENTURE CAPITAL 211 (Douglas Cumming ed., 2012), http://www.oxfordhandbooks.com/view/10.1093/oxfordhb/9780195391596.001.0001/oxfordhb-9780195391596-e-7.

300 *See, e.g.*, Bronwyn H. Hall, *The Private and Social Returns to Research and Development*, *in* TECHNOLOGY, R&D, AND THE ECONOMY 140 (Bruce L.R. Smith & Claude E. Barfield eds., 1996) (providing evidence that the social return to R&D is much above the private return); *see* Zvi Griliches, *The Search for R&D Spillovers*, 94 SCANDINAVIAN J. ECON. S29, S29–36 (1992) (evaluating calculations of the social rates of return for research and development); Margalioth, *supra* note 272, at 501, 512–13; BRANSCOMB & AUERSWALD, *supra* note 94, at 2–6.

301 This is due in part to ill-informed notions of "shareholder primacy," which can deter large public companies from embarking on long-term strategic projects with uncertain returns. *See generally* STOUT, *supra* note 258. Managers may abstain from investing in risky innovation if they are under a constant threat of losing their jobs due to a change in both ownership and management. *Id.*; *see also* Andrei Shleifer & Lawrence H. Summers, *Breach of Trust in Hostile Takeovers*, *in* CORPORATE TAKEOVERS: CAUSES AND CONSEQUENCES 33, 33–56 (Alan J. Auerbach ed., 1998), https://www.nber.org/chapters/c2052.pdf [https://perma.cc/49GR-GFQE].

necessary in order to create jobs and spend more (in excess) than the private market would on an initiative,[302] such as construction of a new public university campus. Moreover, politicians can also push for initiatives, projects, and corporations that will essentially be tools to transfer wealth to their supporters, partners, or relatives.[303] This results in the misallocation of scarce government resources to the detriment of the taxpayer, as well as to those who would be better served by a more efficient process for funding innovation.[304] Moreover, governments can elect to pay higher wages to government workers than are customary in the private market, which often surpass the public worker's productivity level.[305]

We seek to address the risk of political capture by calling for largely independent and autonomous incubator management teams who have their own funds or sweat equity invested in the projects or portfolio companies being provided seed capital by the government. In addition, by following the successful Israeli example and requiring that at least 15% of the necessary funding be provided by nongovernment sources, our proposal provides a form of market check on the choice of investments.

CONCLUSION

This Article calls on the U.S. government to enact policies for institutional innovation that will encourage public and private sector experimentation and collaboration by reducing bureaucracy and promoting sustainable relationships and open innovation, while preserving the possibility of obtaining the intellectual property rights that are usually required to give private industry the incentive to innovate and commercialize novel therapeutics and medical devices. Properly harnessing the resources of private industry, universities and research centers, and government, will, we submit, lead not only to

302 *See* Belloc, *supra* note 83, at 9–11.

303 *See id.*

304 *See* Shleifer, *supra* note 261, at 148, 142 (arguing for the "importance of ownership as the source of capitalist incentives to innovate" and that "state firms are inefficient not just because their managers have weak incentives to reduce costs, but because inefficiency is the result of the government's deliberate policy to transfer resources to supporters").

305 Giacomo Corneo & Rafael Rob, *Working in Public and Private Firms*, 87 J. PUB. ECON. 1335 (2003).

improved readiness to respond to CBRN attacks and epidemics, but also to improvements in societal health and overall well-being.

In particular, we propose that Congress and the president enact and implement the Defense of Health Countermeasures Initiative, a multi-prong program that builds on the successes of DARPA and on the Biomedical Advanced Research and Development Authority, including their use of the federal government's Other Transaction Authority to create a national network of public-private incubators governed by contracts[306] of the sort currently used by participants in the European Union's Innovative Medicines Initiative[307] and by certain U.S. inventors, universities and research institutes, and for-profit firms working together with the NIH and other government funders under the Bayh-Dole Act.[308] Our initiative incorporates aspects of the work of Elinor Ostrom on a commons framework, whereby consortia can share certain data pursuant to contracts that structure their interactions by taking into account the knowledge and information resources that they create and exploit.[309] However, unlike the nongovernmental governance structure for commons contemplated by Ostrom, our proposal includes aspects of the Information Commons contemplated by the 21st Century Cures Act, CARB-X, and DRIVe. To provide adequate incentives for private firms to participate, members of a consortium will have the ability to keep certain information and downstream inventions proprietary, by allocating the patent rights by contract, as contemplated by Nobel Laureate Paul Romer, or by disclosing them only to a trusted intermediary pursuant to a confidentiality agreement that preserves future patentability and licensing rights.

We assert that the DHCI will not only help to protect U.S. residents from CBRN attacks and naturally occurring deadly diseases, but will also promote economic growth and increase productivity by ensuring

306 *See* Bagley & Tvarnø, *supra* note 14.

307 *See id.* at 400–01; Gaspar et al., *supra* note 21, at 984–86; *see also How IMI Works*, *supra* note 21. IMI works to "improve health by speeding up the development of innovative medicines, particularly in areas where there is an unmet medical or social, public health need." *Id.* IMI facilitates "collaboration between the key players involved in healthcare research, including universities, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators." *Id.*

308 For a list of legislation concerning innovation, see Block, supra note 34, at 179–80; *see also* Alon-Beck, *supra* note 23, at 284 n.78.

309 *See* Strandburg et al., *Knowledge Commons and the Road to Medical Commons*, *supra* note 246, at 1–5; Strandburg et al., *The Knowledge Commons Framework*, *supra* note 246.

that U.S. biotechnology start-ups can successfully compete in tomorrow's marketplace.[310] We recognize that even this modest proposal will require policymakers to design and institute sweeping innovation policies that will embrace new approaches to management, technologies, and operating methods.[311] Input and assistance from experts in academia, industry, and government will be needed to turn this skeletal proposal into the legislation, regulations, and contracts necessary to give our proposal life. Areas for further research and reflection include, but are not limited to: the application of the competition laws in the United States and the European Union to the partnerships, consortia, and networks we propose; government appropriations; interagency coordination; countermeasure prioritization; bilateral and multilateral opportunities for cooperation; the pricing mechanisms for inventions and equity funded through the DHCI; the appropriate use of government prizes and vouchers to spur innovation;[312] and the provisions necessary to protect basic human rights, especially the right to privacy. At the risk of sounding grandiose, we hope that this Article will help further the dialogues and work necessary to effect real change.

310 *See* Porter & Kramer, *supra* note 69, at 4–6, 12.

311 Block, *supra* note 34; *see also* Mary J. Dent, *A Rose by Any Other Name: How Labels Get in the Way of U.S. Innovation Policy*, 8 BERKELEY BUS. L.J. 128, 130–31 (2011) (stating that "policies that affect the innovation sector are frequently adopted as part of broader packages that have nothing to do with innovation"); Porter & Kramer, *supra* note 69, at 4–5, 7; KENT H. HUGHES, BUILDING THE NEXT AMERICAN CENTURY: THE PAST AND FUTURE OF AMERICAN ECONOMIC COMPETITIVENESS 1–2 (2005).

312 *See* Burstein & Murray, *supra* note 294; *see also* Rutschman, *supra* note 294.