

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

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ABSTRACT

The false alarm of an 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”), is a multi-prong program to create a defensive triad comprising government, private industry, and academia to develop countermeasures for health threats posed by chemical, biological, radiological, and nuclear (“CBRN”) attacks. Key elements of our multi-faceted 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 the use of certain information and trusted intermediaries to protect proprietary information pursuant to cooperative research and development agreements (“CRADAs”), 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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“ 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 Gates¹

I. 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 30 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. Ballistic missile tests by North Korea³ 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?”

The Russians used a weapons-grade nerve agent in an apparent attempt to assassinate a former spy and his daughter in Britain in 2018.⁴ In response, the U.K. Minister of Defence announced that the UK was spending £48m to set up a chemical weapons defense center and vaccinating thousands of British troops against anthrax.⁵

¹ COLLABORATIVE INNOVATION IN DRUG DISCOVERY: STRATEGIES FOR PUBLIC AND PRIVATE PARTNERSHIPS (Rathnam Chaguturu ed., 2014).

² Adam Nagourney, David E. Sanger & Johanna Barr, *Hawaii Panics after Alert about Incoming Missile Sent in Error*, N.Y. TIMES (Jan. 13, 2018), <https://www.nytimes.com/2018/01/13/us/hawaii-missile.html>.

³ See Hasani Gittens, *Trump to North Korean Leader Kim: My Nuclear Button ‘Is Bigger & More Powerful’*, NBC NEWS.COM (Jan. 3, 2018), <https://www.nbcnews.com/politics/donald-trump/trump-north-korean-leader-kim-my-nuclear-button-bigger-more-n834196>. See also Lindsey Bever, Sarah Kaplan & Abby Ohlheiser, *Speaking of Science: 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.

⁴ *Novichok: Murder Inquiry after Dawn Sturgess Dies*, BBC.COM (July 9, 2018), <https://www.bbc.com/news/uk-44760875>. Two more Britons were poisoned by the same nerve agent in July 2018, causing at least one death. *Id.*

⁵ *UK to Set up £48m Chemical Weapons Defence Centre*, THE GUARDIAN.COM (Mar. 15, 2018), <https://www.theguardian.com/politics/2018/mar/15/uk-set-up-48m-chemical-weapons-defence-centre-gavin-williamson>.

Anthrax-laced letters killed five and sickened fifteen Americans in 2001.⁶ Syria used Sarin gas on its own citizens in 2017 and 2013.⁷ 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 we are woefully unprepared to address threats of chemical, biological, radiological, and nuclear (“CBRN”) attacks and other emergency events that can cause massive human casualties.⁸ Such threats come not only from states at war using traditional military means of delivery, but also from non-state sponsored terrorist groups⁹ and naturally occurring diseases such as antibiotic-resistant bacteria and Ebola. Even though CBRN attacks are a recognized national security hazard and public health

⁶ 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. ASSOC. 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 (2001), <http://www.nejm.org/doi/full/10.1056/NEJMoa012948> (“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 Ten Cases Reported in the United States*, 7 EMERGING INFECTIOUS DISEASES 933, 934 (2001), <http://www.cdc.gov/ncidod/eid/vol7no6/pdf/jernigan.pdf> (“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.”).

⁷ *Sarin Gas Used as Weapon in Syria, Says Chemical Weapons Watchdog*, NBC NEWS.COM (June 30, 2017), <https://www.nbcnews.com/news/world/sarin-gas-used-weapon-syria-says-chemical-weapons-watchdog-n7784>.

⁸ See *Global Proliferation of Weapons of Mass Destruction, Vol. 1: Hearings Before the Permanent Subcomm. on Investigations of the Comm. on Governmental Affairs, United States Senate*, 104th Cong. 1st Sess. (Part I) (1995); U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *PROLIFERATION OF WEAPONS OF MASS DESTRUCTION: ASSESSING THE RISK*, OTA-ISC-559 (1993).

⁹ See *Global Proliferation of Weapons of Mass Destruction*, *supra* note 10; *PROLIFERATION OF WEAPONS OF MASS DESTRUCTION*, *supra* note 10. 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.”); see also Bertalan Meskó, *Disruptive Technologies Push Bioterrorism to a Whole New Level*, MEDICAL FUTURIST, <http://medicalfuturist.com/disruptive-technologies-bioterrorism/> (last visited Mar. 7, 2018).

concern,¹⁰ 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.¹¹ Successfully addressing this threat will require combining the “rapidly growing” and “complex [governmental] science and technology base”¹² 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 entrepreneurship¹³ and translational medicine¹⁴ by facilitating the movement of medical

¹⁰ See RICHARD A. FALKENRATH, ROBERT D. NEWMAN & BRADLEY A. THAYER, *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).

¹¹ See Jason Matheny, Michael Mair, Andrew Mulcahy & Bradley T. Smith, *Incentives For Biodefense Countermeasure Development*, 5(3) *BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, & SCIENCE* 228, 228 (2007), <http://docs.house.gov/meetings/IF/IF14/20160519/104953/HHRG-114-IF14-20160519-SD006.pdf> (“medical 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”). See also Notice, Office of the Assistant Secretary for Preparedness and Response; HHS Public Health Emergency Medical Countermeasures Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats. 72 Fed. Reg. 20117 (Apr. 23, 2007).

¹² See RICHARD NELSON, *NATIONAL INNOVATION SYSTEMS: A COMPARATIVE ANALYSIS* (1993).

¹³ 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 (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 William Aulet & Fiona Murray, *A Tale of Two Entrepreneurs: Understanding Differences in the Types of Entrepreneurship in the Economy* (May 1, 2013), <https://ssrn.com/abstract=2259740>.

¹⁴ See John C. Reed, *NCATS Could Mitigate Pharma Valley of Death*, *GENETIC ENGINEERING & BIOTECHNOLOGY NEWS* (May 15, 2011), <http://www.genengnews.com/gen-articles/ncats-could-mitigate-pharma-valley-of-death/3662/>. See also Arti K. Rai, Jerome H. Reichman, Paul F. Uhlir & Colin Crossman, *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 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 NIH's Molecular Libraries Small Molecule Repository contains more than 100,000 small molecules generated by the academic researchers. *General Information*, MOLECULAR LIBRARIES INITIATIVE, <https://mli.nih.gov/mli/compound-repository/mlsmr-compounds/> (last visited Mar. 13, 2018). These molecules are released into the public domain and 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 et al., *supra*, at 7.

research and discoveries from “bench to bedside.”¹⁵ The pharmaceutical industry is highly concentrated,¹⁶ and “the development of new pharmaceuticals is both high risk¹⁷ and high cost,¹⁸ with new drugs costing a billion dollars or more to bring to market.”¹⁹

¹⁵ See Constance E. Bagley & Christina D. Tvarnø, *Pharmaceutical Public-Private Partnerships: Moving from the Bench to the Bedside*, 4 HARV. BUS. L. REV. 373 (2014) (“governments 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.”). See also Editorial Board, *NIH Tries a New Approach to Speed Drug Development*, WASH. POST (Feb. 8, 2014), http://www.washingtonpost.com/opinions/nih-tries-a-new-approach-to-speed-drug-development/2014/02/08/bf30ba18-8ea1-11e3-b227-12a45d109e03_story.html; *Accelerating Medicines Partnership*, NAT’L INSTS. OF HEALTH, nih.gov/science/amp/index.htm (last visited Mar. 7, 2018); *Budget*, NAT’L CENTER FOR ADVANCING TRANSLATIONAL SCIENCES, <http://www.ncats.nih.gov/about/budget/budget.html> (last visited Mar. 7, 2018); *Alliances at NCATS*, NAT’L CTR. FOR ADVANCING TRANSLATIONAL SCI., <https://ncats.nih.gov/alliances/about> (last visited Mar. 7, 2018); *About*, EUROPEAN FED’N FOR PHARMACEUTICAL SCI., <http://www.eufeps.org/about> (last visited Mar. 7, 2018).

¹⁶ “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 15, at 377 n.24. See also Anand Grover, Brian Citro, Mihir Mankad & Fiona Lander, *Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability Under the Right to Health*, 40 J. L., MED. & ETHICS 234, 238 (2012).

¹⁷ See Bagley & Tvarnø, *supra* note 15, at 379. See also Valerie Gutmann Koch, *Incentivizing the Utilization of Pharmacogenetics in Drug Development*, 15 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).

¹⁸ See also Matheny, Mair, Mulcahy & Smith, *supra* note 11, at 229 tbl. 1. “R&D Process for a Typical New Drug”; see also J.A. DiMasi, R.W. Hansen & H.G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003); see also C.P. Adams & V.V. Brantner, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 HEALTH AFF., 420 (2006); see also PHARMACEUTICAL RES. & MANUFACTURERS OF AM., *MEDICINES IN DEVELOPMENT, INFECTIOUS DISEASES, 2013 REPORT* 46 (2013); see also I. Kola & J. Landis, *Can the Pharmaceutical Industry Reduce Attrition Rates?*, 3 NAT. REV. DRUG DISCOVERY 711 (2004).

¹⁹ See Matheny, Mair, Mulcahy & Smith, *supra* note 11; NAT’L INSTS. OF HEALTH, *PHARMA INDUSTRY 2011 PROFILE* 10 (2011). As Valerie Koch notes, others dispute this calculation. Koch, *supra* note 18, 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)). See also ALFONSO

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-prong initiative for addressing the threats of CBRN attacks we introduce in Part IV builds on the successes of the 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 partnerships²⁰ of the sort currently used by participants in the European Union’s Innovative Medicines Initiative (“IMI”) and the Action Plan Against the Rising Threats from

GAMBARDELLA, LUIGI ORSENIGO & FABIO PAMMOLLI, GLOBAL COMPETITIVENESS IN PHARMACEUTICALS: A EUROPEAN PERSPECTIVE 11–13 (2000), http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/compreg_nov2000_en.pdf (“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.”).

²⁰ See Bagley & Tvarnø, *supra* note 15.

Antimicrobial Resistance²¹ and by certain U.S. entities under the Bayh-Dole Act.²² Our initiative also includes another component: identifying and generating “ecosystems of excellence”²³ that will house incubators that will bring together all the players and

²¹ The European Union’s Innovative Medicines Initiative (“IMI”), Europe’s largest public-private partnership in the life sciences, was launched in 2008. *Innovative Medicines Initiative, Latest News*, <http://www.imi.europa.eu/> (last visited Mar. 15, 2018). It has a budget of Euro 5.3 billion and has funded almost 100 projects. 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 13, at 16–17 (footnotes omitted). See Rogerio Gaspar et al., *Toward a European Strategy for Medicines Research (2014-2020): The EUFEPS Position Paper on Horizon 2020*, 47 EUR. J. PHARMACEUTICAL SCIENCES 979, 980 (2012). For more information on the Innovative Medicines Initiative (IMI), see <http://www.imi.europa.eu/about-imi/how-imi-works>.

²² See Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–212 (1980)). There is a long list of important federal legislation designed to foster innovation, including Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. § 3701 *et seq.* (1980); Small Business Innovation Development Act of 1982, 15 U.S.C. § 638; National Cooperative Research Act, Pub. L. No. 98-462, 98 Stat. 1815 (1984) (codified as amended at 15 U.S.C. §§ 4301–4305); NSF Establishes Program for Engineering Research Centers (1985); Small Business Technology Transfer Act of 1992, Pub. L. No. 102-564, 106 Stat. 4249 (codified as amended at 15 U.S.C. § 638); Department of Commerce Advanced Technology Program (ATP) (1988); Manufacturing Extension Program (1988); Defense Industrial and Technology Base Initiative (1991); High-Performance Computing Act of 1991, Pub. L. No. 102-194, § 102, 105 Stat. 1495, 1598-99 (codified at 15 U.S.C. § 5512); Small Business Research and Development Enhancement Act of 1992, 15 U.S.C. § 638. 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. (forthcoming).

²³ JOSH LERNER, BOULEVARD OF BROKEN DREAMS, WHY PUBLIC EFFORTS TO BOOST ENTREPRENEURSHIP AND VENTURE CAPITAL HAVE FAILED AND WHAT TO DO ABOUT IT (2012).

resources needed to support break-through multi-disciplinary discoveries. This new model will provide platform, 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 a hydrogen bomb. In the 2018 letter by Rachel Bronson, the CEO and President of the Union of the Concerned Atomic Scientists, she stated:

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 strategic and intermediate-range battlefield nuclear arsenals.²⁴

President Trump has called for increasing the U.S. defense budget by 7% to \$716 billion for fiscal 2019,²⁵ 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.²⁶

Part II 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 science, the Internet, and self-driving vehicles.

²⁴ Rachel Bronson, Statement from Rachel Bronson, President and CEO, BULLETIN OF THE ATOMIC SCIENTISTS (Jan. 25, 2018), <https://thebulletin.org/sites/default/files/2018%20Doomsday%20Clock%20Statement.pdf>. See also Lindsey Bever, Sarah Kaplan & Abby Ohlheiser, *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.

²⁵ Anthony Capaccio & Erik Wasson, *Trump's \$716B 2019 Defense Budget Request*, REALCLEARDEFENSE.COM (Jan. 27, 2018), www.realcleardefense.com/2018/01/27/trump039s_716b_2019_defense_budget_request_299912.html.

²⁶ *Id.* See also Fidler, *supra* note 9; see also Bertalan Meskó, *supra* note 9.

In Part III we discuss several of the most significant of government initiatives undertaken after the terrorist attacks on 9/11 and their strengths and shortcomings. Lest we repeat the mistakes of the past, Part III 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.²⁷

In Part IV we propose creation of the Defense of Health Countermeasures Initiative, a multi-prong initiative 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 V discusses potential challenges to collaboration and our responses thereto. Part VI concludes with a summary of our proposal and describes areas for further research.

II. The Government as Market Actor

Noble Prize 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.²⁸ 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.²⁹ As demonstrated by the Manhattan Project during World War II and the Defense Advanced Research Projects Agency 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 Part V.A), and the 21st Century Cures Act³⁰ (discussed in Part II.C), can spur commercial efforts to innovate.

A. The Defense Advanced Research Projects Agency (DARPA)

²⁷ See Capaccio & Wasson, *supra* note 25. See also T. O'Toole & T.V. Inglesby, *Toward Biosecurity*, 1(1) BIOSECUR. BIOTERROR 1 (2003); L. Gilfillan et al., *Taking the Measure of Countermeasures: Leaders' Views on the Nation's Capacity to Develop Biodefense Countermeasures*, 2(4) BIOSECUR. BIOTERROR 320 (2004); L. DeFrancesco, *Throwing Money at Biodefense*, 22(4) NAT. BIOTECHNOL. 375 (2004).

²⁸ Robert M. Solow, Nobel Prize Laureate, Prize Lecture: Growth Theory and After, (Dec. 8, 1987), http://www.nobelprize.org/nobel_prizes/economics/laureates/1987/solow-lecture.html.

²⁹ LERNER, *supra* note 23.

³⁰ Pub. L. No. 114-255.

The Defense Advanced Research Projects Agency (“DARPA,” formerly known as “ARPA”) is a prime example of a successful governmental intervention in the market.³¹ Created during the 1960s, following the Soviet’s successful and unexpected launch of the first satellite Sputnik,³² DARPA provided funding to members from the scientific community, public sector, university-based researchers, industry syndicates, and private corporations (including start-ups).³³ 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.³⁴ 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.³⁵ According to Erica Fuchs,

the 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.³⁶

To minimize abuse or waste, DARPA staff transferred resources from unproductive groups to more promising, productive, and profitable ones.³⁷

³¹ Richard N. Kuyath, *The Untapped Potential of the Department of Defense's "Other Transaction" Authority*, 24 PUB. CONT. L.J. 521 (1995). See LERNER, *supra* note 23. See also Fred Block, *Swimming Against the Current: The Rise of a Hidden Developmental State in the United States*, 36 POL. & SOC’Y 169 (2008) (according to Block, in 1962, ARPA’s Information Processing Techniques Office (“IPTO”) was originally established, and played a central role in the development of computer science. IPTO granted funds to establish computer science departments at major universities and financed a series of research projects that successfully pushed forward developments in human-computer interface.).

³² See Block, *supra* note 31, at 176.

³³ See Alon-Beck, *supra* note 22 (“ARPA operated small offices staffed with top engineers and scientists, who were given extensive budget autonomy to sponsor promising ideas.”). See Block, *supra* note 40.

³⁴ See Alon-Beck, *supra* note 22.

³⁵ See Alon-Beck, *supra* note 22. See also Block, *supra* note 31.

³⁶ Erica R.H. Fuchs, *Cloning DARPA Successfully*, 26(1) ISSUES IN SCIENCE & TECH. 65 (2009), <http://www.jstor.org/stable/43315003>.

³⁷ Block, *supra* note 31 (stating that ARPA employed visionary and creative technologists and gave them the autonomy to grant research funds).

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.”³⁸ It took a risk-bearing role to create the infrastructure for the high technology world of today.³⁹ Commercial fruits of government participation include not only computers and the Internet but also jet planes, rockets, radar, lasers, civilian nuclear energy, GPS, and biotechnology.

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.”⁴⁰ 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.”⁴¹ 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.⁴²

³⁸ See Alon-Beck, *supra* note 22. See also Robert C. Hockett & Saule T. Omarova, “Private” Means to “Public” Ends: Governments as Market Actors, 15 THEOR. INQ. IN LAW 53 (2014). Nelson found that the national security concerns of the nations had been central in shaping their innovation systems. NELSON, *supra* note 12, at 508. See also PETER DRUCKER, INNOVATION AND ENTREPRENEURSHIP 257 (1985).

³⁹ See Alon-Beck, *supra* note 22. See also Hockett & Omarova, *supra* note 38; see also Marc Berejka, *The 11th Annual Digital Broadband Migration: Symposium: The Dynamics of Disruptive Innovation: A Case for Government Promoted Multi-Stakeholderism*, 10 J. TELECOMM. & HIGH TECH. L. 1 (2012). For a list of federal legislation promoting innovation, see statutes cited *supra* in note 32.

⁴⁰ Alan Pentz, *Agencies Can Seed Future Success with Creative Investment*, GOVEXEC.COM (Feb. 8, 2016), <http://www.govexec.com/excellence/nextgen-strategist/2016/02/agencies-can-seed-future-success-creative-investment/125747/>.

⁴¹ *Id.*

⁴² See Block, *supra* note 31, at 175 (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(9) RESEARCH POL’Y 1133 (2010). See also John Sedgwick, *The Men from DARPA*, PLAYBOY, Aug. 1, 1991, 108, 122, 154–56. See Alon-Beck, *supra* note 22. See Block, *supra* note 31 (“ARPA operated small offices staffed with top engineers and scientists, who were given extensive budget autonomy to sponsor promising ideas.”).

Thus, government has proven its ability to spur competition and be a powerful market actor.⁴³

The DARPA model is an example of spurring innovation 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.”⁴⁴ As discussed further below, DARPA used its “Other Transaction Authority” to remove some of the administrative barriers that previously stopped commercial companies from participating in the government marketplace.

B. In-Q-Tel

Another successful example of the government as a market participant is the first government-funded venture capital firm, In-Q-Tel.⁴⁵ Launched in 1999 by the U.S. Central Intelligence Agency (“CIA”), In-Q-Tel’s charge was to “swim in the Valley”⁴⁶ and invest in emerging technology firms (making small stake investments by utilizing venture-like processes).⁴⁷ In-Q-Tel allowed the CIA to invest in high technology firms that did not do

⁴³ See Hockett & Omarova, *supra* note 38; LERNER, *supra* note 23.

⁴⁴ See Kuyath, *supra* note 31. 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>.

⁴⁵ During the time of its 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), <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,’ Smith says.”). See also LERNER, *supra* note 23, at 176 (“For many of the start-ups, which had targeted corporate customers, the challenges of breaking into government procurements were daunting.”). See Alon-Beck, *supra* note 22. See also John T. Reinert, *In-Q-Tel: The Central Intelligence Agency as Venture Capitalist*, 33 NW. J. INT’L L. & BUS. 677 (2013) (noting that there are attempts/desires by government agencies (Army, NASA & USA Postal Service) to invest in technology ventures. He cites Deals & Deal Makers—Memo to Techies: This Army Wants Your Energy Ideas, WALL ST. J., May 9, 2003, at C5; News Release, *NASA Forms Partnership with Red Planet capital, Inc.*, NASA (Sept. 20, 2006), http://www.nasa.gov/home/hqnews/2006/sep/HQ_06317_red_capital.html). See also Marc Kaufman, *NASA Invests in Its Future with Venture Capital Firm*, WASH. POST, Oct. 31, 2006, at A19; Joe Davidson, *Postal Service Desperate for Good Ideas*, WASH. POST, June 23, 2010, at B03.

⁴⁶ Then CIA Director George Tenet said In-Q-Tel was created for this reason. See Alon-Beck, *supra* note 22. See also Reinert, *supra* note 54.

⁴⁷ See LERNER, *supra* note 33, at 176 (In-Q-Tel also served as a bridge that was able to present new firms to the portfolio of the CIA and to underline the role of the government as a new customer for products developed that were by emerging growth firms). See also BUS. EXEC. FOR NAT’L SEC., ACCELERATING THE ACQUISITION AND IMPLEMENTATION OF NEW TECHNOLOGIES FOR

business with the government before, and served as a bridge between the government (as a customer for products and services) and emerging growth technology firms.⁴⁸

In-Q-Tel was successful for many reasons, including its geographic proximity⁴⁹ to Silicon Valley and its ability to simplify the process of federal procurement, by using Other Transaction Authority (“OTA”) agreements.⁵⁰ OTA is a flexible contracting vehicle designed to reduce disincentives non-traditional government bidders have trying to contract with the federal government by reducing the transaction costs.⁵¹ We discuss OTA further in Part 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.”⁵² 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 VC funding, the CIA’s investments were “smart money,” which provided the portfolio companies not only cash but also “intellectual capital [and] technology-related experience.”⁵³ The CIA also offered “the Agency as a

INTELLIGENCE: THE REPORT OF THE INDEPENDENT PANEL ON THE CENTRAL INTELLIGENCE AGENCY IN-Q-TEL VENTURE 6 (C. Lawrence Meador et al. eds., 2001), <http://news.findlaw.com/cnn/docs/inqtel/inqtel80701rpt.pdf> [hereinafter BENS REPORT] (comparing the In-Q-Tel model with the traditional VC model).

⁴⁸ See Alon-Beck, *supra* note 22.

⁴⁹ See Alon-Beck, *supra* note 22. 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?* (Working Paper 2010), <https://ssrn.com/abstract=1568131> (According to Bengtsson & Hsu, “personal similarity matters in the 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 information costs. We infer that lower information costs associated with similar personal characteristics allow VCs to make larger investments.”). See also Ola Bengtsson, *Repeated Relationships Between Venture Capitalists and Entrepreneurs* 3–5 (Working Paper No. 1, 2007) (Bengtsson examined data on 1500 serial entrepreneurs. He found that a failed entrepreneur is twice as likely to repeat VC relationships (as evaluated against a successful entrepreneur).

⁵⁰ See Kuyath, *supra* note 31. According to Kuyath, OTAs are in line with the purpose of the Federal Acquisition Streamlining Act of 1994, Pub. L. No. 103-355, 108 Stat. 3243 (1994).

⁵¹ See Kuyath, *supra* note 31.

⁵² BENS REPORT, *supra* note 47. See *About IQT*, <https://www.iqt.org>.

⁵³ See BENS REPORT, *supra* note 47.

⁵³ *Id.*

potential test-bed.”⁵⁴ 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”⁵⁵

To encourage recruitment of established managers and staff from the venture capital industry, and to prevent them from leaving to more lucrative private positions, the CIA offered a rewarding compensation scheme, which was very unusual compared with typical government jobs.⁵⁶ 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 pre-specified portion of each employee’s salary and invested alongside the portfolio.⁵⁷

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, 2016.⁵⁸ The act established “Information Commons” initiatives to facilitate broad open and responsible sharing of data.⁵⁹ Signaling the value of large data sets comprising information garnered from electronic health records (“EHRs”), Roche, the pharmaceutical giant, agreed in February 2018⁶⁰ to pay \$1.9 billion to acquire Flatiron Health, a privately held New York based healthcare technology company.⁶¹ Flatiron Health collects clinical data on cancer patients, and it has previously teamed up⁶² with public

⁵⁴ See BENS REPORT, *supra* note 47.

⁵⁵ See BENS REPORT, *supra* note 47.

⁵⁶ See LERNER, *supra* note 23, at 176.

⁵⁷ For example, in 2012, its CEO, Christopher Darby, earned roughly \$1 million. See Steve Henn, *In-Q-Tel: The CIA’s Tax-Funded Player in Silicon Valley*, NPR (July 16, 2012), <https://www.npr.org/sections/alltechconsidered/2012/07/16/156839153/in-q-tel-the-cias-tax-funded-player-in-silicon-valley>.

⁵⁸ See Mary A. Majumder, Christi J. Guerrini, Juli M. Bollinger, Robert Cook-Deegan & Amy L. McGuire, *Sharing Data Under the 21st Century Cures Act*, 19 GENETICS IN MED. 1289 (2017), <https://ssrn.com/abstract=2974404>.

⁵⁹ See *id.* (“At the same time, the Act exacerbates or neglects several challenges, including 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.”).

⁶⁰ See Lydia Ramsie, *Pharma Giant Roche is Buying Cancer Tech Startup Flatiron Health for \$1.9 Billion*, BUSINESSINSIDER.COM (Feb. 15, 2018), <http://www.businessinsider.com/roche-acquires-flatiron-health-for-19-billion-2018-2?r=UK&IR=T>.

⁶¹ “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.COM (Feb. 15, 2018), <https://www.cnbc.com/2018/02/15/roche-buying-flatiron-health-backed-by-alphabet.html>.

⁶² On their partnerships and milestones, see <https://flatiron.com/blog/roche/>.

parties, including the Food and Drug Administration (“FDA”)⁶³ and the National Cancer Institute, academic medical centers,⁶⁴ and private parties, such as independent community oncology practices,⁶⁵ 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.⁶⁶ To successfully compete in tomorrow’s market place, promote growth, and protect its citizens as well as increase productivity and expand economic and social value,⁶⁷ U.S. policymakers must institute sweeping innovation policies to modernize the U.S. innovation infrastructure.

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

⁶³ See Nick Paul Taylor, *FDA Teams with Flatiron for Real-world Cancer Data Analytics Project*, FIERCEBIOTECH (May 27, 2016), <https://www.fiercebiotech.com/it/fda-teams-flatiron-for-real-world-cancer-data-analytics-project>. See also Michael Mezher, *Woodcock: Drug Safety Surveillance System Ready for Full Operation*, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Feb. 3, 2016), <https://www.raps.org/news-articles/news-articles/2016/2/woodcock-drug-safety-surveillance-system-ready-for-full-operation> (“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.”).

⁶⁴ See Nick Paul Taylor, *Roche Pens \$1.9B Deal to Buy Oncology Data Firm Flatiron*, FIERCEBIOTECH (Feb. 16, 2018), <https://www.fiercebiotech.com/biotech/roche-pens-1-9b-deal-to-buy-oncology-data-firm-flatiron>.

⁶⁵ 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.” See Press Release, Flatiron, 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/>.

⁶⁶ 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 in stake is nothing less than the future prosperity and security of our nation.”).

⁶⁷ See Michael E. Porter & Mark R. Kramer, *Creating Shared Value: How to Reinvent Capitalism – and Unleash a Wave of Innovation and Growth*, 89 HARV. BUS. REV. 1, 5 (Jan.–Feb. 2011).

from DoD in 1987. By 2013, DoD provided less than 20 percent of the U.S. R&D, whereas commercial R&D increased its spending by 200 percent between 1987 and 2013.⁶⁸ Today, however, the military and commercial demands in the United States have diverged drastically,⁶⁹ resulting in declining civilian-military technology spillovers.⁷⁰ 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).⁷¹

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 spillovers⁷² and thereby encourage the formation (and survival) of new entrepreneurial firms and new lines of business in existing firms.⁷³

The government is not a profit-maximizing entity⁷⁴ so is in a better position than private investors to deal with situations of uncertainty requiring long-term investments in radical innovation.⁷⁵ Government actors are often not as efficient as private firms,⁷⁶ but

⁶⁸ See Tim Cooke, Innovation by and for the Government (Oct. 2, 2017), <http://www.govexec.com/excellence/promising-practices/2017/10/innovation-and-government/141433/>.

⁶⁹ Kenneth Flamm & Thomas L. McNaugher, *Rationalizing Technology Investments*, in RESTRUCTURING AMERICAN FOREIGN POLICY (J. D. Steinbruner ed., 1989) (citing declines in the share of basic research in DoD research and development spending, as well as increase in the Congressional demand for military research and development programs to yield near-term applications in weapons systems.).

⁷⁰ *Id.* An exception is the DoD funding of the Small Business Innovation Research ("SBIR") program, on which it spends approximately \$1 billion in grants annually. *SBIR/STTR Award Size Flexibility*, BIR/STTR (Sept. 15, 2014), http://www.sbir.gov/sites/default/files/3_award_size_ipc_report.pdf.

⁷¹ See DAVID C. MOWERY & NATHAN ROSENBERG, *PATHS OF INNOVATION: TECHNOLOGICAL CHANGE IN 20TH-CENTURY AMERICA* (1998).

⁷² See DAVID B. AUDRETSCH, *ENTREPRENEURSHIP: A SURVEY OF THE LITERATURE*, ENTERPRISE PAPERS, NO. 14, 5 (European Communities 2003), at 9 (discussing "knowledge spillover" and how "small firms account for a disproportional share of new product innovations given their low R&D expenditures.").

⁷³ LERNER, *supra* note 33.

⁷⁴ See DAVID A. LEWIS, ELSIE HARPER-ANDERSON & LAWRENCE A. MOLNAR, *INCUBATING SUCCESS. INCUBATION BEST PRACTICES THAT LEAD TO SUCCESSFUL NEW VENTURES* (2011) ("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 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.* at 8.

⁷⁵ *Id.*

⁷⁶ *Id.*

they can alleviate market inefficiencies and failures by addressing the tragedy of the commons,⁷⁷ monitoring economic progress and market trends, and guiding local systems and intra-industrial innovation to meet social and military needs.⁷⁸ By promoting long-term development strategies, governments can serve as “bridge builders” between private business and innovative industries.⁷⁹ 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, which combine the government’s forward-thinking policies and funds and the private sector’s innovative efforts, as well as the support from nonprofit organizations (such as private disease foundations) and private intermediaries. There are several financing models of incubators, ranging from public non-profit, quasi-public, to private non-profit.⁸⁰ 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 in which the “average time between the ‘key enabling discovery’ and the introduction of a drug is 12-15 years.”⁸¹

But governments and industry cannot fill the countermeasure pipeline alone. Institutes of higher learning (and national systems of innovation⁸²) play critical roles in the new knowledge economy.⁸³ 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 be blind to a wide range of other institutions that have played key roles in stimulating growth and driving innovation.⁸⁴ In the case of drug discovery, “Publicly funded research, occurring at universities and the National Institutes of Health, over the years has produced a great majority of the key

⁷⁷ See Hockett & Omarova, *supra* note 38 (explaining the “market-making” role of the government—“government’s playing a particular risk-bearing role that private actors themselves sometimes but not always are able to play either (a) makes a publicly beneficial market possible, or (b) facilitates an incipient such market’s growth to critical mass.”).

⁷⁸ *Id.*

⁷⁹ See KAO, *supra* note 66, at 198 (“They will serve as bridge builders between creative industries and the business mainstream, following models such as the Learning Lab in Denmark, and Arts & Business in the UK. They would be mechanisms for linking federal, regional, and urban development strategies.”).

⁸⁰ 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.” Rathnam Chaguturu, *Preface*, in COLLABORATIVE INNOVATION IN DRUG DISCOVERY, *supra* note 1, at xx.

⁸¹ *Id.* at xxiv. See also Fillipo Belloc, *Innovation in State-owned Enterprises: Reconsidering Conventional Wisdom*, 48 J. ECON. ISSUES 821 (2014).

⁸² The term “systems” means a “set of institutional actors that, together, play the major role in influencing innovation performance.” See NELSON, *supra* note 12.

⁸³ See NELSON, *supra* note 12. See also Philippe Larédo & Philippe Mustar, *Public Sector Research: A Growing Role in Innovation Systems*, 42 MINERVA 11 (2004).

⁸⁴ Laredo & Mustar, *supra* note 83.

enabling discoveries underlying nearly 80% of the important drugs.”⁸⁵ Typically “the academic laboratory . . . identifies the interesting molecular targets that are important enzymes and proteins in various biochemical and physiological processes.”⁸⁶ The U.S. government funded and made publicly available the sequencing of the human genome, but it took academic scientists to convert the basic science into innovative discoveries, including “the biomarkers of disease identified in genomics, proteomics, and biochemistry studies . . .” and the “identification of new messenger molecules and their receptors”⁸⁷ For example, the University of California and Stanford University were instrumental in developing the gene sequencing techniques, which biotech companies like Genentech commercialized.⁸⁸

To develop new treatments, vaccines and protective devices, government agencies need to collaborate with academia and industry to identify the specific challenges not being 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

⁸⁵ Chaguturu, *supra* note 80, at xix–xx.

⁸⁶ *Id.*

⁸⁷ Ferid Murad, *Foreward*, in COLLABORATIVE INNOVATION IN DRUG DISCOVERY, *supra* note 1, at xvi.

⁸⁸ See also Mark Edwards, Fiona Murray & Robert Yu, *Value Creation and Sharing Among Universities, Biotechnology and Pharma*, 21(6) NATURE BIOTECHNOLOGY 618 (2003). <https://ssrn.com/abstract=904260> (“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. 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”).

commercialization⁸⁹ necessary to show proof of concept and feasibility.⁹⁰ Accordingly, the Defense of Health Countermeasures Initiative we propose in Part IV is designed to allow the government to make direct equity investments in seed projects through the DHCI incubators (“DHCI Incubators”) and national platforms for networks of innovation hubs (“DHCI Ecosystems of Excellence”), but at the same time encourage private actors to take part in the financings of such projects and make it possible for universities and academic scientists to share in the economic proceeds through Bayh-Dole 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 and distortions.

III. Existing Measures to Deal with the Threat of Chemical, Biological, Radiological & Nuclear Attacks

Following the terror events of 9/11, especially 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 research and development of medical countermeasures, such as diagnostic tests, drugs, vaccines, and other treatments, that can minimize the impact of a CBRN attack.⁹¹

⁸⁹ 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 we do not need to do exactly what others are doing, but 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.”

Philipp Marxgut, Interview with Charles Wessner, Director of the Program on Technology, Innovation, and Entrepreneurship at the National Academy of Sciences, BRIDGES (Oct. 16, 2008), at 19, <http://ostaustralia.org/bridges-magazine/volume-19-october-16-2008/item/3585-innovation-policy-in-the-us-an-interview-with-charles-wessner>.

⁹⁰ The United States is already in competition with China for preeminence in the field of artificial intelligence. Like the space race, the AI race is likely to have a major impact on the next generation of innovation. Although China is actively funding startups, the United States has lagged in its funding, relying instead on private actors like Google. *See, e.g., DoD Is Fighting ISIS with Google’s AI*, THE DOWNLOAD FROM MIT TECH. REV (Mar. 7, 2018), newsletters@technologyreview.com.

⁹¹ See Science and Technology Issues in the 115th Congress, which can be accessed at: <https://www.everycrsreport.com/reports/R44786.html> (“Policymakers identified a lack of such

Despite these efforts, the current pipeline of new countermeasure 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 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).”⁹²

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,”⁹³ by coordinating 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

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.”).

⁹² 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.” Bagley & Tvarnø, *supra* note 23, at 13 n.62 (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 GEORGE S. FORD, THOMAS M. KOUTSKY & LAWRENCE J. SPIWAK, U.S. DEP’T OF COMMERCE, DISCUSSION PAPER, A VALLEY OF DEATH IN THE INNOVATION SEQUENCE: AN ECONOMIC INVESTIGATION (Sept. 2007), <http://www.osec.doc.gov/Report-Valley%20of%20Death%20Funding%20Gap.pdf>; see LEWIS BRANSCOMB & PHILLIP AUERSWALD, U.S. DEP’T OF COMMERCE, BETWEEN INVENTION AND INNOVATION: AN ANALYSIS OF FUNDING FOR EARLY- STAGE TECHNOLOGY DEVELOPMENT, ADVANCED TECHNOLOGY PROGRAM, NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST), NIST GCR 02841 (Nov. 2002), <http://www.atp.nist.gov/eao/gcr02-841/gcr02-841.pdf>. See also PHILLIP AUERSWALD, LEWIS BRANSCOMB, NICHOLAS DEMOS & BRIAN MIN, U.S. DEP’T OF COMMERCE, UNDERSTANDING PRIVATE-SECTOR DECISION MAKING FOR EARLY-STAGE TECHNOLOGY DEVELOPMENT, A “BETWEEN INVENTION AND INNOVATION PROJECT” REPORT, NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST), NIST GCR 02-841A (Sept. 2005), <http://www.nist.gov/tpo/sbir/upload/gcr02-841a.pdf>; Ederyn Williams, *Crossing the Valley of Death*, INGENIA, Dec. 30, 2004, at 21, <http://www2.warwick.ac.uk/services/ventures/valley.pdf> (discussing valley of death in the UK); Philipp Marxgut, *Interview with Charles Wessner, Director of the Program on Technology, Innovation, and Entrepreneurship at the National Academy of Sciences*, BRIDGES, Oct. 16, 2008, at 19, <http://ostaustria.org/bridges-magazine/volume-19-october-16-2008/item/3585-innovation-policy-in-the-us-an-interview-with-charles-wessner>.

⁹³ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 107 Pub. L. No. 188, 116 Stat. 594 (2002).

illness,”⁹⁴ (2) 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,

⁹⁴ See Deborah W. Gould, David Walker & Paula W. Yoon, *The Evolution of BioSense: Lessons Learned and Future Directions*, 132 PUBLIC HEALTH REPORTS (Supplement 1) 7S-11S (2017) (The initial BioSense program had four goals: (1) improve the nation’s capabilities for conducting near-real time bio surveillance and health situational awareness; (2) advance analytics for pre-diagnostic 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.). See also Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat 594 (2002); J.W. Loonsk, *BioSense: A National Initiative for Early Detection and Quantification of Public Health Emergencies*, 53 MORB. MORTAL WKLY. REP. 5E (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).” See C.A. Bradley, H. Rolka, D. Walker & J. Loonsk, *BioSense: Implementation of a National Early Event Detection and Situational Awareness System*, 54 MORB. MORTAL WKLY. REP. 11 (2005); J.I. Tokars, R. English, P. McMurray & B. Rhodes, *Summary of Data Reported to CDC’s National Automated Biosurveillance System, 2008*, 30 BMC MED. INFO. DECISION MAKING 30 (2010).

and nuclear threat agents,”⁹⁵ and (3) BioWatch, a program “designed to sample the air in major metropolitan areas for pathogens that terrorists might use.”⁹⁶

B. BioShield

Of the three programs authorized by the Public Health Security and Bioterrorism Preparedness and Response Act, 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 ten years before the product is likely to be fully developed. 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, for the reasons provided below.⁹⁷

1. Reasons for Limited Success of the First BioShield Project

⁹⁵ 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 customer. Acquisitions under Project BioShield are restricted to products in development that are potentially licensable within eight 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 four 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 U.S. population sufficient to affect national security. At the time of writing, seven 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 agents to treat ingestion of certain radiological particles; and (7) botulinum antitoxins. Additional acquisition contracts are expected to be awarded in 2007.”).

⁹⁶ *Id.*

⁹⁷ *See id.* (“Despite these efforts, the federal government still lacks medical countermeasures for many CBRN threats, including Ebola.”). Since the 2007 publication of the Russell article cited *supra* in note 95, 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.COM (JUNE 8, 2018), <https://www.forbes.com/sites/stephenbrozak/2018/06/08/merck-and-achaogen-two-companies-working-with-barda-to-fight-emerging-health-threats/#686518984fd0>.

The disappointing results of BioShield 1 were due in part to the lack of adequate monetary incentives⁹⁸ to motivate private pharmaceutical companies to invest the hundreds of millions of dollars in research and development necessary to successfully produce a new medical countermeasure.⁹⁹ The following are the five broad stages in the innovation process, as well as the financial sources that are usually available at each stage. 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),¹⁰⁰ and from private corporate resources, such as the funds large corporations allocate to research and development. Second is the stage of proof of concept or invention, for which financing sources usually include private angel investors, corporate research and development funds, and government funding from SBIR phase II (Research/Research and Development)¹⁰¹ and technology labs. Third is the early-stage

⁹⁸ FRANK GOTTRON, CONG. RESEARCH SERV., R43607, THE PROJECT BIOSHIELD ACT: ISSUES FOR THE 113TH CONGRESS 1 (2014) (“Representatives of the pharmaceutical industry attributed the paucity of CBRN agent countermeasures to the lack of a significant commercial market.” See, example, Alan Pemberton, Pharmaceutical Research and Manufacturers of America, Testimony before the U.S. House of Representatives Select Committee on Homeland Security, May 15, 2003.

⁹⁹ See *id.* Joseph Larsen, former deputy head of BARDA, stressed the importance of incentives, stating that both push and pull government incentives are often required to get major pharmaceutical companies to participate. Interview with the second author. 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.

¹⁰⁰ 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 mandates the 11 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 United States Government. See CHARLES WESSNER, SBIR AND THE PHASE III CHALLENGE OF COMMERCIALIZATION: REPORT OF A SYMPOSIUM (2007), http://www.nap.edu/openbook.php?record_id=11851&page=10 [hereinafter SBIR and the Phase III Challenge] (according to Wessner, “[c]ommercializing 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.”). See also *SBIR Mission and Program Goals*, SBIR/STTR, <http://www.sbir.gov/about/about-sbir> (last visited Mar. 16, 2018) (The following are the programs objectives: “Stimulate technological innovation; Meet Federal research and development needs; Foster and encourage participation in innovation and entrepreneurship by socially and economically disadvantaged persons; and Increase private-sector commercialization of innovations derived from Federal research and development funding.”).

¹⁰¹ See *SBIR Mission and Program Goals*, *supra* note 101.

technology development stage, which is often termed the Valley of Death because of the entrepreneur's difficulty obtaining financing for this stage.¹⁰² 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.¹⁰³

PHSBPRA provided inadequate R&D funding to get private actors across the Valley of Death.¹⁰⁴ 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."¹⁰⁵

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.¹⁰⁶ After the anthrax attacks

¹⁰² See Bagley & Tvarnø, *supra* note 15. See also Alon-Beck, *supra* note 22.

¹⁰³ See also Alon-Beck, *supra* note 22.

¹⁰⁴ See also *id.*

¹⁰⁵ See Janet Temko, *The Project BioShield Act of 2004: An Innovation Failure* (2006) (student paper, Harv. Univ.), <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). "Moreover, 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 Project BioShield: Contracting for the Health and Security of the American Public: Hearings Before the Comm. on Gov't Reform, 108th Cong. 16 (2003) (statement of Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases) ("However, 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.").

¹⁰⁶ See Temko, *supra* note 105. See also Kuyath, *supra* note 31, on the authority of ARPA due to OTAs ("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 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. 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

in 2001, the government forced Bayer to lower the already discounted price of the Cipro drug by threatening “to force compulsory licensing of the patent on Cipro to enable generic companies to enter the market.”¹⁰⁷ The PHSBPRA failed to address this issue.

Third, the PHSBPRA lacked adequate indemnification provisions that would shield pharmaceutical companies from liability for new drugs and vaccines. Wyeth spent millions defending lawsuits related to its smallpox vaccines.¹⁰⁸ The fact that vaccines require animal testing and cannot be ethically tested on humans make such concerns particularly acute.¹⁰⁹ Fourth, the PHSBPRA did not reduce the lengthy FDA approval process (which can take ten to fifteen years).¹¹⁰ Fifth, the failure of the procurement contract whereby VaxGen, a

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.”).

¹⁰⁷ See Temko, *supra* note 105. 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). See Gregory M. Lamb, *New Buffer for Bioterror’s Tempest*, CHRISTIAN SCIENCE MONITOR, July 1, 2004, at 14 (“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, Education, Labor, and Pensions, 109th Cong. 45-46 (2005) (response to questions of the committee by Chuck Ludlam, Esq., former legal counsel to Senator Joseph Lieberman) (“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.”).

¹⁰⁸ See Temko, *supra* note 105, at 11–12 (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.”).

¹⁰⁹ See *id.* 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.”).

¹¹⁰ See Temko, *supra* note 105. See PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW, CASES AND MATERIALS* 514 (2nd Ed. 1991); see Janene Boyce, *Disclosure of Clinical Trial Data: Why Exemption 4 of the Freedom of Information Act Should be Restored*, 2005 DUKE

small biotechnology company agreed to provide millions of doses of an unproven anthrax vaccine, deterred other small (and large) private companies from collaborating with the government.¹¹¹

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.¹¹² 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.¹¹³ Finally, Eliah Zerhouni and Anthony Fauci, the directors of the NIH and NIAID, were criticized for putting too much emphasis on government research.

L. & TECH. REV. 3, 8 (2005). *See also* James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLA. J. INT'L L. 261, 340 (2002) ("The forgoing process of drug approval takes at least seven years."); *Crossing the Valley of Death: Bringing Promising Medical Countermeasures to BioShield: Hearing before the Comm. on Health, Education, Labor and Pensions, Bioterrorism and Public Health Preparedness Subcomm., 109th Cong. 17 (2005)* (Statement of Joe Palma, Medical Director, Chemical/Biological Defense Programs, Office of the Deputy Assistant to the Secretary, U.S. Department of Defense) ("Fewer than 100 candidates will receive approval by the FDA, and once a product receives FDA approval it can take, in our estimation, between eight and 10 years and \$500 million to \$800 million to bring it to market.'). As discussed in Part V.A, there is precedent for providing expedited review for orphan drugs and drugs for neglected diseases through the use of tradeable vouchers.

¹¹¹ *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), <http://www.gao.gov/products/GAO-08-88> ("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 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 two 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 (a) the aggressive delivery time line for the vaccine, (b) VaxGen's lack of in-house technical expertise--a condition exacerbated by the attrition of key company staff as the contract progressed--and (c) 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 changed 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.").

¹¹² *See* Temko, *supra* note 105.

¹¹³ *See id.*

C. BARDA AND OTAs

To address the shortfalls of the BioShield program, and further encourage the development and procurement of CBRN medical countermeasures, the 109th 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”). Since then, BARDA has made substantial progress closing the innovation gap by stimulating search and development through public-private partnerships with various stakeholders, including industry.¹¹⁴

1. Other Transaction Authority

Since 2013, BARDA has provided non-dilutive funding and technical advisory support to its partners pursuant to the flexible contracting vehicle Other Transaction Authority (“OTA”).¹¹⁵ OTA collaborators are not required to comply with the typical lengthy and time-consuming procurement requirements or to change their standard business practices.¹¹⁶ Given the flexibility inherent in collaborations governed by OTAs, 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.¹¹⁷

¹¹⁴ Christopher Houchens, *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/>. Pursuant to President Obama’s 2015 Combating Antibiotic Resistant Bacteria (“CARB”) initiative, the U.S. Department of Health and Human Services’ Biomedical Advanced Research and Development Authority (hereinafter “BARDA”) and the National Institutes of Health’s National Institute of Allergy and Infectious Diseases created the Global Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (“CARB-X”), a nonprofit public-private partnership headquartered at Boston University School of Law. *Gates Foundation, UK Commit Nearly \$52 Million to Fight Superbugs*, PHILANTHROPY NEWS DIGEST (May 23, 2018), <http://philanthropynewsdigest.org/news/gates-foundation-uk-commit-nearly-52-million-to-fight-superbugs>. CARB-x “brings together leaders in industry, philanthropy, government, and academia with the aim of rejuvenating the antimicrobial pipeline for the next 25 years.” Boston University School of Law, *Combating Antibiotic Resistance on a Global Scale*, www.bu.edu/law/faculty-scholarship/carb-x/ (last visited July 9, 2018). The project has raised more than \$500 million in funding and has more than thirty-three projects underway. *Gates Foundation, supra* note 114.

¹¹⁵ According to Kuyath, OTAs are in line with the purpose of the Federal Acquisition Streamlining Act of 1994, Pub. L. No. 103-355, 108 Stat. 3243 (1994). *See* Kuyath, *supra* note 31.

¹¹⁶ *Id.*

¹¹⁷ *See id.*

When using OTA, BARDA is not required to comply with the abundant 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.”¹¹⁸ Thus, used correctly, OTA contracts can attract leading-edge, biotech and pharma 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” industry and venture capitalists use to funding research and development by diversifying investments, funding multiple rounds dependent upon success,¹¹⁹ and not trying to pick a national champion.¹²⁰ BARDA is accordingly able to support a “company’s [and the government’s] effort to simultaneously and in parallel develop multiple drug candidates.”¹²¹

2. Use of OTA to Form Public-Private Partnerships

Both DARPA and BARDA have used OTA to establish public-private partnerships (“PPPs”) to deal with the technology 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.”¹²² In order to develop a PPP,¹²³ the conventional community of stakeholders is expanded to

¹¹⁸ See Kuyath, *supra* note 31. See also U.S. GOVERNMENT ACCOUNTABILITY OFF., GAO-16-209, REPORT TO THE RANKING MEMBER, COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY, HOUSE OF REPRESENTATIVES, FEDERAL ACQUISITIONS, USE OF ‘OTHER TRANSACTION’ AGREEMENTS LIMITED AND MOSTLY FOR RESEARCH AND DEVELOPMENT ACTIVITIES, (2016), <https://www.gao.gov/assets/680/674534.pdf>

(“agencies told GAO the authority allowed them to develop customized agreements This flexibility allowed agencies to address concerns regarding intellectual property and cost accounting provisions”).

¹¹⁹ See CONSTANCE E. BAGLEY & CRAIG E. DAUCHY, *THE ENTREPRENEUR’S GUIDE TO LAW AND STRATEGY* 438–95 (5th ed. 2018).

¹²⁰ See *Houchens*, *supra* note 115.

¹²¹ *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.”).

¹²² Louis Witters, Revital Marom & Kurt Steinert, *The Role of Public-Private Partnerships in Driving Innovation*, in *THE GLOBAL INNOVATION INDEX OF 2012*, 81 (WIPO 2012), <https://www.globalinnovationindex.org/userfiles/file/GII-2012-Report.pdf>.

¹²³ Anat Alon-Beck developed the Coalition Model in her dissertation (on file with the authors). See Alon-Beck, *supra* note 32.

include the private sector (entrepreneurial and established firms); management; academia and research community; industry and economic development organizations; federal, state, regional and local governments; 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 and Hoffmann-La Roche (both 2016), and Pfizer (2017).¹²⁴ OTAs have also been used to enter into international collaborations with other funding agencies, such as the European Union's Innovative Medicines Initiative (to co-fund the development of one of AstraZeneca's lead antibacterial candidates), and to jointly support other product development.¹²⁵ Finally, OTAs have made it possible for the U.S. government and its contractors to enter into consortiums.¹²⁶

¹²⁴ See Michael J. Eichberg, *Public Funding of Clinical-Stage Antibiotic Development in the United States and European Union*, 13(3) HEALTH SECUR. 156 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4486734/>. See Houchens, *supra* note 115.

¹²⁵ Bagley & Tvarnø, *supra* note 25, at 400 (“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.”). See also 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. See also *IMI Joint Undertaking Model Grant Agreement Core*, http://www.imi.europa.eu/sites/default/files/uploads/documents/Rev_Grant_Agreement_2011/IMI_Grant_Agreement_rev2011_Core.pdf; *IMI Joint Undertaking Model Grant Agreement Core* at 4, http://www.imi.europa.eu/sites/default/files/uploads/documents/Rev_Grant_Agreement_2011/IMI_Grant_Agreement_rev2011_Core.pdf. On joint support of other product development, see Houchens, *supra* note 115.

¹²⁶ See, e.g., Press Release, Global Defense, DoD Seeks to Establish Consortium for CBRN Countermeasures, Diagnostics, (May 20, 2015), <https://globalbiodefense.com/2015/05/20/dod-seeks-to-establish-consortium-for-cbrn-countermeasures-diagnostics/> (“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 Press Release, CBRNE Central, Special Operations Forces Countering Weapons of Mass Destruction OTA (Aug. 30, 2017), <https://cbrnecentral.com/special-operations-forces-countering-weapons-mass-destruction-ota/10789/> (“The U.S. Army has released a competitive solicitation to

Unfortunately, the federal government's policies since 2001¹²⁷ 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 are likely to market products."¹²⁸

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 (version 1).¹²⁹ As a result of public criticism,¹³⁰ they subsequently introduced a second draft, which was adopted by several states. As with the first version, various civil rights groups criticized it for providing excessive powers to state governors on the expense of health care agencies.¹³¹

IV. Defense of Health Countermeasures Initiative (DHCI)

We call on the U.S. Government to build on the success of DARPA and BARDA and the effective use of Other Transaction Authority to establish the Defense of Health Countermeasures Initiative. The DHCI includes the creation of a public-private network of "ecosystems of excellence" comprising triads of universities and other research institutions, private pharmaceutical and biotechnology firms, and government actors to

establish an agreement with a single new or established consortium to develop and mature technologies which support Countering Weapons of Mass Destruction (CWMD).").

¹²⁷ See Matheny, Mair, Mulcahy & Smith, *supra* note 13. See also C. Lam, C. Franco & A. Schuler, *Billions for Biodefense: Federal Agency Biodefense Funding, FY2006–2007*, 4(2) BIOSECUR. BIOTERROR 113 (2006).

¹²⁸ See Matheny, Mair, Mulcahy & Smith, *supra* note 13 ("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 Table 2. Incentives for Biodefense Countermeasure R&D. *Id.* See M.C. Trull, T.V. du Laney & M.D. Dibner, *Turning Biodefense Dollars into Products*, 25(2) NAT. BIOTECHNOL. 179 (2007). See also U.S. DEP'T OF HEALTH & HUMAN SERVS., PROJECT BIOSHIELD: ANNUAL REPORT TO CONGRESS, AUGUST 2006–2007.

¹²⁹ Model State Emergency Health Powers Act, Version 1, <https://biotech.law.lsu.edu/blaw/bt/MSEHPA.pdf>.

¹³⁰ *Model State Emergency Health Powers Act*, AM. CIVIL LIBERTIES UNION (ACLU), <https://www.aclu.org/other/model-state-emergency-health-powers-act>; *Model State Emergency Health Powers Act*, NATIONAL VACCINE INFORMATION CENTER (NVIC), <http://www.nvic.org/Vaccine-Laws/model-state-emergency-health-powers-act.aspx>.

¹³¹ Model State Emergency Health Powers Act, Version 2, <http://www.aapsonline.org/legis/msehpa2.pdf>.

form incubators for the development of effective CBRN countermeasures (the “Incubators” or “DHCIIs”).

A. Government as a Key Risk-Taker

The DHCI builds on the concept that the government needs to be a key risk-taker and invest in knowledge, human capital, and innovation to encourage knowledge spillovers.¹³² The DHCI is designed to complement, and not to replace, the private market efforts in financing and growing emerging growth firms and 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 National Institutes of Health’s Roadmap Initiatives, which have been “integral to engaging academia in drug discovery research and have been effectively leveraged to help build the chasm between basic research activities and the commercialization of a drug.”¹³³ 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.”¹³⁴

1. 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 to create the Central Health Incubators Bureau (“CHIB”),¹³⁵ which 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 and the Red Cross. To avoid undue political interference, the members of CHIB should be granted the sort of independent authority given the civilians chosen to determine which military bases should be closed.¹³⁶ The European Union’s Innovative Medicines Initiative and the Israeli

¹³² See AUDRETSCH, *supra* note 73, at 9; LERNER, *supra* note 23.

¹³³ Chagaturu, *supra* note 80, at xxi.

¹³⁴ *Id.* at xx.

¹³⁵ This term is taken from the Israeli case study.

¹³⁶ Jim Garamone, *Why Civilian Control of the Military?*, U.S. DEP’T OF DEFENSE (May 2, 2001) <http://archive.defense.gov/news/newsarticle.aspx?id=45870>.

Technology Incubators (discussed in Part IV.B.1.a) offer an example of how such an arrangement might be structured.¹³⁷

B. Technology Innovation and Business Incubators

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.¹³⁸ Joseph Mancuso established the first U.S. business incubator, the Batavia Industrial Center in Batavia, New York, in 1959.¹³⁹ For the purpose of this paper, 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 incubator management, 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 young, growing companies.”¹⁴⁰

1. Types of Incubators

There are different forms of technology and business incubators. They can generally be divided into the following four types, ranging from “virtual incubators”¹⁴¹

¹³⁷ Bagley & Tvarnø, *supra* note 15.

¹³⁸ The use of the “technology business incubators” as a strategic development tool in the United States became popular in the mid-1980s.

¹³⁹ See LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 74 (“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 United States. Approximately 7,000 incubation programs are now in operation around the world.”).

¹⁴⁰ *Id.*

¹⁴¹ See LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 74 (the terms “virtual incubators” and “Incubators without walls” are synonymous. The virtual incubators are “business 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

(with no walls), “incubators with walls,”¹⁴² “accelerators,”¹⁴³ to “international incubators.”¹⁴⁴ Although there is no one incubator practice or policy that guarantees favorable results, we believe that the DHCI Incubators should typically be part of a shared-use facility, where entrepreneurs and entrepreneurial firms are physically located.¹⁴⁵ Preferably, each incubator will be near established pharmaceutical and bio-tech firms as well as research universities and other academic institutions with strong departments in life

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.”).

¹⁴² *See id.* (An “incubator with walls” is defined as 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.”).

¹⁴³ *See id.* (stating there is no definitive definition of ‘business accelerator’ in the literature. However, the term accelerator 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.”).

¹⁴⁴ It should be noted that there is no clear definition of the terms ‘international business incubator’ or ‘accelerator’ in the literature. Additionally, there is no clear empirical research or evaluation of these models. This paper will address the accelerator and current efforts to explain it. *See* LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 74 (the international form of business incubation program has recently emerged, in order to help foreign firms to enter the U.S. market. They further claim that the “international 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.”).

¹⁴⁵ Although there are “virtual” incubators, “without walls,” we recommend shared physical space to promote collaboration of the transfer of tacit knowledge.

sciences, engineering, and business. As Robert Urban, global head of Johnson & Johnson Innovation, explained, “Success requires density and proximity.”¹⁴⁶

Consider, for example, Lab Central, in Cambridge, Massachusetts, a shared use affordable, move-in-ready laboratory facility suitable for early-stage research. Its founding sponsors include Triumvirate Environmental and Johnson & Johnson Innovation. A 70,000 square-foot facility in the heart of the Kendall Square, Cambridge, biotech innovation hub, and near Harvard University and the Massachusetts Institute of Technology, LabCentral was designed as a launchpad for high-potential life-sciences and biotech startups. It offers fully permitted laboratory and office space for as many as 60 startups, comprising approximately 200 scientists and entrepreneurs. It is a private, nonprofit institution, which was funded in part by two \$5 million grants from the Massachusetts Life Sciences Center, with support from its real-estate partner, MIT.

To paraphrase Doug Crawford, the executive director of a LabCentral affiliate QB3/UCSF:

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 location, supporting services and other needed resources.¹⁴⁷

The shared facilities are designed to encourage cooperation among the participating entrepreneurs as well as between entrepreneurs and various stakeholder groups. For the purpose of this initiative, the term “stakeholders” refers to the following groups of public and private partners that will have a role in forming the incubator: management, private sector, academia, industry, government, financial sector, and other traditional stakeholders.¹⁴⁸

¹⁴⁶ Interview with the first author. For more information about Johnson & Johnson Innovation and its incubators and partnerships, see <https://www.jnjinnovation.com/about-us>.

¹⁴⁷ K.D. Harrison, N.S. Kadaba, R.B. Kelly & D. Crawford, *Building a Life Sciences Innovation Ecosystem*, 4(157) SCI. TRANSLATIONAL MED. 157 (2012).

¹⁴⁸ 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 the main campus in Storrs, Connecticut, specializing in computer science and related high technology. The Program offers:

- Incubator facilities featuring wet labs and access to instrumentation

Each of the incubators will have its own unique differentiating characteristics, which will depend on its regional and historical influences, as well as their stakeholders.¹⁴⁹

-
- Collaboration with Scientific Experts
 - Technically trained employees, fellows, interns and graduates
 - The university's world-class library resources
 - Customized business planning and mentoring.

UCONN, Office of the Vice President for Research, Wet Labs & Offices, <https://tip.uconn.edu/availablespace> (last visited July 7, 2018). There are resident entrepreneurs and legal counsel available to assist the start-ups. Interview with Mostafa Analoui, Executive Director of Venture Development at TIP, and the first author.

¹⁴⁹ See KAO, *supra* note 66, for more suggestions.

The participants in CARB-X, the antibiotic-resistant drug initiative discussed *supra* in note 114, include:

- As Executive Director, Kevin Outterson, a leading health law researcher at Boston University who has collaborated in global projects to address antibiotic resistance. The executive team “includes experts with decades of experience in antibiotic drug development, including John Rex, Senior Vice President at Astra Zeneca,” and Barry Eisenstein at Merck.
- The National Institutes of Health’s National Institute of Allergy and Infectious Disease (“NIAID”), which “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.”
- MassBio and the California Life Sciences Institute, which “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.”
- The Broad Institute of Massachusetts Institute of Technology and Harvard University, which “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.”
- RTI International, which “will provide technical and regulatory support services to product developers in the partner 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.”

Boston University School of Law, *supra* note 114. In addition, two nongovernmental organizations — the Bill and Melinda Gates Foundation and the Wellcome Trust — will provide funding and

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.”¹⁵⁰ To produce an optimal outcome and overcome certain of the challenges faced by the Small Business Administration’s cluster initiative,¹⁵¹ this paper draws on Israel’s successful use of incubators to develop its high technology industry (discussed next) as well as the work of Lewis, Harper-Anderson and Molnar, who analyzed and surveyed the top performing incubation programs in the United States.

a. *The Israeli Technology Incubator Program*

The Israeli Technology Incubator program utilized shared-use facilities to spur innovation and cross-fertilization. The Israeli Office of the Chief Scientist initiated the program in 1991 in part to provide employment for the engineers and scientists who immigrated to Israel from the former Soviet Union¹⁵² as well as laid-off engineers from the military sector.¹⁵³ By providing a small amount of funds to start a business (seed capital)¹⁵⁴ for entrepreneurs and early-stage companies with a promising idea, the program

other support. *Gates Foundation, supra* note 114. For more information about CARB-X, see CARB-X, <https://carb-x.org/> (last visited July 9, 2018).

¹⁵⁰ Murad, *supra* note 88, at xvii-xviii.

¹⁵¹ See also BERNA DEMIRALP, MARK TURNER & ALEXANDRE MONNARD, THE EVALUATION OF THE U.S. SMALL BUSINESS ADMINISTRATION’S REGIONAL CLUSTER INITIATIVE, YEAR ONE REPORT (JUNE 2012), <http://www.sba.gov/sites/default/files/files/Y1%20Pilot%20Cluster%20Evaluation.pdf>.

¹⁵² See Amnon Frenkel, Daniel Shefer & Michal Miller, *Public vs. Private Technological Incubator Programs: Privatizing the Technological Incubators in Israel* (paper presented at the 4th Congress of the European Regional Science Association, 23-27 August 2005, Amsterdam) (2005). See also Manuel Trajtenberg, *R & D Policy in Israel: An Overview and Reassessment*, NBER (Oct. 2000) (Working Paper No. 7930) (“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.”).

¹⁵³ See DANIEL SHEFER & AMNON FRENKEL, AN EVALUATION OF THE ISRAELI TECHNOLOGICAL INCUBATORS PROGRAM AND ITS PROJECTS – FINAL REPORT, IFISE ISRAELI FINANCING INSTRUMENTS FOR THE SUPPORT OF ENTREPRENEURSHIP, THE S. NEAMAN INSTITUTE FOR ADVANCED STUDIES IN SCIENCE AND TECHNOLOGY, TECHNION – ISRAEL INSTITUTE FOR ADVANCED STUDIES IN SCIENCE AND TECHNOLOGY (2003), <http://ifise.unipv.it/Download/final-draft3.pdf>.

¹⁵⁴ It should be noted that, in Israel, incubators usually provide seed capital, whereas venture-capital funds provide start-up capital. See also Frenkel, Shefer & Miller, *supra* note 153.

“transformed” engineers into technological entrepreneurs¹⁵⁵ and thereby encouraged innovation and stimulated growth. The program was also intended to stimulate and encourage linkages and cooperation between entrepreneurs, academic institutions, private industry, and government procurement officials.¹⁵⁶

The Israeli government established twenty-eight incubators between the years of 1990 and 1993.¹⁵⁷ 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.¹⁵⁸ The incubators’ geographic locations ranged from metropolitan areas to peripheral ones.¹⁵⁹

The program offered only temporary support, which was usually limited to two years.¹⁶⁰ The main goal was to generate successful firms that can leave the facility within the program’s time frame in a financially and organizationally self-sustained and viable state.

The companies seeking to participate in the program had to go through a rigorous selection process. To be accepted, the project (idea) had to be based on innovative research and development and be capable of being commercialized and exported to the appropriate market.¹⁶¹ It was the responsibility of the incubator’s manager, who often was assisted by a group of professional advisors, to select eight to twelve projects from a multitude of applicants.¹⁶²

i) Governance

¹⁵⁵ *Id.*

¹⁵⁶ The academic peer review of the marketable research gauges whether the idea or a project in question can be commercialized, thereby strengthening the relationship between academic research and private industry.

¹⁵⁷ See Frenkel, Shefer & Miller, *supra* note 152.

¹⁵⁸ *Id.*

¹⁵⁹ See Frenkel, Shefer & Miller, *supra* note 152 (“The aim of the technological incubator program, as a development program “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 program. 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 venture capital supply, business and legal consultation, and the filtering of valuable ideas. Obviously, however, it cannot help in increasing the supply of skilled labor.”).

¹⁶⁰ See Trajtenberg, *supra* note 151 (According to Trajtenberg, 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.”).

¹⁶¹ *Id.*

¹⁶² *Id.*

Initially, the Israeli technology incubators were not-for-profit quasi-governmental entities.¹⁶³ They were managed by the incubator's manager, as well as by public actors, such as research institutions, universities, or municipalities. The public managers provided budding companies with start-up resources, such as low-cost shared-use facilities or labs,¹⁶⁴ as well as a variety of services tailored to the specific needs of the participating firm, including the firm's level of management skills, overall development of innovation, and industry sector, as well as its geographic regional location. The services included mentoring, assistance with the research and development or business planning, hiring management, clerical services, organizational analysis, legal and accounting guidance, and networking (such as introducing entrepreneurs to potential partners and investors).

Following the selection process, the incubator manager, the professional advisors, and the entrepreneur were responsible for drafting a "project folder," which was then submitted to the incubator's steering committee.¹⁶⁵ The steering committee was typically chaired by the incubator's manager¹⁶⁶ and usually comprised members from the following stakeholder groups: research institutions and academia, industry representatives, and community leaders¹⁶⁷

ii) Financing Mechanisms

The Israeli government provided financial support both to the incubator's management, as well as to the programs' participants. Annual grants to the management of up to \$175,000 per year were available.¹⁶⁸ The government also provided grants to each of the seed companies participating in the program of up to \$150,000 per year for a maximum of two years.¹⁶⁹

The Israeli government allocated a grant to each project that could reach up to 85% of the project's approved budget.¹⁷⁰ The remaining 15% of the budget, termed the

¹⁶³ Catarina Wylie, *Vision in Venture: Israel's High-Tech Incubator Program*, 10 CELL CYCLE 855 (March 15, 2011) <http://www.landesbioscience.com/journals/cc/Israeli-IncubatorCC10-6.pdf?nocache=1570288485>.

¹⁶⁴ The OCS established about twenty-four incubation centers, which finance entrepreneurial ideas that are submitted to the incubator's steering committee. 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 accepted by the program. See Frenkel, Shefer & Miller, *supra* note 153.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ See Frenkel, Shefer & Miller, *supra* note 152.

“complementary financing,”¹⁷¹ had to be supplied by the entrepreneur (or by a private partner brought in by the entrepreneur, in return for a certain amount of equity in the project).¹⁷² Research in 2003 showed that the incubator programs were able to attract non-government financing sources, by attracting private investors and by collecting fees from “royalties, sale of shares and dividends, and strategic partnerships.”¹⁷³ The firm paid the Israeli government royalties to repay the grant once successful. If the new venture failed, the government did not require repayment of the money invested.¹⁷⁴

iii) Annual Evaluations

Each of the projects accepted into the incubator program was evaluated on a yearly basis. Although seed capital was usually limited for up to two years of operation,¹⁷⁵ in limited circumstances, mainly when the project is from the biotech field, a third year of government support could be granted.¹⁷⁶

iv) Privatization

The Israeli Technological Incubator programs were privatized in 2002 and converted into public-private partnerships, organized in the form of incubator joint

¹⁷¹ *See id.*

¹⁷² *See id.* (According to Miller, Shefer & Frenkel, “From a small annual budget of \$2 million at the beginning in 1991, the technological incubator program increased its annual budget to \$32 million in 2002. As of 2003, total government grants to the program amounted to \$285 million (see: www.incubators.org.il). 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 Ph.D. degree).”).

¹⁷³ *See* SHEFER & FRENKEL, *supra* note 153. (Shefer and Frenkel assessed the successes of the Israeli Technological Incubator Program in 2003, which was ten years following its establishment. They concluded that generally the program has fulfilled its purpose, because approximately 86.4% of the projects (during the years 1999 to 2001) have graduated from the program, while 7% of these projects were also able to secure immediate financial support following graduation. According to Shefer & Frenkel, these statistics indicate that the programs were successful. It should be noted, however, that incubators that were located in geographic areas that are considered the periphery, actually experiences lower levels and rates of success (when compared with programs located in central regions). According to Shefer & Frenkel, these findings suggest that vast government support is still needed in the initial stage of the incubator programs. However, government support in the programs can be gradually reduced over time, especially once private financing sources are attained. Yet, there is a caveat, it seems that technological incubators that are located in peripheral regions do require more public support, as well as for a longer period of time (as compared to incubators located in central regions of the country).

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

companies.¹⁷⁷ Once the private sector was able to provide private capital for the incubators, policy makers concluded that government funding was no longer necessary.¹⁷⁸

The incubator joint company reduced its shares (which were not tradable¹⁷⁹) by increasing capital from external investment.¹⁸⁰ Wholly privately owned incubator models then started to emerge in Israel.¹⁸¹

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.¹⁸² Success rates were measured by the ability of entrepreneurial firms, after graduation from the program, to obtain subsequent funding as well as continue growing their operations.¹⁸³ Following graduation from the incubator program, many companies were able to create jobs and attract international venture capital funds.¹⁸⁴

The Israeli government further privatized the programs by establishing a franchise system, whereby the government licensed the incubators to experienced equity investment firms, which granted management support to the portfolio companies and extensively invested in the incubator startup projects.¹⁸⁵ Since 2002, the franchise model used a new repayment mechanism.¹⁸⁶ Originally, the Israeli government provided funding for projects directly to the public technological incubator program.¹⁸⁷ In that way, the program was the agent in charge of transferring the government funding to the individual companies. Moreover, the program, not the startup firm, was accountable for repaying the grant, usually within a four-year period from the date in which the startup firm graduated from the program.¹⁸⁸ In order to guarantee that the money would be repaid, the Israeli government held shares in each of the funded startup firms. If the incubator did not repay the grant in a timely manner period, the government had the right to decide whether or not to sell its stake in the startup. According to Yossi Smoler, the Director of the Technological

¹⁷⁷ *See id.*

¹⁷⁸ *See* Frenkel, Shefer & Miller, *supra* note 152 (“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 to private enterprises could increase their efficiency and thereby, the efficiency of the whole economic system (Eckstein et al., 1998). Results have shown though, that privatization increases efficiency and innovation if it is done in a wise manner (Kikeri et al., 1994).”).

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ Interview with Yossi Smoler, *quoted in* Wylie, *supra* note 163.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

Incubators Program, the repayment mechanism was “too complex and wasn’t something in which the government wanted to be involved in.”¹⁸⁹ Today, the government allocates funds directly to the startup company and the company pays off the amount via royalties and interest (usually three to five percent of royalties plus a market-rate interest).¹⁹⁰

v) *Results*

In summary, the Israeli Incubator programs exceeded the initial goals of their founders, facilitating the development of a world-class high tech industry in Israel. 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 the research and development initiatives with international partners (via bilateral or multilateral cooperation) and contributes to the expansion of global innovative markets. Among these expanding markets are the United States, China, and India.¹⁹¹

2. Structure

The DHCI Incubators should be largely autonomous organizations, usually structured as not-for-profit corporations, B corporations, or limited liability companies with limits on the transfer of ownership and buy-back 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.¹⁹²

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 the academy and the industry while ensuring that funds are distributed to research projects that are deemed worthy by scientists, not just business people seeking short-term profits.¹⁹³

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ 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 (USA) and Victoria (Australia).

¹⁹² See further discussion of the theory introduced by Lynn A. Stout, *The Corporation As Time Machine: Intergenerational Equity, Intergenerational Efficiency, and the Corporate Form*, 38 SEATTLE U. L. REV. 685 (2015), in the next part, discussing corporate governance.

¹⁹³ See Block, *supra* note 31 (According to Block, the NIH officials and policy makers rely heavily on the peer review model, in which funds are distributed to research projects that were deemed worthy by scientists). See also AN ASSESSMENT OF THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM AT THE NATIONAL INSTITUTES OF HEALTH (Charles Wessner ed., 2009), <http://www.ncbi.nlm.nih.gov/books/NBK11455/>.

3. Financing

The Department of Defense, the NIH, the Central Health Incubators Bureau, and other government agencies will provide seed funding in response to requests for proposals. Such grants are frequently limited to no more than two years.¹⁹⁴ However, because these projects are from the biotech field, a third, fourth and fifth year of government support could be granted, after due assessment.¹⁹⁵ It should be noted that accelerator capital is even for a shorter time period of a few months (i.e., five months or less).

Building on the Israeli incubator model, the funds should be invested in the portfolio companies in the incubator, and not given to the incubator management. However, in most cases, it will be the firm, and not the government, who will own the technology with certain residual rights belonging to the academic institution with a portion of the royalties being payable to the inventors in accordance with the Bayh-Dole Act. The firm will be required to repay the government grant once successful, perhaps (if one follows the Israeli example) with royalties equal to three to five percent of revenues plus market-rate interest.¹⁹⁶ If the new venture fails, the government will not require repayment of the money invested.¹⁹⁷ Both the public and private participants 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 incubator sponsors). According to a study by Lewis, Harper-Anderson and Molnar, public sector support will contribute to incubator program's

¹⁹⁴ See Israeli example in FRENKEL & SHEFER, *supra* note 153.

In June 2018, BARDA announced the creation of the Division of Research, Innovation, and Ventures (“DRIVE”), whose

mission will be to accelerate research, development, and availability of transformative countermeasures to protect Americans. 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.

Steve Brozak, *An Unlikely Biotech Investor: The Government*, FORBES.COM (JUNE 8, 2018), <https://www.forbes.com/sites/stephenbrozak/2018/06/08/merck-and-achaogen-two-companies-working-with-barda-to-fight-emerging-health-threats/#686518984fd0>. Brozac, *supra* note 97. zzz

¹⁹⁵ FRENKEL & SHEFER, *supra* note 153.

¹⁹⁶ See Israeli Incubator's example in the article by Wylie. See Wylie, *supra* note 163.

¹⁹⁷ *Id.*

success.¹⁹⁸ Moreover, the study illustrates that incubator programs that enjoy larger budgets (both revenues and expenditures) outperform incubators that have to deal with budget constraints.¹⁹⁹

Accordingly, the managers of the incubator should be expected to line up investments from other private and public sources representing roughly 15% of each portfolio company's approved budget.²⁰⁰ Getting private capital to supplement the government investment will increase the total capital introduced into the market, as well as provide networking opportunities (perhaps resulting in follow-on investments from such sources) for the portfolio companies. As discussed below, the managers should also be expected to contribute funds or sweat equity.

4. Other Governmental Actors and Roles

Governmental actors can undertake various tasks. Regional, state and federal governments are likely to be present through initiatives such as research and development grants and other funding. Various agencies, such as commerce, labor and economic development, execute such initiatives, whereas economic development companies usually represent the local government. All these government entities can serve as a future client or provider for certain firms in the incubator.

The following are four significant additional roles that government can play, which were suggested by economists Muso and Katz.²⁰¹ First, federal policymakers may provide

¹⁹⁸ See LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 74 (“this research suggests that some level of public sector investment contributes to greater incubator outcomes in terms of job creation, graduation rates, etc.”).

¹⁹⁹ *Id.* (“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.”).

²⁰⁰ “ARPA almost always requires 50 percent cost-matching for ‘other transactions.’” Kuyath, *supra* note 31. “[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.

²⁰¹ Mark Muso & Bruce Katz, *The New “Cluster Moment”: How Regional Innovation Clusters Can Foster the Next Economy*, BROOKINGS (Sept. 21, 2010), <http://www.brookings.edu/research/papers/2010/09/21-clusters-muro-katz> (“strong 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.”).

incubator stakeholders around the nation with information and foundational resources.²⁰² This implies that the managers of the incubators should recruit the involvement of federal agencies, and in particular, the following: Commerce (DOC/NIST), Defense (DOD), Education (ED), and Energy (DOE); the National Aeronautics and Space Administration (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.²⁰³ Regional clusters are defined as “geographic concentrations of inter-connected companies and institutions in a particular field,” which include “governmental and other institutions.”²⁰⁴ The state government should encourage university-industry partnership, 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.²⁰⁵ 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.²⁰⁶

5. Management

The Incubators may be managed in one of two ways. The Central Health Incubators Administration or an existing agency such as DARPA could hire internal executive managers for each Incubator who are tasked with facilitating the collaboration and

²⁰² *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.”).

²⁰³ *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.”).

²⁰⁴ MICHAEL PORTER, *THE COMPETITIVE ADVANTAGE OF NATIONS* 154 (1990). See also Hal Wolman & Diana Hincapie, *Clusters and Cluster-Based Development: A Literature Review and Policy Discussion* (George Washington Institute of Public Policy, Working Paper, 2010).

²⁰⁵ Muso & Katz, *supra* note 201, 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.”).

²⁰⁶ *Id.* (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.”).

coordination efforts.²⁰⁷ As noted earlier, it is important for the program managers to be largely autonomous, as was the case with DARPA projects. Subject to approval by the Steering Committee, these would include setting goals, supervising staff, and most of all limiting the dangers of political pressures and abuse.²⁰⁸

Alternatively, the federal government could contract with trusted partners or trusted intermediaries, who are third parties with expertise vetting potential projects and ensuring that the cooperation, exchange of information, incentives, operational pieces, quality controls, and ethics and compliance systems are in place. They too would report to the Steering Committee.

Subject to government approval, using OTAs, and the approval of the Steering Committee, the top management will be expected to set a clear (and well-defined) mission statement, investment processes and goals, in addition to a robust plan for fees that will be collected from rents and other services. Areas to be addressed include the following.

First, who are the incubator's potential clients (the entrepreneurs and firms that will want to participate in the program)? Which industry sectors are they from? What is their level of development?²⁰⁹ What is their level of management skills?

Second, in which region will the incubator be located? Is it a technology or non-technology oriented region? Is it considered a central or periphery geographic area? What is the industrial capacity of the region?²¹⁰

Third, who are the various stakeholders and potential sponsors (partners) in the region? How do they vary in terms of resources, missions, and requirements?

²⁰⁷ It is further proposed that the hubs should offer affordable and comfortable housing in order to attract talent.

²⁰⁸ See Sean Silverthorne, *Government's Positive Role in Kick-Starting Entrepreneurship*, HARV. BUS. SCH. (Dec. 7, 2009), <http://hbswk.hbs.edu/item/6318.html>.

²⁰⁹ See *SBIR Mission and Program Goals*, *supra* note 101 (For comparison SBIR guidelines, Phase I definition and eligibility for funding: "Phase I. 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.").

²¹⁰ See LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 74 (noting that "[i]ncubator 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.").

This initiative encourages incubator managers to collaborate with higher institutions and research agencies because higher education institutions have a key role in the new knowledge economy,²¹¹ especially since they can provide innovative solutions and address the particular needs of the region's core industry. Therefore, the academic entities in this category will play a variety of roles within the incubator. They will encourage collaboration, cooperation, open innovation, shared-use facilities and technology transfer from the participating research institutions to marketable products or manufacturing process. Also, they will provide guidance to the businesses involved in the incubator.

a) Selection of In-House Managers

The process for selection of the program manager is extremely important.²¹² When selecting the managers, the Central Health Incubators Administration (or other government agency) should consider the following: the reputation and experience of the manager, particularly with regard to the region in question; the industries (or research) that the agency would like to promote in the region; seed investments and training entrepreneurial firms; as well as the manager's ability and thy to bring on additional investments from local and regional stakeholders. Prospective executive managers should be asked to compete for the right to participate in the incubator initiative.²¹³

The bidding process could also take into account the following: maximum fraction of capital that the executive manager (or management group) will be willing to invest in the incubator portfolio companies, as well as the size of incubator that the manager seeks to establish.

²¹¹ See also Laredo & Mustar, *supra* note 83. See NELSON, *supra* note 12; NATIONAL SYSTEMS OF INNOVATION: TOWARDS A THEORY OF INNOVATION AND INTERACTIVE LEARNING (Begt-Åke Lundvall ed., Anthem Press 1992) (first person to use term; national system of innovation is social and dynamic); SYSTEMS OF INNOVATION: TECHNOLOGIES, INSTITUTIONS AND ORGANIZATIONS (Charles Edquist ed., 1997).

²¹² See LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 74 (“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.”).

²¹³ See Fannie Chen, *Structuring Public-Private Partnerships: Implications from the “Public-Private Investment Program for Legacy Securities,”* 46 COLUM. J.L. & SOC. PROBS. 509 (2013) (“building a process whereby private parties compete for participation in a PPP 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.”).

The 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 or in return for a cash investment in the portfolio company or both).²¹⁴ 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 research and development. The incubators' managers will also be subject to the oversight of the private market, because if the portfolio firms are successful in the future, then the managers will be compensated with their equity stake.

b) Selection of Trusted Partners or Intermediaries

Similar criteria might be used for trusted partners or intermediaries except they would not be eligible to receive equity or have any responsibility to invest their own funds.

6. Steering Committee

Each Incubator should have a Steering Committee which, according to the Israeli experience, should usually be chaired by the executive manager of the Incubator's management group.²¹⁵ The Steering Committee should include a technology transfer specialist; an executive from an incubator graduate firm;²¹⁶ accounting, intellectual property (patent assistance), and general legal experts;²¹⁷ representatives from research institutions and academia; industry representatives; local government and economic development agency officials;²¹⁸ and representatives from any other stakeholders involved with the incubator.²¹⁹

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

It will be important for the team managing the public-private partnership both to engender the trust of all parties and to help negotiate a long-form contract that ensures that

²¹⁴ See AlphaLab example *infra* note 235.

²¹⁵ FRENKEL & SHEFER, *supra* note 153.

²¹⁶ LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 74.

²¹⁷ *Id.*

²¹⁸ See LEWIS, HARPER-ANDERSON & MOLNAR, *supra* note 74 (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.").

²¹⁹ FRENKEL & SHEFER, *supra* note 153.

the proper incentives are in place.²²⁰ Commons theory posits that private arrangements can be effective to govern shared resources, such as information and data.²²¹ In this respect, our proposal incorporates aspects of the work of Noble Prize 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.²²² 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 contemplates that the government will be one of the contracting parties.

To promote 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 transaction. The parties recognize that the benefit of joint optimization requires specific legal clauses.
2. The parties agree to fulfill their obligations within the agreed binding clauses in respect to 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, openness, trust, and collaboration.
4. The contract shall stay 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 the tool to create added value.

²²⁰ See Bagley & Tvarnø, *supra* note 45, at 396 (“The prisoners’ dilemma shows that the parties, acting alone, will self-optimize. A well-crafted and fully enforceable PPPP contract can help prevent self-optimization and instead promote joint optimization and efficient allocation of added value.”).

²²¹ See Katherine J. Strandburg, Brett M. Frischmann & Michael J. Madison, *Knowledge Commons and the Road to Medical Commons* and *The Knowledge Commons Framework*, in GOVERNING MEDICAL KNOWLEDGE COMMONS (Katherine J. Strandburg, Brett M. Frischmann & Michael J. Madison eds., Cambridge Univ. Press 2017).

²²² Nobel Prize Laureate Elinor Ostrom is known for “her analysis of economic governance” 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 (Cambridge Univ. Press 1990). See also Elinor Ostrom & Charlotte Hess, *A Framework for Analyzing the Knowledge Commons*, in UNDERSTANDING KNOWLEDGE AS A COMMONS: FROM THEORY TO PRACTICE (Charlotte Hess & Elinor Ostrom eds., MIT Press 2006). 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) and Robert P. Merges, *Response: Individual Creators in the Cultural Commons*, 95 CORNELL L. REV. 793 (2010). See also Elinor Ostrom, *Response: The Institutional Analysis and Development Framework and the Commons*, 95 CORNELL L. REV. 807 (2010). See Katherine J. Strandburg, Brett M. Frischmann & Michael J. Madison, *Knowledge Commons and the Road to Medical Commons*, in GOVERNING MEDICAL KNOWLEDGE COMMONS, *supra* note 220.

5. The parties shall take the steps necessary to optimize the transaction. 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 transaction.
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 the books and calculations concerning the transaction.
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 with the objectives of achieving:
 - a) Mutual cooperation and trust
 - b) Openness
 - c) Joint research
 - d) Common goals
 - e) An understanding of each other's values and the joint value of the transaction
 - f) Innovation
 - g) Improved efficiency
 - h) Delivery in accordance with Key Performance Indicators (KPIs) and timetables
 - i) Optimization of the transaction.
9. 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 transaction 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 specific strategic alliance guideline: When a problem arises, the first responsible director shall gather the parties and, based on the following objectives, 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 a mediator and finally an arbitrator. 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 transaction. 223

²²³ See Strandburg, Frischmann & Madison, *supra* note 220 (“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.”).

8. Selection 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.²²⁴ Once the Steering Committee has approved a project or portfolio company, the Central Health Incubators Bureau 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 Central Health Incubators Administration will, absent exigent circumstances, be expected to obtain peer review of the proposals, as happens now with both NIH and IMI grants, and also request additional advice from independent experts, depending on the industry and research objectives.²²⁵ To ensure that 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.²²⁶

To be accepted into the program, the project (idea) must be innovative, based in sound research and development, and capable of being commercialized and exported to the appropriate market. The industry scope is the core activity or common denominator that links the participating actors.²²⁷ The 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 this initiative is to encourage the adoption of the stakeholder approach to strategic management,²²⁸ which is intended to give managers a framework

²²⁴ See Israeli Incubator Model, as discussed in FRENKEL & SHEFER, *supra* note 153.

²²⁵ *Id.*

²²⁶ Thomas Sinkjær, *Fund Ideas, Not Pedigree, to Find Fresh Insight*, NATURE.COM (Mar. 6, 2018), <https://www.nature.com/articles/d41586-018-02743-2> ("Anonymous applications free scientists to make bold proposals, and 'golden tickets' free reviewers to bet on them.").

²²⁷ See THOMAS ANDERSSON, SYLVIA SCHWAAG-SERGER, JENS SØRVIK & EMILY W. Hansson, THE CLUSTER POLICIES WHITEBOOK, IKED - INTERNATIONAL ORGANISATION FOR KNOWLEDGE ECONOMY AND ENTERPRISE DEVELOPMENT (2004), http://www.clusterplattform.at/fileadmin/user_upload/clusterbibliothek/916TheClusterPoliciesWhitebook.pdf.

²²⁸ See also R. Edward Freeman & John McVea, *A Stakeholder Approach to Strategic Management* (Working Paper No. 01-02), <http://faculty.wvu.edu/dunnc3/rprnts.stakeholderapproach.pdf>.

("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

within which to deal with constant changes in the environment, society, technology and industry.²²⁹ Accordingly, the Incubator managers will be able to actively design a new direction for the incubator,²³⁰ as needed to take into account how the incubator can affect the environment in addition to how the environment possibly will affect the incubator,²³¹ 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 immediate results and profits.²³² Such emphasis on investment in long-term research and development will provide current and future generations with the ability to enjoy the wealth generated from the innovative projects.²³³

Each of the projects in the incubator program should be evaluated on a yearly basis.²³⁴ If a project is running over budget or behind schedule and otherwise not meeting expectations, then after the program manager gives the management a reasonable time to get it back on track, the program manager or CHIB should have the power to terminate the project, with all rights reverting to the portfolio company.

9. 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) as well as political capture (i.e., management being pressured by local stakeholders to accept friends, relatives, or political allies into program), the following incentives are designed to encourage the management to be diligent in selecting the companies that will join the incubator portfolio.

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

environment of the 1980’s. . . . A new conceptual framework is needed.”[Freeman, 1984, pg. 5] A stakeholder approach was a response to this challenge.”).

²²⁹ See also *id.* (“The purpose of stakeholder management was to devise methods to manage the myriad groups and relationships that resulted in a strategic fashion.”).

²³⁰ FRENKEL & SHEFER, *supra* note 153.

²³¹ FRENKEL & SHEFER, *supra* note 153.

²³² See Stout, *supra* note 192.

²³³ See *id.* (Stout gave examples of the ways in which the results of research and development by large public corporation 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.”)).

²³⁴ See Israeli example in FRENKEL & SHEFER, *supra* note 153.

supervising the funding from the various stakeholder groups, providing venture capital-like support services to the portfolio companies, such as preparing the business plan, research and development strategy, clerical services, organizational analysis, legal and accounting guidance.²³⁵ 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.²³⁶ Managers who have invested their own capital in the portfolio incubator companies will have a stake in making sure that they do not pick "lemons."²³⁷ Having an equity stake also reduces the dangers of management shirking²³⁸ and not acting in the best interests of the companies and their investors.²³⁹ It may also lessen the effects of political pressures from the government agencies involved.

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

²³⁵ See also Muso & Katz, *supra* note 201 ("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."). 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." LERNER, *supra* note 33.

²³⁶ For example, an accelerator program, AlphaLab, a nationally-ranked startup accelerator program based in Pittsburgh, Pennsylvania, receives 5% 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. Information obtained from <http://alphalab.org/faq/>.

²³⁷ See George A. Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism*, 84 (3) Q.J. ECON. 488, 493 (1970) (Akerlof discusses the "adverse selection" problem, as well as firms' offerings of equity that may be associated with the "lemons" problem). See also Manuel Utset, *Reciprocal Fairness, Strategic Behavior & Venture Survival: A Theory of Venture Capital Financed Firms*, 2002 WIS. L. REV. 45, 56 (2002). See also PAUL A. GOMPERS & JOSH LERNER, *THE VENTURE CAPITAL CYCLE* 129 (1999).

²³⁸ See Michael C. Jensen & William H. Meckling, *Theory of the Firm: Managerial Behavior, Agency Costs and Ownership Structure*, 3 J. FIN. ECON. 305 (1976) ("[T]he 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 those common in the performing arts and the market for real estate.").

²³⁹ See LERNER, *supra* note 23.

The DHCI is based on the “open-innovation”²⁴⁰ and “commons”²⁴¹ 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 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,²⁴² thereby reducing the cost of carrying out research and development²⁴³ and increase the likelihood of developing products or services that would otherwise not exist or would remain untapped in the economy.²⁴⁴ 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 process²⁴⁵ and boost the accuracy of customer targeting and market research. Finally, they increase the potential for viral marketing.²⁴⁶ Firms that have successfully used open innovation include Intel, Cisco, and Microsoft.²⁴⁷

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

²⁴⁰ The term “open innovation” was coined by Henry Chesbrough, adjunct professor and faculty director of the Center for Open Innovation at the Haas School of Business at the University of California. 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.” See HENRY WILLIAM CHESBROUGH, *OPEN INNOVATION: THE NEW IMPERATIVE FOR CREATING AND PROFITING FROM TECHNOLOGY* (2003).

²⁴¹ See Strandburg, Frischmann & Madison, *supra* note 220.

²⁴² 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) (according to West and Gallagher, 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; ERIC VON HIPPEL, *THE SOURCES OF INNOVATION* (Oxford Univ. Press 1988) (there are four sources of external knowledge: first, supplier and customer; second, university, government and private laboratories; third, competitors; and fourth, other nations).

²⁴³ See CHESBROUGH, *supra* note 240.

²⁴⁴ See also Yoram Margalioth, *Not a Panacea For Economic Growth: The Case of Accelerated Depreciation*, 26 VA. TAX REV. 493 (2007); see also C.I. Jones, *Growth and Ideas*, in 1B *HANDBOOK OF ECONOMIC GROWTH* 1063 (P. Aghion & S. Durlauf eds., 2005).

²⁴⁵ 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 prototype. See Stephan Marais & Corne Schutte *The Development of Open Innovation Models to Assist the Innovation Process*, Univ. of Stellenbosch, South Africa 96 (2010) (In 23rd Annual SAIIE Conference).

²⁴⁶ See Marais & Schutte, *supra* note 245 (“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.”).

²⁴⁷ See CHESBROUGH, *supra* note 239.

firm or institution. This is already being done with a high through-put program whereby promising small molecules or biologics owned by pharma and biotech firms are matched against pathogens and pathways or genes identified by academic scientists pursuant to cooperative research and development agreements (“CRADAs”). 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 strains. In such a case, the drug might be manufactured by a large pharmaceutical firm but the government would be the sole customer.²⁴⁸

11. Ecosystems of Excellence

If our initiative is properly implemented, it should lead to the formation of “ecosystems of excellence,”²⁴⁹ sometimes called “clusters,”²⁵⁰ with the following positive results. First, it can foster geographic connections between the various regions where the incubators are located.²⁵¹ Second, it can boost new enterprise formation²⁵² and help firms survive the Valley of Death²⁵³ by stimulating low-cost collaboration between early-stage

²⁴⁸ Thanks to Yale Professor Jo Handelsmann for this example.

²⁴⁹ 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 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.

²⁵⁰ PORTER, *supra* note 204 (Approximately twenty years ago, Michael Porter, a Harvard Business School professor, introduced and popularized the concept of “clusters.”).

²⁵¹ PAUL R. KRUGMAN, *GEOGRAPHY AND TRADE* (1991) (discussing the significance of geographical economics).

²⁵² PORTER, *supra* note 204.

²⁵³ *Id.* See discussion on Valley of Death *supra* Parts III, III.B.1, and IV.B.11. (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 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 Noble Prize Laureate Elinor Ostrom on the commons.).

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).²⁵⁴ Third, it can foster innovation and commercialization through dense knowledge flows and spillovers, including networking and data gathering and sharing.²⁵⁵ Finally, it can foster competition and encourage firms to innovate.²⁵⁶

The Bureau should be in charge of developing platforms that will allow the various incubator program managers to meet, share their progress, difficulty, achievements, as well as 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.²⁵⁷ For example, in 2001, respondents complained that “they did not have the necessary agreements in place to put the plans into operation rapidly... they ran into trouble reaching clinicians to provide them with guidance, and that they had not anticipated the number of entities with which they would have to communicate.”²⁵⁸

We note that there is controversy concerning the issue of whether foreign companies or entrepreneurs should be able to participate in programs that are funded by American taxpayers. However, in today’s global economy, such collaborations are necessary and even inevitable.²⁵⁹ Therefore, international firms should be able to participate (as partners of American firms) unless their involvement would pose a threat to national security.

²⁵⁴ See also Stout, *supra* note 192, at 692 (definition of “stakeholders”).

²⁵⁵ See Muso & Katz, *supra* note 201. 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 204. Absent the cluster, individual companies would lack access to certain information, such as market research and supply chain analysis. *Id.*

²⁵⁶ See Muso & Katz, *supra* note 201. PORTER, *supra* note 204. See also Harald Bathelt, Anders Malmberg & Peter Maskall, *Clusters and Knowledge: Local Buzz, Global Pipelines and the Process of Knowledge Creation*, 28 PROGRESS IN HUMAN GEOGRAPHY 31 (2004) (clusters strongly encourage and pressure companies to innovate both to stay competitive and to increase profitability).

²⁵⁷ See Temko, *supra* note 106. See also past example of failure to deal with the Anthrax incidents of 2001. U.S. GOV’T ACCOUNTABILITY OFFICE, BIOTERRORISM: PUBLIC HEALTH RESPONSE TO ANTHRAX INCIDENTS OF 2001, 1 (2003) [hereinafter BIOTERRORISM: PUBLIC HEALTH RESPONSE TO ANTHRAX INCIDENTS OF 2001].

²⁵⁸ BIOTERRORISM: PUBLIC HEALTH RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 257, at 1.

²⁵⁹ See above discussion on cross-regional collaboration.

V. 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,²⁶⁰ 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.

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. ²⁶¹ Reasons include the federal government's inflexible fight for control over intellectual property rights and software warranties; ²⁶² unreasonable, time-consuming and very costly delays in funding due to such things as shifts in government priorities and changing strategies and procurement needs; ²⁶³ complex cost accounting requirements; and the "long, onerous and costly federal acquisition process." ²⁶⁴ 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 government. ²⁶⁵ In contrast, it took only three part-time employees, two months and thousands of dollars to prepare the same bid for a private firm.

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 attack on Pearl Harbor gave birth to the field of operations research as the country scrambled to arm and clothe its soldiers and build fleets of ships, submarines, 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

²⁶⁰ See also Dorothy Leonard-Barton & William A. Kraus, *Implementing New Technology*, HARV. BUS. REV., Nov. 1, 1985.

²⁶¹ See Cooke, *supra* note 68.

²⁶² *Id.*

²⁶³ *Id.*

²⁶⁴ *Id.*

²⁶⁵ *Id.*

of how the Food and Drug Administration (“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.

We applaud the FDA’s willingness to consider accepting aggregated patient data of the sort gathered by Flatiron based on electronic health records to be used in lieu of expensive and time-consuming clinical trials.²⁶⁶ This may be particularly appropriate when a drug already approved for one clinical use is being considered for another (so-called repurposing).

B. Lack of a Unified Healthcare Infrastructure

Some maintain (including certain members of Congress) that the first BioShield initiative failed because the enabling act did not address the United States’ healthcare infrastructure problem. 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.²⁶⁷

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 bio-tech firms.²⁶⁸ The markets for allocating risk capital to early stage ventures are inefficient.²⁶⁹ 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 intermediates that

²⁶⁶ 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*, BUSINESSINSIDER.COM (June 2, 2017), <http://www.businessinsider.com/flatiron-health-collaboration-with-fda-data-at-asco-2017-6>.

²⁶⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

²⁶⁸ See BRANSCOMB & AUERSWALD, *supra* note 92.

²⁶⁹ *See id.*

have found a way to address at least some of these information challenges, have abandoned early-stage bio-tech investments in favor of later stage investments,²⁷⁰ in part because they cannot capture the full benefits of such technologies.²⁷¹ Additionally, many large public firms are closing or relocating their research and development labs to sites outside of the United States, as well as shying away from “Moon Shot” investments in research and development initiatives with uncertain returns.²⁷²

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 bridges at least some of the financial inefficiencies and information gaps associated with investment in research and development, but, perhaps, more importantly, 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.²⁷³ Politicians

²⁷⁰ Joseph A. McCahery, Erik P.M. Vermeulen & Andrew M. Banks, *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>.

²⁷¹ 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., The Brookings Institution 1995) (providing evidence that the social return to R&D is much above the private return). See BRANSCOMB & AUERSWALD, *supra* note 92; see Zvi Griliches, *The Search for R&D Spillovers*, 94 SCAND. J. ECON. 29 (Supp. 1992) (evaluating calculations of the social rates of return for research and development). See also Margalot, *supra* note 244.

²⁷² 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 LYNN STOUT, THE SHAREHOLDER VALUE MYTH: HOW PUTTING SHAREHOLDERS FIRST HARMS INVESTORS, CORPORATIONS, AND THE PUBLIC (2012). 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 Summers, *Breach of Trust in Hostile Takeovers*, in CORPORATE TAKEOVERS: CAUSES AND CONSEQUENCES 33-56 (A. Auerbach ed., 1998), <http://www.nber.org/chapters/c2052>.

²⁷³ See Andrei Shleifer, *State Versus Private Ownership*, 12 J. ECON. PERSP. 133 (1998) (arguing that the “importance of ownership as the source of capitalist incentives to innovate; . . . 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.”).

concerned with being re-elected have a strong personal interest in making their constituencies happy. Therefore, they have a tendency to push for more recruitment than necessary in order to create jobs and spend more (in excess) than the private market would on an initiative,²⁷⁴ 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.²⁷⁵ This results in the misallocation of scarce government resources to the detriment of the tax payer as well as those who would be served by a more efficient process for funding innovation.²⁷⁶ 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.²⁷⁷

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.

VI. CONCLUDING THOUGHTS

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 lead not only to 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 the Congress and the President enact and implement the Defense of Health Countermeasures Initiative, a multi-prong initiative 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

²⁷⁴ See Belloc, *supra* note 81.

²⁷⁵ See *id.*

²⁷⁶ See Shleifer, *supra* note 273 (arguing that "Governments throughout the world have long directed benefits to their political supporters, whether in the form of jobs at above-market wages or outright transfers.").

²⁷⁷ Giacomo Corneo & Rafael Rob, *Working in Public and Private Firms*, 87 J. PUB. ECON. 1135 (2003).

create a national network of public-private incubators governed by contracts²⁷⁸ of the sort currently used by participants in the European Union’s Innovative Medicines Initiative²⁷⁹ and by certain U.S. entities under Bayh-Dole Act.²⁸⁰ Our initiative incorporates aspects of the work of Noble Prize 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.²⁸¹ 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 CARB-X. To provide adequate incentives for private firms to participate, members of a consortium will have the ability to keep certain downstream discoveries information proprietary by disclosing it only to a trusted intermediary pursuant to a confidentiality agreement that preserves future patentability.

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 that U.S. biotechnology startups can successfully compete in tomorrow’s market place.²⁸² 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.²⁸³

Furthermore, we do not purport to have all the answers and know that input and assistance from others in academia, industry, and government will be needed to turn this skeletal proposal into the legislation, regulations, and contracts that will be 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 funded through the

²⁷⁸ See Bagley & Tvarnø, *supra* note 13.

²⁷⁹ See *id.*; see Gaspar et al., *supra* note 21. For more information on the Innovative Medicines Initiative (“IMI”), see <http://www.imi.europa.eu/about-imi/how-imi-works>. 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.” 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.”

²⁸⁰ For a list of legislation concerning innovation, see *supra* note 32; see also Alon-Beck, *supra* note 32.

²⁸¹ See *supra* note 221.

²⁸² See Porter & Kramer, *supra* note 67.

²⁸³ Block, *supra* note 31. See also KENT HUGHES, BUILDING THE NEXT AMERICAN CENTURY: THE PAST AND FUTURE OF ECONOMIC COMPETITIVENESS (2005); 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 67.

DHCI; the appropriate use of government prizes and vouchers to spur innovation;²⁸⁴ and the provisions necessary to protect basic human rights, especially the right to privacy. At the risk of being presumptuous, we hope that this Article will help further the dialogues and work necessary to effect real change.

²⁸⁴ See Michael J. Burstein & Fiona Murray, *Innovation Prizes in Practice and Theory*, 29 HARV. J. L. & TECH. 401 (2016). See also Ana Santos Rutschman, *The Priority Review Voucher Program at the FDA: From Neglected Tropical Diseases to the 21st Century Cures Act* (2017), ANNALS OF HEALTH L. (forthcoming), <https://ssrn.com/abstract=2940860>.