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Recommended Citation

Eyal-Cohen, Mirit and Santos Rutschman, Ana, Tax Policy and Pharmaceutical Innovation (November 18, 2020). Saint Louis U. Legal Studies Research Paper No. 2020-34.

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SAINT LOUIS UNIVERSITY SCHOOL OF LAW
Legal Studies Research Paper Series

No. 2020-34

Tax Policy and Pharmaceutical Innovation

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TAX POLICY AND PHARMACEUTICAL INNOVATION

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ABSTRACT

The COVID-19 pandemic has exposed severe underinvestment in sustained research and development (R&D) of vaccines to prevent public health crises. Evidently, policy and lawmakers have attempted to establish incentives for pharmaceutical R&D, spending billions upon billions of dollars in the process. However, they so far utilized a limited set of tools such as patents, grants, and to a lesser extent prizes to encourage discoveries in vaccine technology. In particular, commentators have paid relatively little attention to the role of taxation in delivering efficient vaccine research incentives.

This Article fills this gap in the literature and in policy by examining ways to better employ the tax system to spur investments in vaccine discoveries. We demonstrate that, when designed properly, tax apparatuses can offer an incomparable advantage—its ability to harness market-based mechanisms *ex ante* thus economize on resources, administrative costs, regulatory capture, and information problems. By contrast, other regulatory interventions currently used to stimulate investment in R&D, require resource-intensive interventions, either through the provision of advanced funding or other types of administrative resources, or both.

Building on this analytical framework, the Article offers a novel insight: the market-based characteristics of tax incentives make the tax system especially well-suited to address underinvestment in pharmaceutical innovation, particularly in the field of vaccine research. Based on this insight, we develop here a proposal for tax policy that spurs research in vaccines for emerging infectious diseases before outbreaks occur in a more simplified, administrative, and efficient manner than current policy tools. Our proposal provides R&D support in a predictable, streamlined fashion thus minimizing investment risk in uncertain vaccine development processes. It further illustrates how the tax system can be used as an effective tool for equitable distribution of the cost of developing vaccines for emerging diseases, which to date has never been fully explored. Our proposal starts that conversation by offering a blueprint for possible interventions in other traditionally underfunded areas.

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For helpful comments and suggestions, we thank Yonathan Arbel, Ilan Ben-Shalom, Michael Birenhack, William S. Brewbaker III, Shahar Dillbary, Brian Galle, Daniel Hemel, Michael Madison, Jacob Nussim, Peter Oh, Henry Ordower, Lisa Ouellette, Gideon Parchomovsky, W. Nicholson Price II, Rachel Sachs, Stephen Shay, and Alex Raskolnikov. All errors remain our own.

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I. INTRODUCTION

The COVID-19 pandemic has shed renewed critical light on the need for sustained development of vaccines and drugs, which are crucial to prevent, respond to, and attenuate the effects of large-scale public health crises. As the world accompanies the coronavirus vaccine race,¹ as well as the development of COVID-19 therapeutics candidates like the drug remdesivir,² the limitations of current incentives models in biopharmaceutical innovation become readily apparent.

Preventing and preparing for outbreaks of infectious diseases is critical in maintaining health and economic wellbeing. From the Measles outbreaks in the state of New York in 2019 to transnational outbreaks such as Zika in 2015-16 and, more recently, COVID-19—there is a clear need for sustaining a pre-existing R&D infrastructure of some magnitude. In particular, public health preparedness requires robust investment in vaccine R&D, as well as in drugs targeting pathogens often associated with emerging,³ lesser-known⁴ or “non-mainstream”⁵ diseases.

In spite of their considerable public health value and relative cost-effectiveness,⁶ R&D in many of the vaccines and drugs needed before an outbreak occurs—or as one unfolds—is often

¹ See e.g. Andy Ridgway, *Coronavirus Vaccine: The Race to Create a Cure for COVID-19*, SCI. FOCUS (May 27, 2020), <https://www.sciencefocus.com/the-human-body/coronavirus-vaccine-the-race-to-create-a-cure-for-covid-19/>

² See John H. Beigel et al., *Remdesivir for the Treatment of Covid-19 — Preliminary Report*, N. ENGL. J. MED (May 22, 2020), <https://www.nejm.org/doi/full/10.1056/NEJMoa2007764>. See also *infra*, XX.

³ This is the case of COVID-19, the disease caused by a pathogen in the coronavirus family known as SARS-CoV-2. Prior to late 2019, the scientific community was familiar with SARS-CoV (commonly known as SARS), which was first identified in 2003, but not with SARS-CoV-2.

⁴ This is the case of Zika, which was identified for the first time in 1947, but it was not until the 2015-16 outbreak that some of the most of severe effects of Zika infection were reported.

⁵ This is the case of different types of diseases, including the group known as “neglected tropical diseases,” traditionally endemic to the Global South and which have traditionally failed to attract sizable R&D interest, partly due to profitability concerns on the part of R&D players whose business model relies primarily on return-on-investment approaches.

⁶ See *infra*, Part II.C.

intermittent, underfunded or outright non-existent.⁷ In the aftermath of the 2014-16 Ebola outbreak, the World Health Organization characterized the infectious disease R&D status quo as one of lacking preparedness.⁸ In this work, we focus on an overlooked legal and policy lever as a potential catalyst for investment on R&D targeting these traditionally underfunded diseases—the tax system.

Typically, the patent system is regarded as the default placement in the legal system for incentives to investment in risky and resource-intensive research endeavors. Non-patent incentives, such as grants, prizes or insurance reimbursement (funded by tax revenues), have progressively been recognized as important complementary tools in innovation policy. While acknowledged by commentators,⁹ tax law and policy remain nonetheless largely underexplored as meaningful levers in innovation policy. In this Article, we argue that robust innovation policies should make further use of the tax system—not only as a source of revenue—but also as an incentive mechanism that can be implemented efficiently and at minimal cost to participants. Simply put, tax incentives provide capital-constrained private market players with instant *ex ante* rewards without needing to take extra steps extrinsic to conducting R&D in predesignated areas.

We further note that the characteristics of tax-based incentives—chief among which their mobilization of private-sector players through flexible commitment of their economic resources—render them especially well-suited as catalyzers of private investment in traditionally underfunded areas. One of the most prominent of these areas is pharmaceutical R&D on emerging infectious diseases—a group of diseases that includes COVID-19, Zika and Ebola, as well as many of the pathogens that experts predict will cause significant worldwide outbreaks in the near future.¹⁰ Pharmaceutical R&D as a whole has long been known for being capital- and risk-intensive.¹¹ Thus, innovators in this space have long relied on patent incentives combined with broad extra-patent sources of funding.¹² Segments of the pharmaceutical R&D universe, however, have remained chronically underfunded, to the detriment of social welfare as public health is a social good.¹³ For reasons we detail below,¹⁴ the development of vaccines targeting emerging pathogens has long fallen in this category.¹⁵

⁷ See generally Massinissa Si Mehand et al., *The WHO R&D Blueprint: 2018 Review of Emerging Infectious Diseases Requiring Urgent Research and Development Efforts*, 159 ANTIVIRAL RESEARCH 63 (2018), <https://www.sciencedirect.com/science/article/pii/S0166354218305643>

⁸ See Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200 (2018).

⁹ See Hemel & Ouellette, *infra* note 26.

¹⁰ See WORLD HEALTH ORG., AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS (2016), at 6, https://www.who.int/blueprint/about/r_d_blueprint_plan_of_action.pdf?ua=1 (listing emerging infectious “diseases to be urgently addressed”).

¹¹ See, e.g., Tohru Takebe, Ryoka Imai, & Shunsuke Ono, *The Current Status of Drug Discovery and Development as Originated in United States Academia: The Influence of Industrial and Academic Collaboration on Drug Discovery and Development*, 11 CLIN TRANSL SCI. 597, 600 (2018) (reporting success rates of academic drug discovery during clinical trials of 19.3% and industry’s success rates of 9.6%).

¹² See *infra*, Part II.B.

¹³ See WORLD HEALTH ORG., *supra* note 10 (noting a “lack of R&D preparedness” for emerging infectious diseases likely to translate into elevated public health costs).

¹⁴ See *infra*, Part II.C.

¹⁵ See Matthew D. Adler and Eric A. Posner, *Rethinking Cost-Benefit Analysis*, 109 YALE L.J. 165, 188 (1999) (using the example of a vaccine that improved the health of millions of people as a desirable project approved under an uncontroversial social welfare function even if it violates Pareto standard). See also Richard A. Epstein, *In Defense of the “Old” Public Health: The Legal Framework for the Regulation of Public Health*, 69 BROOKLYN L. REV. 1421, 1425-1426 (2004) (defining the theory of public health as tracking the economic conception of public goods, i.e. nonexcludable goods that cannot be given to one unless they are

Using the case study of vaccine development as the paramount example of an area of pharmaceutical R&D in dire need of greater support, we show how developing a technology-specific approach to tax incentives—in this case, tailored to vaccine R&D—is beneficial from an innovation policy and a public health perspective. At the same time, our case study of vaccine research illustrates how the larger prescriptive takeaway of the Article—the need to better design and adopt heterogeneous and pliable forms of tax-based incentives—can be incorporated into the legal system in simplified ways that ensure efficiency and administrability.

The Article proceeds as follows. Following this Introduction, Part II begins by diagnosing structural misalignments between current R&D incentives frameworks—developed mainly through intellectual property (IP) channels—pertaining to socially valuable public goods. This misalignment is especially pronounced in the field of pharmaceutical innovation, and in particular with regard to drugs and vaccines needed for pandemic and epidemic preparedness. Even though these drugs and vaccines offer considerable public health value, underlying R&D is often intermittent, underfunded, or outright non-existent.

Part III discusses non-IP incentives frameworks to promote investment in the vaccine R&D context by surveying current uses of grants, prizes, and other types of incentives. It then shows that tax policy remains consistently underused as a locus for providing incentives to vaccine R&D. We argue that, from an economic efficiency and distributional justice points of view, governments ought to better utilize tax policy to be able to spread the cost of vaccine R&D on all taxpayers rather than the few who might be willing to pay for it. Moreover, this Part demonstrates that properly employing the tax system as part of the fora of innovation policies not only provides superior cost distribution but can also help legislatures with limited information, skills, or capacity to evaluate pharmaceutical innovation and create ripe conditions for preparedness.

Part IV outlines the current universe of tax incentives for domestic innovation, as well as their operation and flaws in the pharmaceutical context. It focuses on five main apparatuses: Immediate R&D Expensing, Research and Experimentation Credit, Orphan Drug Credit, Therapeutic Discovery Project Credit, and Patent Donations. This Part further demonstrates that the current tax system nudges market players away from vaccine research and towards ordinary drug development and mainstream innovation projects. Thereafter, Part V suggests a new framework to better design current tax policy to accommodate vaccine R&D. It proposes a tiered system of refundable mechanisms and complementing routes that prioritize qualified vaccine discovery projects designated by a special health advisory committee. After surveying the potential problems involving such tax routes including abuse and gamesmanship, complexity, and public choice opportunities, the Article demonstrates that our proposed scheme can tackle such issues in a simpler, more equitable and administrable manner.

The Article concludes that the tax system can and should be employed more efficiently to deliver a supporting framework for research and experimentation of viruses and diseases prior to their outbreak. The effectiveness of tax incentives in the vaccine case study lies in their operation *ex ante* and throughout the R&D process while maintaining the independence of market players subject-matter decisions. Tax-based incentives leave major decisions to private parties—making the tax system largely a market-based policy lever—such as a high degree of freedom to choose

also given to another. Public bads, on the other hand, are inflicted upon others without their consent, as are communicable diseases and pollution).

the nature and priority given to each R&D study, the distribution of resources to each experiment, and the desired level of reward for it. Lastly, designed properly, tax incentives can provide innovators utmost flexibility and ways to overcome insurmountable capital constraints and risk-aversion when pursuing new vaccine technology research. They can provide an effective way to receive rewards from society in an early and less uncertain manner rather than waiting to see whether substantial R&D investments in vaccine development, testing, and multiple clinical trials phases ultimately yield successful results and positive private returns.

Establishing tax incentives tailored specifically to vaccines for emerging infectious diseases—such as COVID-19, Zika and Ebola—can bolster much needed vaccine preparedness before outbreaks occur. To date, no work has fully explored how the tax system can be used effectively as a tool to facilitate equitable distribution of the cost of developing drugs and vaccines for emerging diseases. This Article initiates the discussion around optimal design of vaccine R&D incentives and the distribution of their cost. At the same time, we hope to provide a broader blueprint for future work on possible interventions in other traditionally underfunded areas in the environmental, energy and health spaces.

II. A PATENT REGIME TO INCENTIVIZE INNOVATION

A. The Patent System as Catalyst to R&D

The question of how to best promote investment in high-cost, high-risk areas of science and technology has long been debated among scholars and policymakers.¹⁶ These discussions are fueled, at a least to a certain extent, by the concern that some types of goods, albeit welfare-enhancing, might fail to attract sufficient funding and R&D interest from the private sector, while at the same, the public sector alone cannot see them through from early research stages to manufacturing and commercialization.¹⁷

Without a mechanism that counterbalances heightened risk (real or perceived) associated with R&D processes, as Kenneth Arrow has explained, private companies are likely to invest less than is socially optimal in risky endeavors such as invention and research because they cannot fully appropriate the benefits of the product of R&D and because of increasing returns in use.¹⁸ Such unwillingness or inability to bear risks “will give rise to a nonoptimal allocation of resources, in that there will be discrimination against risky enterprises as compared with the optimum”.¹⁹

¹⁶ See, generally FRANK H. KNIGHT, *RISK, UNCERTAINTY, AND PROFIT* 41 (Dover ed. 2006)) (discussing the nature of risk involved in discovering innovation); Joseph A. Schumpeter, *Economic Theory and Entrepreneurial History* (1949), reprinted in *ESSAYS ON ENTREPRENEURS, INNOVATORS, BUSINESS CYCLES, AND THE EVOLUTION OF CAPITALISM* 74 (Richard V. Clemence ed., 1989) (detailing the risks and rewards of innovation); Wesley M. Cohen & Richard C. Levin, *Empirical Studies of Innovation and Market Structure*, in 2 *HANDBOOK OF INDUSTRIAL ORGANIZATION* 1059, 1067 (Richard Schmalensee & Robert D. Willig eds., 1989) (noting the nature of R&D with high risk and long progression); Kenneth Kelly, *The Role of Risk Aversion in the Allocation of Resources to Invention*, NBER Paper, Mar. 1982, <https://www.ftc.gov/system/files/documents/reports/role-risk-aversion-allocation-resources-invention/wp051.pdf> (debating the different views on underinvestment in innovation).

¹⁷ Because they are knowledge-intensive, these goods are often described as non-rivalrous and non-excludable. Non-rivalrous goods can be consumed by multiple users without a reduction in their quantity or quality. Users of non-excludable goods are unable to prevent others from using the same good, absent some intervention designed to eliminate or limit non-excludability, such as the imposition of intellectual property rights. See Joseph Stiglitz, *Knowledge as a Public Good*, in *GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY* (INGE KAUL ET AL., EDS.) (1999).

¹⁸ Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 619 (RICHARD NELSON ED., 1962). But see Jack Hirshleifer, *The Private and Social Value of Information*, 61 *AM. ECON. REV.* 561, 562 (1971) (arguing that the private value of an invention can exceed its social value, leading to an overinvestment in research.)

¹⁹ Arrow, *supra* note 18, at 609.

Against this background, patent systems are viewed primarily as a way to cure market failures of underinvestment in technical and scientific areas.²⁰ Absent patent protection, scholars noted the price of products will be reduced to the marginal cost of copying deterring future investment in developing innovation.²¹ The dominant worldview depicts patents as incentives mechanisms designed to promote investment in areas that might remain underfunded absent the conferral of a legal right that enables the patent holder to enjoy some form of market exclusivity for a certain period of time.²²

According to this narrative, both the main function and justification for the existence of the modern patent system is to tend to problems related to market prospectivity: a would-be investor might shy away from allocating resources to a particular research and development (R&D) project if the anticipated market for an invention is not deemed large or profitable enough to recoup R&D costs and/or turn a profit. Under this logic, patents become especially relevant as catalysts to R&D when there is a misalignment between the value and the cost of socially desirable goods. As further detailed in the next Part, commentators often point out that nowhere is this misalignment more evident than in the case of pharmaceutical and biopharmaceutical innovation.²³ While the development of new preventatives and treatments is of strategic importance from a scientific and public health point of view, a host of other factors render—according to these patent narratives—investments in these socially valuable goods especially risky: high R&D costs, lengthy R&D timelines, scientific complexity and associated risk of failure, cost of regulatory review and, in some cases, potentially limited patient populations indicated for a particular drug.

²⁰ We employ the expression “market failure” in this Article to refer to situations in which certain types of inefficiencies lead to sub-optimal investment in R&D on socially valuable goods. See generally WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 37-40 (2003) (discussing the economic theory underlying patents and the risk of underinvestment as prices reduced to marginal cost of copying). See also Madhavi Sunder, *IP3*, 59 STAN. L. REV. 257, 283 (2006) (noting “market failure is cited as the *raison d’être* for intellectual property, explaining copyright, patent, and even trademark.”). But see Robert P. Merges, *The End of Friction? Property Rights and Contract in the “Newtonian” World of On-Line Commerce*, 12 BERKELEY TECH. L.J. 115, 134 (1997) (arguing the future fair use “will revolve less around market failure, and more around the idea of favoring certain classes of users with a statutory privilege”).

²¹ Gideon Parchomovsky & Peter Siegelman, *Towards an Integrated Theory of Intellectual Property*, 88 VA. L. REV. 1455, 1506 (2002) (stating “in a competitive market the price will be driven down to the marginal cost of copying.”). See also Brett M. Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347, 349 (2000) (determining innovation is a public good that acts as an input for producing a wide range of dependent goods and that various forms of innovation market failure arise, thus certain institutions are better suited for correcting certain forms of innovation market failure.).

²² See e.g. ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* (6TH ED. 2012); WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* (2003).

²³ The word “pharmaceutical” is used in different contexts, but primarily refers to products meeting colloquial, scientific and regulatory definitions of “medicines and drugs.” See WORLD HEALTH ORG., *PHARMACEUTICAL PRODUCTS*, https://www.who.int/topics/pharmaceutical_products/en/. “Biopharmaceutical” refers to a subset of drug or pharmaceutical products, comprised of drugs or other products made of living components and structurally complex, such as biologicals (e.g. many of the drugs used in the treatment of auto-immune or oncology conditions, as well as vaccines). Because this Article focuses primarily on problems arising in the vaccine R&D space—most existing vaccines belonging to the category of biological products—we employ the word “pharmaceutical” when referring to the drug industry at large, and “biopharmaceutical” when discussing vaccine-specific issues or other topics related to complex drugs. See U.S. FOOD & DRUG ADMIN., *VACCINES, BLOOD & BIOLOGICS*, <https://www.fda.gov/vaccines-blood-biologics> (providing an overview of biologics for regulatory purposes).

Predominant economic narratives of intellectual property²⁴ as a system of incentives indispensable to innovation have been gradually nuanced in scholarly literature and commentary.²⁵ And while the catalyzing function of intellectual property still drives many discourses in law- and policymaking milieus, it is now widely acknowledged that incentives located outside the patent and intellectual property ecosystem are necessary to ensure a robust and multi-layered innovation policies due to the failure of patents alone in providing robust incentives for technological advancements in capital and process-intensive areas such as pharmaceutical discoveries as will be explained next.²⁶

B. The Incentives Premise Applied to Pharmaceutical Innovation

Pharmaceutical markets have long been considered as one of the areas of prime application of patent-as-incentives theory.²⁷ Taken as a whole, pharmaceutical R&D tends to occur over timelines that are on average considerably longer than in other areas;²⁸ scientific complexity and uncertainty often renders R&D processes unpredictable, increasing the risk of failure;²⁹ and the industry is heavily regulated, a phenomenon which—while not exclusive to the pharmaceutical industry—further increases the cost of R&D.³⁰ As such, the risk of market failure—in the form of

²⁴ See e.g. LANDES & POSNER, *supra* note 20, at 38; Paul J. Heald, *A Transaction Costs Theory of Patent Law*, 66 OHIO ST. L.J. 473 (2005); WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (1969).

²⁵ See e.g. ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY (2011); Rochelle Cooper Dreyfuss, *Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm*, 31 CARDOZO L. REV. 1437 (2010) (exploring the concept of “IP without IP” introduced by Mario Biagioli); Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017) (describing vaccine R&D processes that do not rely predominantly on IP frameworks); Adam Mossoff, *Who Cares What Thomas Jefferson Thought about Patents - Reevaluating the Patent Privilege in Historical Context*, 92 CORNELL L. REV. 953, 955, 960-963 (2007) (explaining how Jefferson’s intellectual property worldview has exerted a strong influence in American jurisprudence, and tracing Jefferson-centric narratives of patent law to the Supreme Court’s decision in *Graham v. John Deere Co.*, 383 U.S. 1 (1966); Benjamin N. Roin, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007 (2005) (analyzing justifications for the patent system rooted in the disclosure of information in exchange for a bundle of exclusionary rights); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007) (noting the existence of additional incentives mechanisms elsewhere in the regulatory apparatus and the particular role of the Food and Drug Administration as a catalyst for R&D in the pharmaceutical space). See also Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129 (2004) (critiquing the emergence of a particular strand of justifications for intellectual property, known as ex post justifications, and which are based on efficient management frameworks and/or the goal of limiting overuse of information).

²⁶ *Infra*, Part IV. See also generally Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L. J. 544 (2019).

²⁷ Patent systems across the world have been further tailored in the field of biotechnology. See e.g. Dan L. Burk, *Biotechnology in the Federal Circuit: A Clockwork Lemon*, 46 ARIZ. L. REV. 441 (2004) (criticizing the Federal Circuit’s application of patent law to biotechnology cases); Ana Nordberg, *Economic Justification of Patents and Exceptions to Patentability*, 3 NORDIC INTELL. PROP. L. REV. 316 (2012) (examining economic justification for “the existence of a different patentability regime for inventions relating to methods for treatment and diagnostic methods.”)

²⁸ For instance, in the case of vaccines, the complete R&D arc lasts, on average, over a decade. See e.g. INT’L FEDERATION PHARMA. MANUFACTURERS & ASS’N., THE COMPLEX JOURNEY OF A VACCINE (2019), https://www.ifpma.org/wp-content/uploads/2019/07/IFPMA-ComplexJourney-2019_FINAL.pdf; U.S. CTRS. DISEASE CONTROL & PREVENTION, VACCINE TESTING AND THE APPROVAL PROCESS (2014), <https://www.cdc.gov/vaccines/basics/test-approve.html> (describing the stages of vaccine development and regulatory review and approval).

²⁹ See e.g. Petra Oyston & Karen Robinson, *The Current Challenges for Vaccine Development*, 61 J. MED. MICROBIOLOGY (2012), https://www.microbiologyresearch.org/docserver/fulltext/jmm/61/7/889_jmm039180.pdf?expires=1592349082&id=id&acname=guest&checksum=CFB0A39DA971F72C04EABE549E6DD5F0 (listing both scientific and financial challenges associated with vaccine development).

³⁰ U.S. FOOD & DRUG ADMIN., LAWS, REGULATIONS, POLICIES AND PROCEDURES FOR DRUG APPLICATIONS (2014), <https://www.fda.gov/drugs/development-approval-process-drugs/laws-regulations-policies-and-procedures-drug-applications>; *Id.*, DEVELOPMENT & APPROVAL PROCESS (CBER) (2019), <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber> (collectively providing an overview of the regulatory review and approval process to which different types of pharmaceutical drugs are subjected before entering the market).

underinvestment in socially beneficial R&D—is often depicted as heightened in connection with pharmaceutical products than elsewhere in the innovation ecosystem.³¹

While incentives problems in the pharmaceutical arena are sometimes instrumental to justifying the conferral of excessive supra-competitive benefits to the industry—including lax price controls in the United States market³² or cumulative protections within the regulatory apparatus³³— in this Article we rely on existing literature and policy that is grounded in the possibility (and reality) of market failure in pharmaceutical R&D hold true, triggering underinvestment and other detrimental consequences to public health.³⁴

Certain types of diseases with small, seasonal or otherwise temporally limited markets have long been known not to attract sustained R&D interest and funding from the private sector, often relying on support for basic research from the public sector, philanthropic funding, or a combination thereof.³⁵ Examples of these diseases include orphan diseases, which in the United States defined as affecting fewer than 200,000 patients and include Gehrig's disease, Tourette's and rare childhood cancers;³⁶ neglected tropical diseases, and communicable diseases prevalent in tropical and sub-tropical climates, which include Chagas disease and Leishmaniasis.³⁷ Many vaccine-preventable infectious diseases either overlap with or share many of the market characteristics of the previous categories, as further described in the following section.³⁸

These types of diseases are characterized by markets where the misalignment between patent incentives to R&D and public health goals is often apparent, with very few players willing to engage in R&D,³⁹ absent a catalyst such as a pandemic. In order to mitigate some of the market failures traditionally felt in these areas, many commentators and policymakers have focused on other approaches to promoting innovation that rely on non-IP incentives as a complement to existing patent frameworks.⁴⁰

³¹ For studies on the success rate of pharmaceutical drug discovery see *supra* note 11 and accompanying text. See generally, Eisenberg, *supra* note 25, at 370 (2007) (stating the government resolves several market failures and preserving the value for drug companies); Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 MICH. TELECOMM. & TECH. L. REV. 1, 7 (2007) (noting regulation spurs innovation by maintaining the value of new drugs.).

³² See, e.g., Irl B. Hirsch, *Insulin in America: A Right or a Privilege?* 29 DIABETES SPECTR. 130 (2016) (describing insulin prices as skyrocketing in the last decade to the point that patients have been having difficulty affording insulin.).

³³ See *infra* note 123 and accompanying text.

³⁴ See *infra* note 41 and accompanying text.

³⁵ Rutschman, *IP Preparedness*, *supra* note 8, at 1225 (exploring the temporal limitations of vaccine markets for certain infectious diseases).

³⁶ U.S. FOOD & DRUG ADMIN., RARE DISEASES AT FDA (2020), <https://www.fda.gov/patients/rare-diseases-fda>; ID., ORPHAN PRODUCTS: HOPE FOR PEOPLE WITH RARE DISEASES (2018), <https://www.fda.gov/drugs/drug-information-consumers/orphan-products-hope-people-rare-diseases>

³⁷ WORLD HEALTH ORG., NEGLECTED TROPICAL DISEASES, https://www.who.int/neglected_diseases/diseases/en/; U.S. CTRS. DISEASE CONTROL & PREVENTION, NEGLECTED TROPICAL DISEASES (2020), <https://www.cdc.gov/globalhealth/ntd/diseases/index.html>

³⁸ Rutschman, *IP Preparedness*, *supra* note 8, at 1224-44 (describing the specificities of vaccine R&D surrounding Ebola and Zika). Other areas traditionally prone to R&D market failures include antimicrobial resistance. See e.g., Aaron Kesselheim & See Kevin Outterson, 11 YALE J. HEALTH POL'Y, L. & ETHICS (2011); Kevin Outterson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Global Public Health*, 67 U. PITT. L. REV. 67 (2005).XXX.

³⁹ Ana Santos Rutschman, *The Vaccine Race in the Twenty-First Century*, 61 ARIZ. L. REV. 729, 740-41 (2019) (describing vaccine manufacturer attrition from the mid-twentieth century onwards).

⁴⁰ See Adrian Towse & Hannah Kettler, *A Review of IP and Non-IP Incentives for R&D for Diseases of Poverty. What Type of Innovation is Required and How Can We Incentivize the Private Sector to Deliver It?*, FINAL REPORT FOR THE WHO COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH (2005), <https://www.who.int/intellectualproperty/studies/A.Towse.pdf?ua=1>; See e.g. Aaron S. Kesselheim & Kevin Outterson, *Fighting Antibiotic Resistance: Marrying New Financial Incentives to Meeting Public Health Goals*, 29 HEALTH AFF. 1689 (2010).

C. Limitations of IP Incentives Frameworks: The Case of Vaccines

From a market-driven perspective, vaccines—or, more precisely, vaccine technology taken as a whole—are often considered more prone to market failures for being one of the least appealing areas for investment.⁴¹ From the viewpoint of funders and R&D players motivated strictly or primarily by economic considerations, the prospects of return-on-investment tend to be considerably less substantial in the area of vaccines than they are for other types of pharmaceutical innovations.

Unlike existing blockbuster drugs⁴² or drugs treating mainstream diseases such as heart or autoimmune conditions,⁴³ vaccines have several features that inherently hamper commercialization and restrict possibilities of monetization. First, they are primarily deployed to prevent a transmittable disease—a positive outcome in public health terms, but one whose demonstrability and economic impact is much harder to assess, as well as to reconcile with squarely for-profit business models.⁴⁴ As opposed to vaccines, drug treatments are often sold after the firm has already obtained ample information on the probability of contracting the disease.⁴⁵ Second, unlike drugs consumed over long periods of time or in multiple doses, vaccines as a matter of fact cannot attract repeat consumers: one dose is frequently enough to generate long-term immunity,⁴⁶ and even when booster doses are required, they are still few and far between.⁴⁷ Once vaccines become widely used and prevent the spread of the disease they reduce demand for the product along with revenue breakdown.⁴⁸ Lastly, although it is socially preferable to prevent epidemic, like the Covid-19 we have been witnessing some people choosing, depending on their health situation, social exposure, and severity of the disease, to forgo vaccination as part of anti-vaccine ideology.⁴⁹ In recent years, we observe anti-vaccination movement of individuals choosing

⁴¹ Michael Kremer & Christopher M. Snyder, *Why Are Drugs More Profitable Than Vaccines?* NBER Working Paper 9833, <http://www.nber.org/papers/w9833> (analyzing that while vaccines and drug treatments should yield the same revenues, their model is more realistically proving revenue equivalence breaks down for more symmetric information on demand in the case of drugs than vaccines).

⁴² Rutschman, *IP Preparedness*, at 1207-1213.

⁴³ We employ the term “mainstream” to refer to non-rare diseases. Drugs treating mainstream diseases and generating over \$1 billion in revenue in a single year are known as “blockbuster drugs.” Examples of these drugs include Lipitor, which lowers cholesterol in blood, and Humira, which treats a range of auto-immune conditions. See e.g. Laura, *Pfizer’s Lipitor: The Blockbuster Drug That Almost Wasn’t*, HUFF. POST (Dec. 30, 2011), https://www.huffpost.com/entry/pfizers-lipitor-the-block_n_1176252; Alex Keown, *AbbVie Strikes Deal: Blockbuster Humira is Safe Until 2023*, BIOSPACE (Apr. 5, 2018), <https://www.biospace.com/article/abbvie-strikes-deal-with-biogen-blockbuster-humira-is-safe/>.

⁴⁴ See Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. ONLINE 170, 173 (2020). See also Liza Vertinsky et al., *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, ____ (2020).

⁴⁵ Kremer & Snyder, *supra* note 41, at 5.

⁴⁶ A few vaccines require repeat or boost dosages due the need to keep up with rapidly adapting viruses to new strands such as Influenza (yearly) or vaccines whose effectiveness wanes over time such as Tetanus (boost every decade). See U.S. CTRS. DISEASE CONTROL & PREVENTION, WHAT VACCINES ARE RECOMMENDED FOR YOU (2019), <https://www.cdc.gov/vaccines/adults/rec-vac/index.html> (listing recommend vaccines by age group, including vaccines that do not require booster doses). See also Elizabeth Cooney, *Most Adults Don’t Need Booster Vaccinations for Tetanus and Diphtheria*, New Study Concludes, STAT (Feb. 25, 2020), <https://www.statnews.com/2020/02/25/adults-dont-need-booster-vaccinations-for-tetanus-diphtheria-study/>; *Tetanus Shots Needed Every 30 Years, Not Every 10, Say Researchers*, SCI. DAILY (Mar. 22, 2016), <https://www.sciencedaily.com/releases/2016/03/160322133817.htm>

⁴⁷ Rutschman, *The Intellectual Property of Vaccines*, *supra* note 44, at 173-174.

⁴⁸ Kremer & Snyder, *supra* note 41, at 14.

⁴⁹ See Donya Khalili & Arthur Caplan, *Off the Grid: Vaccinations Among Homeschooled Children*, 35 J.L. MED. & ETHICS 471, 471 (2007) (discussing the phenomenon in homeschooled children).

the risk of catching a disease over vaccinating themselves or their children.⁵⁰ They prefer to rely on their immune system—some may say free-ride others’ via herd-immunity— rather than paying the price (monetary and other) of vaccination.⁵¹

These characteristics do not exist in ordinary drugs for diseases that can reoccur or do not infect others, and as such, make most vaccines relatively unprofitable—and in some cases, as described below, outright money-losers.⁵² The world’s best-selling vaccine, known as Prevnar 13 targeting pneumococcal disease,⁵³ generated \$5.69 billion in revenue in the United States in 2017, a number that is projected to increase modestly by 2024 to \$5.76 million.⁵⁴ Gardasil, a vaccine targeting the human papillomavirus (HPV),⁵⁵ came in second in the United States market at \$2.38 billion in 2017, with a projection of \$3.28 billion for 2024.⁵⁶ The fourth and fifth best-selling vaccines in 2017 were already under the \$2 billion threshold.⁵⁷ These numbers pertain to the world’s largest vaccine market, which registered an overall \$27.7 billion in vaccine sales in 2017.⁵⁸ Smaller markets in the developed world, by contrast, typically register numbers in the single digits: in Germany, for example, sales of vaccines generated around \$3 billion in 2017.⁵⁹

While in absolute terms these numbers are significant, contrasting them with revenues generated by non-vaccine products puts the vaccine revenue ecosystem in perspective: during the same year (2017), the largest-grossing drug in the United States market (Humira) generated \$18.43 billion in revenue, while the second and third best-selling drugs brought in \$18.23 billion and \$8.19 billion, respectively.⁶⁰ All top-ten best-selling drugs registered over \$6 billion in sales individually.⁶¹ Accordingly, the National Academy of Sciences has reported radical changes over the last few decades in the vaccine supply system. While more than 25 private firms produced vaccines for the U.S. market in the last 30 years, currently only 5 companies produce all routinely recommended vaccines.⁶²

It is also important to note that the majority of vaccines commercially available today generate significant lower revenues than the best-selling vaccines alluded to above. Public health

⁵⁰ See, e.g., Joanna B. Apolinsky and Jeffrey A. Van Datta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J. L. & PUB. POL’Y 537, 543 (2010) (discussing the roots of the anti-vaccine movement opposing compulsory vaccination on grounds of personal autonomy as well as fear of injury).

⁵¹ Hillel Y. Levin, Stacie Patrice Kershner, Timothy D. Lytton, Daniel Salmon, & Saad B. Omer, *Stopping the Resurgence of Vaccine-Preventable Childhood Diseases: Policy, Politics, and Law*, 20 U. ILL. L. REV. 233, 245 (2020) (“some may argue that the burden of maintaining community immunity should be borne by all people in society equally, especially since those who choose not to vaccinate free-ride on those who do, through the protections afforded by community immunity.”).

⁵² See *infra* note 69 and accompanying text.

⁵³ U.S. CTRS. DISEASE CONTROL & PREVENTION, PNEUMOCOCCAL CONJUGATE (PCV13) VIS (2019), <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/pcv13.html>

⁵⁴ Matej Mikulic, *Top 5 Global Vaccine Products Based on Revenue in 2017 and 2024*, STATISTA (Jul. 22, 2019), <https://www.statista.com/statistics/314566/leading-global-vaccine-products-by-revenue/>

⁵⁵ U.S. CTRS. DISEASE CONTROL & PREVENTION, HUMAN PAPILLOMAVIRUS (HPV) VACCINE (2019), <https://www.cdc.gov/vaccinesafety/vaccines/hpv-vaccine.html>

⁵⁶ Mikulic, *supra* note 54.

⁵⁷ *Id.*, *ib.*

⁵⁸ *Id.*, *ib.*

⁵⁹ *Id.*, *ib.*

⁶⁰ Mark Terry, *Drum Roll, Please! Top 10 Bestselling Drugs in the U.S.*, BIOSPACE (May 21, 2028), <https://www.biospace.com/article/drumroll-please-top-10-bestselling-drugs-in-the-u-s-/>. See also Ana Santos Rutschman, *Regulatory Malfunctions in the Drug Patent Ecosystem*, 70 EMORY L. J. ____ (2020) (explaining how the biologic drug Humira has continued to be commercialized under monopolistic market conditions in the United States, even though Humira’s patent estate began disintegrating in 2016).

⁶¹ See Terry, *supra* note 60.

⁶² INSTITUTE OF MEDICINE, FINANCING VACCINES IN THE 21ST CENTURY: ASSURING ACCESS AND AVAILABILITY 1 (Nat’l Academies Press, 2004) <https://www.ncbi.nlm.nih.gov/books/NBK221816/> (reporting severe erosion in the private vaccine supply system).

authorities, in consultation with scientific experts, issue timelines for recommended vaccination such as the schedules issued by the Centers for Disease Control and Prevention (“CDC”) in the United States.⁶³ Vaccines listed in these official vaccination schedules enjoy relatively stable markets, with predictable and sustained demand over time. Nevertheless, even these routinely scheduled vaccines enjoy modest economic returns within the pharmaceutical universe. Vaccines that are not listed as routine immunizations in the official childhood and adult schedules tend to fare even worse in terms of market performance.⁶⁴ This is the case of vaccines needed when there is an outbreak of infectious diseases that are (or used to be) infrequent in countries in the Global North, such as the Ebola outbreak in 2014-16 and the Zika outbreak in 2015-16.⁶⁵ In both cases, the technology needed to produce vaccine candidates had already been developed or was easily (and inexpensively) adaptable from pre-existing vaccines in the same viral family.⁶⁶ And yet, before the outbreak suddenly and temporarily spiked demand for these vaccines, R&D on these vaccines had come to a standstill.⁶⁷ In the case of the Ebola outbreak, the vaccine candidate literally “sat on a shelf” in the years leading up to the outbreak, failing to attract interest from the private sector.⁶⁸

Following these outbreaks, and in response to a widely recognized lack of sufficient levels of R&D in the vaccine space, the first international public-private partnership dedicated to support vaccine R&D in especially underfunded areas—the Coalition for Epidemic Preparedness Innovations or CEPI—emerged.⁶⁹ CEPI’s preliminary business plan, drafted the year before the partnership was launched, clearly stated that the vaccines for which CEPI would be providing funding were not expected to turn a significant profit.⁷⁰

The specific characteristics of vaccines as commodified goods—in particular the limited number of potential users and uses—make patents a poor default system of incentives to R&D in this area. The dynamics of vaccine R&D models structured around IP incentives are thus often in tension with public health imperatives, which prescribe preparedness and affordability through a robust and continuous R&D.

Moreover, and considering that vaccines are consensually regarded as one of the most cost-effective means of preventing a disease and lessening its burden, underinvestment in vaccine R&D also produces significant undesirable economic effects. Lacking or insufficient vaccine R&D is

⁶³ U.S. CTRS. DISEASE CONTROL & PREVENTION, IMMUNIZATION SCHEDULES (2020), <https://www.cdc.gov/vaccines/schedules/index.html>

⁶⁴ See Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, TEXAS A&M U. J. PROP. L. (forthcoming 2020), draft available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3590912.

⁶⁵ See generally Rutschman, *IP Preparedness*, *supra* note 8.

⁶⁶ *Id.*, at 1224-43.

⁶⁷ See Denise Grady, *Ebola Vaccine, Ready for Test, Sat on the Shelf*, N.Y. TIMES (Oct. 23, 2014), <https://www.nytimes.com/2014/10/24/health/without-lucrative-market-potential-ebola-vaccine-was-shelved-for-years.html>

⁶⁸ Rutschman, *IP Preparedness*, *supra* note 8, at 1221.

⁶⁹ CEPI, OUR MISSION, <https://cepi.net/about/whyweexist/>. See also Rutschman, *The Intellectual Property of Vaccines*, *supra* note 44.

⁷⁰ CEPI, PRELIMINARY BUSINESS PLAN, 2017-2021 (November 2016), (on file with author), at 12 (further establishing that “[i]n the event that a vaccine developed with CEPI support does develop economic value, agreements between CEPI and the vaccine developer will ensure either that CEPI’s investment is reimbursed or that the economic value is shared through royalties or other risk sharing agreements.”).

bound to result in (temporally delayed) costs to health systems dealing with outbreaks of vaccine-preventable diseases while slowing economic growth and upsetting employment.⁷¹

The patent system, in its transversal and largely technology-agnostic architecture,⁷² has so far proved a poor catalyst for vaccine R&D, especially in the case of neglected or orphan diseases.⁷³ As such, predominant R&D models, which remain patent-centric,⁷⁴ have historically led to a scenario of pronounced underinvestment in the development of new vaccines.⁷⁵ This is true even in cases in which the technology needed to produce new vaccines is largely pre-existing or relatively easy to develop from a scientific and technical perspective. In public health terms, this market failure translates into sub-optimal preparedness levels for outbreaks caused by emerging pathogens—many of which are known to the scientific community and expected to cause severe outbreaks in the short-term.⁷⁶ The next Part will discuss the flaws of other non-IP incentives in increasing levels of, and resolving underinvestment in, vaccine research.

III. NON-IP INCENTIVES FRAMEWORKS IN THE VACCINE SPACE

The idea of non-patent incentives has co-existed with patent frameworks from the inception of the patent system in the United States.⁷⁷ Fritz Machlup and several other researchers have traced the idea of non-patent incentives in the United States back to James Madison's proposal of a premium system as the primary mechanism to encourage and reward innovation.⁷⁸

⁷¹ The U.S. economy suffered its biggest blow since the Great Depression in the second quarter as the COVID-19 pandemic. Lucia Mutikani, *Covid-19 Crushes U.S. Economy in Second Quarter; Rising Virus Cases Loom Over Recovery*, BUS. NEWS (JUL. 30, 2020), <https://www.reuters.com/article/us-usa-economy/covid-19-crushes-us-economy-in-second-quarter-rising-virus-cases-loom-over-recovery-idUSKCN24V0FO>. See also Paul Davidson, *US Economy Contracted Record 32.9% in Q2 Amid State Shutdowns, Covid-19 Contagion Fears*, USA TODAY (Jul. 30, 2020), <https://www.usatoday.com/story/money/2020/07/30/economy-gdp-fell-annual-rate-32-9-q-2-amid-covid-19-crisis/5536647002/> (describing economic aftermath of Covid-19 closures).

⁷² On the topic of whether the patent system should be regarded as technology-agnostic or technology-specific, see generally Dan L. Burk & Mark Lemley, *Is Patent Law Technology-Specific?* 17 BERKELEY TECH. L. J., 1155 (2002).

⁷³ U.S. FOOD & DRUG ADMIN, ORPHAN PRODUCTS: HOPE FOR PEOPLE WITH RARE DISEASES (2018), <https://www.fda.gov/drugs/drug-information-consumers/orphan-products-hope-people-rare-diseases>

⁷⁴ Vaccine R&D as a whole now takes place in much more patent-dense environment than in the early and mid-twentieth century, the so-called “golden age” of vaccine innovation. See Rutschman, *supra* note 39 at 730. The COVID-19 vaccine race also illustrates this point, with concerns over the exclusionary power emerging during the early stages of the pandemic. See e.g. Jennifer Hillman, *Drugs and Vaccines Are Coming—But to Whom?*, FOREIGN AFF. (May 19, 2020), <https://www.foreignaffairs.com/articles/world/2020-05-19/drugs-and-vaccines-are-coming-whom>

⁷⁵ Kremer & Snyder, *supra* note 41, at 14 (citing private companies finding vaccines less financially rewarding than drugs.). See also Frederick Chena & Flavio Toxvaerd, *The Economics of Vaccination*, 263 J. THEO. BIO. 105, 106 (2014) (noting that the market for vaccinations is widely believed to be characterized by market failures but demonstrate conditions in which equilibrium non-optimality may be obtained).

⁷⁶ WORLD HEALTH ORG., *supra* note 10, at 6 and 22 (providing an “initial list of diseases to be urgently addressed” as compiled by the World Health Organization after its assessment of a systemic “lack of R&D preparedness” for emerging pathogens). As the World Organization noted with regard to the 2014-16 Ebola outbreak, “[t]here were no vaccines, no treatments, few diagnostics, and insufficient medical teams and trained responders.” *Id.* at 6.

⁷⁷ Fritz Machlup, *An Economic Review of the Patent System*, Study No.15 of Comm. on Judiciary, Subcomm. on Patents, Trademarks, and Copyrights, 85th Cong., 2d Sess., (1958), at 15 (noting that “[p]roposals for systems of prizes and bonuses to inventors, as alternatives to patents, are almost as old as the patent system”).

⁷⁸ *Id.*, *ib. See also generally* Craig A. Nard & Andrew P. Morriss, *Constitutionalizing Patents: From Venice to Philadelphia*, 2 REV. L. & ECON. 223 (2006); Tyler T. Ochoa & Mark Rose, *The Anti-Monopoly Origins of the Patent and Copyright Clause*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 909 (2002).

Today, they have come to be understood as complementary innovation levers alongside the patent system,⁷⁹ playing an important role in the R&D incentives landscape.⁸⁰ In a 2013 study, Daniel Hemel and Lisa Ouellette examined the funding apparatus of the federal government in the United States, calculating “that current annual federal spending on innovation incentives is \$130–\$140 billion for grants, well under \$0.1 billion for prizes, about \$10 billion for R&D tax credits.”⁸¹

In this section, we provide an overview of non-patent incentives to R&D, with an emphasis on pharmaceutical R&D. Given the particularities of vaccine R&D, we turn to specific embodiments of non-patent incentives relating to vaccines. This section illustrates that even non-patent initiatives have many shortcomings that highlight the importance of greater reconsideration of tax-based incentives for vaccine R&D.

A. Grants

As noted in the previous section, the Federal government disburses the overwhelming majority of R&D funding through the grant system.⁸² The current preference for the grant model has been criticized on several accounts,⁸³ with some commentators suggesting that incentives mechanisms operating *ex post*, such as prizes, should absorb a greater share of public funding.⁸⁴

As Nicholson Price explains, criticism of the grant system unfolds primarily in three strands: it leads to poor allocative decisions as grantors lack “market-value knowledge possessed by private firms;” the *ex-ante* nature of grant funding reduces accountability parameters; and risk is distributed unevenly and “suboptimally” between grantor and grantee.⁸⁵

In his analysis of grants administered by the National Institutes of Health (“NIH”), Price nonetheless concludes that the inefficiencies traditionally observed with grant funding might not be as severe as often portrayed.⁸⁶ His study emphasizes the peer review process to which allocative decisions are subjected to; formal and informal accountability mechanisms, such as reporting mechanisms and reputational concerns for repeat applicants; and that the risk shouldered by the granting institution, often translates into valuable social benefits, including the disclosure of confidential negative knowledge surrounding the invention.⁸⁷

In the field of vaccines, and in spite of the blurred terminology, one of the most prestigious awards—the Michelson Prize—is in fact a grant. It is awarded to investigators under 35 years old

⁷⁹ See generally Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Innovation System?*, 2 INNOVATION POL’Y & ECON. 51 (2002); Benjamin N. Roin, *Intellectual Property versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1001–1002 (2014); Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525 (2001).

⁸⁰ Hemel & Ouellette, *infra* note 26, at 545. See also Joshua D. Sarnoff, *Government Choices in Innovation Funding (with Reference to Climate Change)*, 62 EMORY L.J. 1087 (2013) (noting that in spite of the relevance of government funding “we still lack any clear theory or good comparative empirical analyses from which to determine the best form of deploying such massive amounts of government money”).

⁸¹ Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents–Prizes Debate*, 92 TEX. L. REV. 303, 361 (2013). Hemel and Ouellette further note that several states also provide R&D funding for universities and other research facilities. *Id.* at 321. It is worth noting that federal funding for R&D has decreased since Hemel and Ouellette’s study. See e.g. Heidi Ledford et al., *Trump Seeks Big Cuts to Science Funding — Again*, NATURE (Mar. 11, 2019), <https://www.nature.com/articles/d41586-019-00719-4>

⁸² *Supra* note 81 and accompanying text.

⁸³ See generally W. Nicholson Price II, *Grants*, 34 BERKELEY TECH. L.J. 1, 6 (2019) (reviewing the grant system in the U.S.).

⁸⁴ See e.g. Jonathan H. Adler, *Eyes on a Climate Prize: Rewarding Energy Innovation to Achieve Climate Stabilization*, 35 HARV. ENVTL. L. REV. 1, 4 (2011) (making the case for a shift in government funding from climate change-related research from grants to prizes). See also Love & Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, *infra* note XX and accompanying text.

⁸⁵ Price, *supra* note 83, at 6.

⁸⁶ Price, *supra* note 83, at 7.

⁸⁷ Price, *supra* note 83, at 7.

“who are applying disruptive concepts and inventive processes to advance human immunology, vaccine discovery, and immunotherapy research across major global diseases.”⁸⁸ The Human Vaccines Project, a decade-long, transnational and multi-party research project modeled after the Human Genome Project,⁸⁹ was created partly as a response to the growing scientific and infrastructural challenges in immunology and vaccine R&D.⁹⁰ Its goal is to accelerate R&D on new vaccines, alongside diagnostics and treatments.⁹¹

While highly prestigious and relevant in the scientific discipline(s) it covers, the Michelson Prize also speaks to the general limitations of prize models. The awards are made to individuals as opposed to research projects, and their amount—\$150,000 as of the 2020 edition⁹²—is far from substantial. One of its principal funders—the Human Vaccines Project—was designed as a decade-long research partnership (like the Human Genome Project before it), which means that the prize itself is to some extent conditioned by the existence of, and funding for, the awarding entity. While there is nothing inherently wrong with temporally limited award formats, they speak to the small-scale nature of much of the funding available to vaccine R&D. These limitations further illustrate a greater need for incentives that work with market-driven approaches, such as the framework we propose for tax-based incentives in Part V.

Within the realm of public-sector funding, grants from federal agencies acting in the public health sphere have traditionally played an important role in supporting vaccine R&D.⁹³ As of June 2020, for instance, there were 26 open grant funding opportunity announcements from the National Institute of Allergy and Infectious Diseases (NIAID).⁹⁴ In addition to regular support for vaccine R&D through its grant systems, NIAID, National Institute of Health (NIH) and other federal agencies also provide funding during public health crises like COVID-19.⁹⁵ Yet, while the total amount of federal grants offered to pharmaceutical innovations is considerable, the amount granted to vaccine awardee is not significant enough to tilt the scale towards investments in vaccine research compared to mainstream pharmaceutical and technological innovations in the pre-pandemic setting.

B. Prizes

Even though they receive only a small fraction of public-sector funding,⁹⁶ incentives systems based on prizes have long enjoyed favor among many commentators looking for

⁸⁸ HUMAN VACCINES PROJECT, ABOUT THE MICHELSON PRIZES, <https://www.humanvaccinesproject.org/michelsonprizes/>

⁸⁹ *Id.*, *ib.* See also U.S. INST. HEALTH & HUM. SERV., THE HUMAN GENOME PROJECT, <https://www.genome.gov/human-genome-project>

⁹⁰ HUMAN VACCINES PROJECT, *supra* note 88.

⁹¹ *Id.*, *ib.*

⁹² *Id.*, *ib.*

⁹³ See U.S. NAT’L INST. ALLERGY & INFECT. DISEASES, VACCINES (2017), <https://www.niaid.nih.gov/research/vaccines> (providing an overview of NIAID’s role in funding vaccine R&D); *Id.*, FUNDING OPPORTUNITY FOCUSES ON INNOVATIVE VACCINE RESEARCH (2017), <https://www.niaid.nih.gov/grants-contracts/funding-opportunity-focuses-innovative-vaccine-research> (listing funding opportunities for vaccine R&D in the HIV space); *Id.*, NEW R01 AND R21 FUNDING OPPORTUNITIES TO SUPPORT UNIVERSAL INFLUENZA VACCINE RESEARCH (2018), <https://www.niaid.nih.gov/grants-contracts/universal-influenza-vaccine-research-foa> (listing funding opportunities for vaccine R&D for a universal flu vaccine).

⁹⁴ NAT’L INST. ALLERGY & INFECT. DISEASES, OPPORTUNITIES & ANNOUNCEMENTS (2020), <https://www.niaid.nih.gov/grants-contracts/opportunities?combine=vaccine&search=vaccine> (last visited May 30, 2020).

⁹⁵ See e.g. MEDICAL COUNTERMEASURES, BARDA AND SANOFI PREPARE FOR STUDIES OF COVID-19 VACCINE, <https://www.medicalcountermeasures.gov/newsroom/2020/psc-sanofi-recombinant/>. For example, the NIH so far awarded grants totaled \$6.9 billion for Covid-19 related research. NIH, Grants Funded Under Special COVID-19 Appropriations, https://projectreporter.nih.gov/reporter_SearchResults.cfm?icde=50791251.

⁹⁶ See *supra* note 81 and accompanying text.

complementary levers to intellectual property in innovation policy.⁹⁷ Before intellectual property grew into the default incentives regime for scientific and technical innovation, prizes were used more often across different fields of science.⁹⁸ Perhaps the most famous example is that of prizes offered in the eighteenth century by several European countries—most notably by the United Kingdom—for solutions to the then-unsolved problem of how to reliably measure longitude at sea.⁹⁹

Today, examples of prizes for technical and scientific innovation can be found in the public¹⁰⁰ and private¹⁰¹ sectors alike. At the conceptual level, they are often proposed as sets of large-scale rewards for success in the high-cost, high-risk area of pharmaceutical R&D,¹⁰² although in practice relatively few “mega-prizes” exist.

As noted by several commentators and synthesized by Hemel and Ouellette, the prize system, even in its complementary function within the innovation ecosystem, is not immune to problems and inefficiencies.¹⁰³ If set by the government, prizes are subject to “risks of politicization, rent-seeking, and mismanagement.”¹⁰⁴ Moreover, because the sum and terms of the rewards are set ex ante, prizes are also subject to problems of under- and over-evaluation.¹⁰⁵ And, as noted below in connection with incentives for vaccine R&D, prizes set by institutions in both the public and the private sectors are subject to budgetary and other financial constraints.

Consequently, prizes proper are much more infrequently deployed in vaccine innovation systems.¹⁰⁶ They are nonetheless routinely theorized both by scholars and outside academia.¹⁰⁷ Most recently, they have been proposed as a way to bolster R&D on COVID-19 vaccines while the pandemic unfolds. In an allusion to the longitude prizes described in Part III.A.2,¹⁰⁸ Chris Callaghan has suggested a “Longitude Prize” for COVID-19 vaccines of “many billions of pounds” that would be funded through contributions collected by the World Health Organization or the United Nations.¹⁰⁹ Hemel and Ouellette have proposed “a large cash prize” for the successful

⁹⁷ See e.g. Roin, *Intellectual Property versus Prizes: Reframing the Debate*, *supra* note 79; Amy Kapczynski, *The Cost of Price*, 59 UCLA L. REV. 970, 976 (2012); Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003); Michael Kremer & Heidi Williams, *Incentivizing Innovation: Adding to the Tool Kit*, 10 INNOVATION POL’Y & ECON. 1 (2010);

⁹⁸ Roin, *supra* note 79; Kapczynski, *The Cost of Price*, *supra* note 97, at 973.

⁹⁹ LONGITUDE PRIZE, THE HISTORY, [HTTPS://LONGITUDEPRIZE.ORG/CHALLENGE/HISTORY](https://longitudeprize.org/challenge/history)

¹⁰⁰ See e.g. U.S. OFFICE SCI. & TECH., IMPLEMENTATION OF FEDERAL PRIZE AUTHORITY: FISCAL YEAR 2015 PROGRESS REPORT (2016), https://obamawhitehouse.archives.gov/sites/default/files/fy2015_competes_prizes_report.pdf (describing greater public-sector investment in inducement prizes).

¹⁰¹ See e.g. Alan MacCormack et al., *Spurring Innovation Through Competitions*, MIT SLOAN MANAGEMENT REV. (Sept. 17, 2013), <https://sloanreview.mit.edu/article/spurring-innovation-through-competitions/> (describing the 2010 Progressive Insurance Automotive X-Prize, awarding \$10 million to the development of a vehicle with breakthrough energy efficiency).

¹⁰² See e.g., Bruce G. Charlton, *Mega-prizes in Medicine: Big Cash Awards May Stimulate Useful and Rapid Therapeutic Innovation*, 68 MED. HYPOTHESES 1 (2007), <https://pubmed.ncbi.nlm.nih.gov/17052861/>

¹⁰³ Hemel & Ouellette, *supra* note 81, at 326.

¹⁰⁴ *Id.* at 327.

¹⁰⁵ *Id.*, *ib.*

¹⁰⁶ See Hemel & Ouellette, *supra* note 81 and accompanying text.

¹⁰⁷ See James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANN. HEALTH L. 155 (2009) (proposing four possible embodiments of prize models for vaccines and other types of drug).

¹⁰⁸ See *supra* note 99 and accompanying text. The allusion further references the revival of the Longitude Prize in the United Kingdom in 2014. See Jon White, *Astronomer Royal: Why We Need a New Longitude Prize*, NEW SCIENTIST (May 19, 2014), <https://www.newscientist.com/article/dn25589-astronomer-royal-why-we-need-a-new-longitude-prize/>

¹⁰⁹ Chris Callaghan, *Would a Longitude Prize Speed Production of a Covid-19 Vaccine?*, WORLD U. RANKINGS (Mar. 28, 2020), <https://www.timeshighereducation.com/blog/would-longitude-prize-speed-production-covid-19-vaccine>

development of any vaccine targeting COVID-19, conditioning payment of the prize to the requirement “that the firm makes the vaccine available to patients at low or zero cost.”¹¹⁰

While greater attention and resources directed towards vaccine R&D is desirable—particularly when it bolsters already extraordinary manifestations of goodwill in the vaccine R&D space, as it happens during a pandemic—prizes offered as a public health crisis unfolds are an intrinsically limited incentives mechanism. Outbreak-spiked funding for vaccine R&D has historically been short-lived and limited by shifting financial dynamics and the political economy.¹¹¹ In addition to implementation constraints, proposals like Callaghan’s also have to contend with institutional limitations, as illustrated by the ways in which criticism of the World Health Organization has affected its operative and reputational power during COVID-19.¹¹²

Moreover, prizes created during large-scale public health crises constitute, at best, remedial approaches. While Hemel and Ouellette’s proposal would potentially solve affordability issues hovering over emerging coronavirus vaccines¹¹³—which can also be addressed in other forms by the legal system¹¹⁴—they do not address the fundamental shortcomings of incentives to vaccine R&D before an outbreak takes place. Without any meaningful prize system in place, a few months into the COVID-19 pandemic there were well over one hundred different vaccine R&D projects,¹¹⁵ as well as over two hundred drugs being considered for therapeutic purposes.¹¹⁶ Alas, patents, grants, and prizes have not been successful in instigating similar interest in vaccine R&D in the pre-crisis setting.

C. Other Types of Incentives: Regulatory Ad Hoc Incentives and Reimbursement Schemes

A strand of legal literature focusing on innovation law and policy has progressively added to the traditional roster of non-patent incentives that operate specifically in pharmaceutical R&D. Following her 2007 account of the Food and Drug Administration (“FDA”) as an information-production agency, Rebecca Eisenberg has identified different ways in which the Agency plays a catalyzing role in pharmaceutical innovation policy.¹¹⁷ These include the awarding of market and

¹¹⁰ Daniel Hemel & Lisa Larrimore Ouellette, *Want a Coronavirus Vaccine, Fast? Here’s a Solution*, TIME MAGAZINE (Mar. 4, 2020).

¹¹¹ Rutschman, *IP Preparedness*, at 1225 (noting how outbreak-spiked funding is often lost on short-lived R&D projects and tends to shrink fairly quickly).

¹¹² See e.g. Paige Winfield Cunningham, *The Health 202: WHO Has Stumbled Repeatedly in Communicating About the Coronavirus*, WASH. POST (Jun. 10, 2020), <https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2020/06/10/the-health-202-who-has-stumbled-repeatedly-in-communicating-about-the-coronavirus/5edfc29d602ff12947e88660/>; Paul LeBlanc, *Fauci Voices Support for World Health Organization After Trump Terminates US Relationship*, CNN (Jun. 11, 2020), <https://www.cnn.com/2020/06/11/politics/fauci-world-health-organization-coronavirus/index.html>

¹¹³ See Ed Silverman, *Azar Has a ‘Tin Ear’ When it Comes to Pricing a Potential Coronavirus Treatment*, STAT (Feb. 27, 2020), <https://www.statnews.com/2020/02/27/azar-coronavirus-affordable-trump/>.

¹¹⁴ See generally Sapna Kumar, *Patents, Pharma, and the Pandemic* (on file with authors). See also Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH (2017).

¹¹⁵ By mid-June 2020, some sources put the number of vaccine-specific COVID-19 R&D projects around 130, while others reported over 160 projects. WORLD HEALTH ORG., DRAFT LANDSCAPE OF COVID-19 CANDIDATE VACCINES (Jun. 9, 2020), <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>; Jonathan Corum & Carl Zimmer, *Coronavirus Vaccine Tracker*, N.Y. TIMES (last updated Jun. 12, 2020), <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

¹¹⁶ MILKEN INST., COVID-19 TRACKER, <https://airtable.com/shrSAi6t5WFwqo3GM/tblEzPQS5fnc0FHYR/viweyymxOAtNvo7yH?blocks=bipZFzhJ7wHPv7x9z> (listing over 230 R&D projects as of June 10, 2020).

¹¹⁷ Eisenberg, *supra* note 30, at 346.

data exclusivities to first market-entrants,¹¹⁸ which prevent the FDA from approving follow-on drugs for certain periods of time,¹¹⁹ thus conferring a de facto monopoly-like position to drug manufacturers who gain FDA approval for first-of-its-kind drugs. Market and data exclusivities are independent of the status of patent protection.¹²⁰ Yaniv Heled, who has emphasized how these FDA-administered exclusivities constitute “regulatory competitive shelters,”¹²¹ has also noted that these types of exclusivities are “limited almost exclusively to FDA regulation,”¹²² reflecting how pharmaceutical R&D players can take advantage of (and even abuse) some forms of incentives that are not available in other technical and scientific areas.¹²³

Still at the FDA level, another type of incentive mechanism is the priority review voucher system,¹²⁴ which was established to encourage pharmaceutical companies to engage in R&D on traditionally underfunded diseases by offering a voucher to sponsors of novel drugs in this area who successfully obtain FDA market approval.¹²⁵ The voucher can then be redeemed to expedite regulatory review of an unrelated drug—in practice, a drug targeting a mainstream disease¹²⁶—by the same sponsor, or sold to a competitor.¹²⁷ The system covers vaccine-preventable infectious diseases like Ebola and Zika, as well as other neglected tropical diseases.¹²⁸ The transferability option of the voucher system naturally has made it highly susceptible to gamesmanship and abuse by pharmaceutical companies that obtain vouchers in underfunded R&D but utilize the special expedited review in R&D of unrelated profitable drugs.

Elsewhere in the administrative state, Rachel Sachs and others have made the case that insurance reimbursement, such as through the Medicare¹²⁹ and Medicaid¹³⁰ programs, should also be considered. They demonstrated such insurance programs can serve as a form of incentive to pharmaceutical R&D by promising consistent demand (albeit at lower prices) for vaccines.

¹¹⁸ There are also market exclusivities available to some follow-on innovators. Follow-on innovators can be either sponsors of generic versions of small-molecule drugs, or sponsors of biosimilar versions of large-molecule drugs.

¹¹⁹ *Supra* note 118 (defining follow-on innovators).

¹²⁰ U.S. FOOD & DRUG ADMIN., FREQUENTLY ASKED QUESTIONS ON PATENTS AND EXCLUSIVITY (2020), <https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity>

¹²¹ Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299 (2015).

¹²² *Id. ib.*

¹²³ For a critique of (overly) cumulative layers of incentives in the pharmaceutical and biopharmaceutical space, see e.g. Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals - Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419 (2012).

¹²⁴ See David B. Ridley et al., *Developing Drugs for Developing Countries*, 25 HEALTH AFF. 313, (2006) (proposing the voucher system).

¹²⁵ See e.g. Alexander Gaffney et al., REGULATORY EXPLAINER: EVERYTHING YOU NEED TO KNOW ABOUT FDA’S PRIORITY REVIEW VOUCHERS, REG. AFF. PROFESSIONALS SOC’Y (2016), <http://www.raps.org/Regulatory-Focus/News/2015/07/02/21722/Regulatory-Explainer-Everything-You-Need-to-Know-About-FDA%E2%80%99s-Priority-Review-Vouchers/>.

¹²⁶ See Ana Santos Rutschman, *The Priority Review Voucher Program at the FDA: From Neglected Tropical Diseases to the 21st Century Cures Act*, 26 ANNALS HEALTH L. 71 (2017) (critiquing the implementation of the voucher system).

¹²⁷ See e.g. Chelsey Dulaney, *United Therapeutics Sells Priority-Review Voucher to AbbVie for \$350 Million*, WALL ST. J. (Aug. 19, 2015), <https://www.wsj.com/articles/united-therapeutics-sells-priority-review-voucher-to-abbvie-for-350-million-1439981104>; Richard Staines, *Priority Review Voucher Prices Fall Again After Spark’s \$110m Sale*, PHARMAPHORUM (May 1, 2018), <https://pharmaphorum.com/news/spark-sells-priority-review-voucher-to-jazz/> (noting the progressive after the record set in 2015).

¹²⁸ U.S. FOOD & DRUG ADMIN., TROPICAL DISEASE PRIORITY REVIEW VOUCHERS: GUIDANCE FOR INDUSTRY (2016), <https://www.fda.gov/media/72569/download>

¹²⁹ Mark A. Lemley, Lisa Larrimore Ouellette, & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 NYU L. REV. 75 (2020).

¹³⁰ Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J. L. & TECH. 153 (2016).

Similarly, other federal programs such as the Vaccines for Children Program (“VFC”) enable the CDC to buy recommended vaccines at discount prices.¹³¹ These vaccines are then made available through state, local and territorial health departments or agencies to VFC providers at no cost for eligible populations.¹³² The VFC program covers Medicaid-eligible, uninsured and underinsured children, as well as American Indian and Alaska Native children. The program is restricted to childhood vaccines recommended by the Advisory Committee on Immunization Practices,¹³³ which constitutes the backbone of official vaccination schedules.¹³⁴ Vaccines typically needed during a pandemic—which tend to align with the spectrum of diseases traditionally placed under the umbrella of neglected tropical diseases or other types of neglected diseases—fall outside the VFC program. Similarly, some adult vaccines are covered by state Medicaid programs,¹³⁵ but coverage is significantly more limited when compared to the VFC program.¹³⁶

At the international level, there are procurement mechanisms to buy and distribute vaccines in developing countries.¹³⁷ Gavi, the Vaccine Alliance, a public-private partnership created in 2000, is the largest and leading institution in this field, sourcing multilateral funding for, and assisting in the distribution of, different types of vaccines across low- and middle-income countries.¹³⁸ Currently, Gavi supports in varying ways 17 different types of vaccines.¹³⁹ Some of these are childhood vaccines, such as the Measles-Rubella vaccines, while others target traditionally underfunded diseases, such as the Typhoid and oral Cholera vaccines.¹⁴⁰ Alas, these collaboration initiatives provide limited profit opportunities (if any) to participant pharmaceutical firms.

To summarize this Part, the disjunction between public health needs and business models dependent on the monetization of patent rights, coupled with the relative paucity of the current non-IP incentives landscape as applied to vaccines are not free of inefficiencies themselves. Underinvestment in vaccine R&D remains a significant hurdle at the present time. This prompts us to consider the possibility of exploring underused levers in the non-IP incentives landscape. Next, we explore the role of tax incentives for spurring investment in innovation in the pharmaceutical, and specifically, vaccine research domain.

¹³¹ U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, VACCINES FOR CHILDREN PROGRAM (VFC) (2016), <https://www.cdc.gov/vaccines/programs/vfc/index.html>

¹³² U.S. MEDICAID, QUALITY OF CARE VACCINES, <https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/quality-of-care-vaccines/index.html>

¹³³ U.S. CTRS. DISEASE CONTROL & PREVENTION, *Advisory Committee on Immunization Practices Policies and Procedures* (2018), <https://www.cdc.gov/vaccines/acip/committee/downloads/Policies-Procedures-508.pdf>

¹³⁴ U.S. CTRS. DISEASE CONTROL & PREVENTION, CHILDHOOD IMMUNIZATION SCHEDULE (2013), <https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-child-immun-bw-office.pdf>

¹³⁵ See QUALITY OF CARE VACCINES, *supra* note 132.

¹³⁶ See generally Sara Rosenbaum et al., *The Epidemiology of U.S. Immunization Law: Medicaid Coverage of Immunizations for Non-institutionalized Adults*, NAT’L IMMUNIZATIONS PROGRAM REPORT (2003), https://publichealth.gwu.edu/departments/healthpolicy/DHP_Publications/pub_uploads/dhpPublication_5F6FC614-5056-9D20-3D48DB884F5C18C8.pdf, at 6.

¹³⁷ See GAVI, A ROADMAP FOR THE FUTURE: COUNTRY-OWNED DECISIONS IN VACCINE PROCUREMENT, <https://www.gavi.org/sites/default/files/document/country-owned-decisions-roadmap---public-summary.pdf> (defining vaccine procurement “as the set of several steps and considerations that ultimately result in vaccines being purchased and delivered into the hands of a country government for distribution and immunization among its people”).

¹³⁸ GAVI, <https://www.gavi.org>

¹³⁹ GAVI, VACCINE SUPPORT, <https://www.gavi.org/programmes-impact/types-support/vaccine-support>

¹⁴⁰ *Id. ib.*

IV. CURRENT TAX INCENTIVES FOR DOMESTIC PHARMACEUTICAL INNOVATION

We turn our attention here to the role of tax law and policy for two reasons: first, within the pharmaceutical innovation literature—and, more broadly, within the legal literature—tax-based incentives have received far less attention than other incentives frameworks. Second, and more important, reliance on the tax system offers a significant advantage over other types of non-IP incentives, which require greater shares of *ex ante* financing for the incentive to be disbursed and passed along to R&D players. While set by the public sector, tax incentives create an enabling framework that is self-incorporated by private-sector players and investors. In this sense, they constitute a public policy tool that takes advantage of market forces and market actors, rather than deriving funding from pre-existing, limited budgets.

In focusing on tax law and policy in this Part and the next, our point is not that tax-based incentives are preferable or comparatively superior to other forms of non-patent incentives. Rather, we argue that tax incentives have been underused or used inefficiently to stimulate R&D in vaccines and underfunded diseases areas. We contend that tax incentives can be tailored in more creative ways to further innovation policy goals in vaccine R&D, in particular those that are closely aligned with the pursuit of public health imperatives.

At present, there are several tax apparatuses that are available for companies conducting research, including but not limited to, pharmaceutical research. Immediate Expensing for R&D provides a faster way to recover the cost of investment in innovation. The Research and Experimentation credit (“R&D credit”)¹⁴¹ offers companies a direct reduction in their tax bills in return for increasing spending on in-house research. The Basic Research credit ensures that companies benefit from outsourcing scientific investigations and collaborating with universities. The Orphan Drug Credit aims to alleviate some of the development costs of drugs for rare diseases at the clinical-trial phase. Finally, Patent Donations provide a charitable deduction for intellectual property donated to nonprofit organizations.¹⁴²

As this Part will reveal, these tax incentives are complex and costly and, thus, may not significantly modify the nature of the industry, particularly not in the context of vaccine development. Moreover, while they might contribute to the growth of private research enterprise, they have been criticized for mainly rewarding large firms, that may abuse the benefits, and spike drug prices and insurance premiums.¹⁴³

A. Immediate R&D Expensing

It is a basic rule in tax law that the costs of doing business incurred while creating or developing an asset with useful life extending beyond the taxable year are capitalized and depreciated.¹⁴⁴ Nevertheless, added in 1954, section 174 of the Tax Code provides taxpayers with

¹⁴¹ In this paper, we use the term “research and development” and “research and experimentation” interchangeably although the latter is more restrictive than the former and does not necessarily specific immediate commercial applications. The term “research and experimentation” tracks back to immediate expensing under § 174. See Stephen E. Shay, J. Clifton Fleming, Jr., Robert J. Peroni, *R&D Tax Incentives: Growth Panacea or Budget Trojan Horse?*, 69 TAX L. REV. 419, 422 n.15 (2016).

¹⁴² We focus here on tax provisions relating to pharmaceutical innovation and do not examine other tax provisions that relate to the intersection of tax, IP, and R&D including depreciation of computer software, amortization of copyrights, selling or exchanging patents or other IP to foreign corporations, etc. See generally Lily Kahng, *The Taxation of Intellectual Capital*, 66 FLA. L. REV. 2229, 2267-77 (2014) (referencing extensive literature on taxation of intangibles); Xuan-Thao Nguyen & Jeffrey A. Maine, *Equity and Efficiency in Intellectual Property Taxation*, 76 BROOK. L. REV. 1, 1-8 (2010) (reviewing and criticizing tax rules relating to patents, copyrights, and trademarks).

¹⁴³ See *infra* notes 202-208 and accompanying text.

¹⁴⁴ 26 U.S.C. §§167, 263.

a faster way to recover their costs relating to research and development.¹⁴⁵ Companies can elect to immediately deduct certain research and experimentation costs or capitalize them over a period of 5–10 years.¹⁴⁶ Because inflation diminishes the value of money—along with the axiom that a dollar saved today is worth more than a dollar saved in the future—most taxpayers will prefer to deduct expenses immediately rather than incrementally depreciate them over a number of years. Yet, companies with substantial short-term losses such as small and startup companies with no positive income to offset against the deduction will likely not benefit as much from this tax incentive and choose to defer the R&D deduction to later years.¹⁴⁷ Still, the Joint Committee on Taxation estimated that in 2020, the federal government will lose \$2.5 billion in tax revenue due to early expensing for R&D mostly by larger and established firms.¹⁴⁸

The Tax Code defines qualified research and experimentation expenses eligible for expensing as those used for testing in the exploratory or lab setting related to the development or improvement of a product.¹⁴⁹ A product is defined for those purposes as including any pilot, model, process, formula, method, patent, etc.¹⁵⁰ To qualify as eligible for immediate expensing, the expenditure is categorized according to the nature of its related activity, not just the idea or the product. For example, wages of employees engaged in R&D, expenses to update and maintain research facilities, supplies utilized for experimentation or trials, and administrative guidance or computer software used in the research process are by their nature expenses that normally qualify when they relate to developing or improving a product.¹⁵¹ Yet, there are also expenses specifically disallowed even if they are part of developing or improving a product, such as acquisition of patents, models, production or process, advertising or promotions, quality control testing, and effectiveness or consumer surveys.¹⁵² The acquisition or improvement of land or of depreciable or depletable property also is not eligible for R&D expensing.¹⁵³ As discussed above, research expenses cannot be claimed twice, thus expenses deducted immediately under section 174 are reduced by the amount of the R&D credit.

Scholars have debated altogether the efficiency of immediate expensing and accelerated capital recovery policies in furthering government goals to generate economic stimulus by increasing the positive net present value of certain capital investments.¹⁵⁴ Some have argued that expensing—as a general rule not just for R&D—represents bad tax policy and hefty subsidy for investments without special public merit.¹⁵⁵ Others have noted expensing encourages a waste of capital by promoting investments that absence the tax benefit would not have been made.¹⁵⁶

¹⁴⁵ Internal Revenue Code of 1954, ch. 736, 68A Stat. 66 (codified as amended at 26 U.S.C. § 174).

¹⁴⁶ 26 U.S.C. § 174(a), (b).

¹⁴⁷ *Id.* 26 U.S.C. §§ 174(f)(2), 59(e). Moreover, some companies might choose to defer the deduction in order to mitigate the effect of the alternative minimum tax adjustment for research expenditures. 26 U.S.C. § 56(b)(2).

¹⁴⁸ See Staff of the Joint Comm. on Taxation, 114th Cong., Estimates of Federal Tax Expenditures for Fiscal Years 2019-2023, at tbl.1 (Comm. Print 2019); US Department of the Treasury, Tax Expenditures, available at <https://home.treasury.gov/policy-issues/tax-policy/tax-expenditures#:~:text=Tax%20expenditures%20are%20defined%20by,exceptions%20may%20be%20viewed%20as.>

¹⁴⁹ Treas. Reg. § 1.174-2(a)(1) and (2).

¹⁵⁰ Treas. Reg. § 1.174-2(a)(11).

¹⁵¹ Treas. Reg. § 1.174-2.

¹⁵² Treas. Reg. § 1.174-2(a)(6).

¹⁵³ 26 U.S.C. § 174(c).

¹⁵⁴ See e.g., Rebecca N. Morrow, *Accelerating Depreciation in Recession*, 19 FLA. TAX REV. 465, 488-90 (2016) (arguing data is mixed on whether these policies achieved this intent).

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¹⁵⁶ See e.g., Calvin H. Johnson, *Capitalize Costs of Software Development*, 124 TAX NOTES 603, 612 (2009) (calling for the elimination of 100% expensing).

In the recent tax reform introduced by the Tax Cuts and Jobs Act the government abruptly eliminated R&D expensing starting 2021.¹⁵⁷ In the following years, amounts paid or incurred for research or experimental expenditures must be capitalized and amortized ratably over five years.¹⁵⁸ Legal academics Xuan-Thao Nguyen and Jeffrey Maine criticized these sudden changes in tax policy claiming they were made without proper notice or legislative reasoning.¹⁵⁹ They warned such disruptive changes threaten the future of innovation in the United States as to drive research and innovation activities offshore to Europe and China.¹⁶⁰

B. Tax Credits for Increasing Research Activities and Basic Research

In 1981, Congress added section 41 to the Tax Code as a temporary research credit to stimulate private research and development and reverse a decline in research activities conducted in the private sector during those years.¹⁶¹ The R&D credit benefited from wide bipartisan support and endorsement by prominent leaders from the high-tech, integrated circuits, telecommunications, and computer industries.¹⁶² Accordingly, over several decades, it endured multiple renewals, extensions, and retroactive extensions until it became permanent in 2015.¹⁶³ Although not geared specifically towards pharmaceutical firms, it certainly can be, and has been, claimed by such companies.¹⁶⁴

As its title specifies, the R&D credit applies only to incremental research expenditures, aiming to incentivize firms to increase their average R&D expenses rather than rewarding them for R&D expenditures they have incurred regardless of any credit. To achieve this ambitious endeavor, the R&D credit provides a dollar-per-dollar reduction against the tax imposed up to 20 percent of the amount of their “qualified research expenses”¹⁶⁵ over a base amount.¹⁶⁶ Such expenses include, for example, wages paid to research employees and supplies used in research. Such costs can be considered qualified research expenses under the credit if they are incurred for the purpose of discovering information that is technological in nature in the development of a new

¹⁵⁷ Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, 131 Stat. 2054. See also Jacob Puhl, *Brady Doubles Down on 100 Percent Expensing at Ways and Means Hearing*, DELOITTE (May 19, 2017), http://newsletters.usdbriefs.com/2017/Tax/TNV/170519_1.pdf.

¹⁵⁸ 26 U.S.C. § 174(a)(1)-(2) (2020).

¹⁵⁹ See Xuan-Thao Nguyen & Jeffrey A. Maine, *Attacking Innovation*, 99 B.U.L. REV. 1687, 1689 (2019) (warning against recent changes in U.S. patent system, a decline in direct funding of research, and a weakening of tax policy tools used to encourage new innovation).

¹⁶⁰ *Id.*

¹⁶¹ The Economic Recovery Tax Act, P.L. 97-34, 95 Stat. 172 (1981). See Joint Committee on Taxation, *General Explanation of the Economic Recovery Tax Act of 1981*, H.R. 4242, Pub. L. 97-34, 97th Cong. 119 (1981) (reporting civilian research to GNP ratio is 1.5 percent, compared with 1.9 percent for Japan and 2.3 percent for West Germany).

¹⁶² See Mirit Eyal-Cohen, *Unintended Legislative Inertia*, 55 GA L. REV. _ (2020) (describing the history of the research credit that was created as part of a cluster of temporary provisions to allow flexible legislation).

¹⁶³ The R&D credit been extended 17 times, of which 7 times retroactively. In 2015, President Obama signed into law the Protecting Americans from Tax Hikes (PATH) Act, Pub. L. No. 114-113 (2015) that made the credit permanent and, for the first time, permitted small businesses to use the credit to offset both their regular, Alternative Minimum Tax, and payroll tax liabilities. For a detailed legislative history of the acts extending the R&D credit see Eyal-Cohen, *Unintended Legislative Inertia*, Appendix (2021).

¹⁶⁴ Out of 6,241 manufacturing firms that claimed the research credit in tax year 2013, about 812 firms were in the chemical manufacturing field (13%). Statistics of Income, Corporation Research Credit, Table 2. Corporations Claiming a Credit for Increasing Research Activities on Form 6765 [1][2]: Selected Items, by Manufacturing Subsectors, Tax Year 2013, <https://www.irs.gov/statistics/soi-tax-stats-corporation-research-credit>.

¹⁶⁵ 26 USC § 41(b). Contract research expenses are limited to 65 percent of any amount paid to any person (other than an employee of the taxpayer) for qualified research. 26 USC § 41(b)(3)(A).

¹⁶⁶ In calculating the credit, the firm’s base period research was not permitted to be less than 50% of the current year’s research spending. The credit’s statutory rate was initially set at 25 percent and applied only to increases in a firm’s research spending over its average spending in a base period consisting of the previous three years. *Id.*

or improved business component of the taxpayer as part of a process of experimentation.¹⁶⁷ Moreover, the purpose of the research has to relate to obtaining knowledge about a new or improved function, performance, or reliability or quality, but not style, taste, cosmetic, or seasonal design factors.¹⁶⁸ Regardless of whether they meet these prerequisites, expenses are ineligible if they are incurred after the beginning of commercial production; if they are related to the adaptation or duplication of existing business components; or if they involve market research, routine data collection, routine testing or inspection, quality-control testing, social science research, grant-funded research, or research conducted outside the United States.¹⁶⁹

The credit amount is calculated by multiplying the company's "fixed-base ratio" by their average annual gross receipts for the preceding four taxable years.¹⁷⁰ The fixed-base ratio is a historical percentage denoting the company's total "qualified research expenditures" over total gross receipts.¹⁷¹ For start-up companies with fewer than three years of gross receipts, the calculation is multifaceted, starting from a fixed-base percentage of 3 percent and thereafter gradually transitioning to a fixed-base ratio based on actual R&D.

Much of the R&D credit's ineffectiveness derives from its complexity and several arrangements added to refrain from punishing firms that maintain a solid R&D record,¹⁷² to avoid benefiting companies that increase their R&D spending immediately after the base period,¹⁷³ and to permit companies to elect a simpler way to calculate the credit.¹⁷⁴ Alas, these noteworthy goals add many additional components to the R&D credit and much intricacy. In addition, in order to narrow misuse, gaming, or overclaiming, the R&D credit contains several anti-abuse rules. For example, the credit is not available for government-funded research or via private grant.¹⁷⁵ Companies claiming the credit cannot "double dip," thus, they must reduce immediate expensing for the amount of the credit.¹⁷⁶ The R&D credit can be combined with the Orphan Drug Credit for the clinical stage but not for the same expenses. Moreover, many states offer R&D tax credits to encourage in-state innovation that can be combined with the R&D tax credit at the federal level.¹⁷⁷

The R&D tax credit also comes with a high price tag. The Joint Committee on Taxation estimates that in 2020, the federal government will lose \$12.6 billion due to the R&D credit.¹⁷⁸ Yet, due to the difficulty in evaluating innovation output and tracing it to R&D spending, little is

¹⁶⁷ 26 U.S.C. § 41(d)(1).

¹⁶⁸ 26 U.S.C. § 41(d)(3).

¹⁶⁹ 26 U.S.C. § 41(d)(4)(B)-(H).

¹⁷⁰ 26 U.S.C. § 41(c)(1).

¹⁷¹ 26 U.S.C. § 41(c)(3).

¹⁷² 26 U.S.C. § 41(c)(3)(C) ("In no event shall the fixed-base percentage exceed 16 percent.").

¹⁷³ 26 U.S.C. § 41(c) (providing that at a minimum, the base amount is no less than 50 percent of the qualified research expenses for that year.).

¹⁷⁴ Firms can elect to use an alternative simplified manner to calculate the R&D credit as 14 percent of qualified research expenses for the taxable year as exceeds 50 percent of the average qualified research expenses for the 3 preceding taxable years. 26 U.S.C. § 41(c)(4)(A). If the taxpayer has no qualified research expenses in any of 3 preceding taxable years the alternative simplified credit rate is 6 percent of qualified research expenses. 26 U.S.C. § 41(c)(4)(B).

¹⁷⁵ 26 U.S.C. § 41(d)(4)(H).

¹⁷⁶ 26 U.S.C. § 280C(c)(1).

¹⁷⁷ Catherine Fazio, Jorge Guzman, Scott Stern, *The Impact of State-Level R&D Tax Credits on the Quantity and Quality of Entrepreneurship*, NBER Working Paper No. 26099, <https://www.nber.org/papers/w26099> (casting doubt as to the efficacy of state-level R&D tax credits and observing a decline in the rate of formation of growth-oriented startups over time).

¹⁷⁸ See Staff of the Joint Comm. on Taxation, 114th Cong., Estimates of Federal Tax Expenditures for Fiscal Years 2019-2023, at tbl.1 (Comm. Print 2019).

known about the effects of tax incentives in spurring innovation. During congressional debates on whether to extend the R&D credit, the National Science Foundation supported the renewal of the credit for its contribution to a positive research growth trend.¹⁷⁹ Over the years, studies on the correlation between the R&D tax credit and R&D spending have been mixed.¹⁸⁰ Some noted that a dollar of R&D credit is associated with a dollar of investment in R&D, while others claimed a different ratio.¹⁸¹ Regardless, what these studies do not tell us is whether such R&D spending would *not* have happened independent of the R&D credit and as a normal part of the company's innovation efforts and attempts to procure supra competitive profits.

Lastly, it is worth noting that when Congress enacted the R&D credit, it also created the Basic Research Credit.¹⁸² The basic research credit offers corporations a credit for expenditures made to qualified nonprofit organizations for collaborative primary research. The definition of basic research entails domestic original examination for the development of scientific knowledge not having an explicit commercial objective. Basic research payments are cash amounts paid by a corporation to a qualified educational or tax-exempt organization for basic research pursuant to a written agreement between the parties.¹⁸³ The basic credit calculation is not similar to the general R&D credit, which adds yet more complexity to an already intricate incentive system and increases hurdles of new and smaller firms trying to secure tax benefits.¹⁸⁴ By enacting the basic research tax credit the government sought to encourage taxpayers to engage, and reward them for their investments, in primary research that has no specific commercial objective in hope that later on firms and investors will continue to develop that knowledge.

C. Orphan Drug Tax Credit ("Orphan Drug Credit")

Aside from the R&D tax credit and immediate R&D expensing that apply to all types of investments in innovation, the Tax Code provides an apparatus designed specifically to encourage pharmaceutical research. In 1983, the Orphan Drug Act created a new temporary tax credit for expenditures related to human clinical testing for rare diseases in the FDA approval process.¹⁸⁵ This credit focused on rare disorders and uncommon ailments that lack commercial pharmaceutical sponsorship (i.e., "orphaned") due to their limited potential of financial profits resulting from a

¹⁷⁹ See National Science Foundation, National Patterns of R&D Resources, 1994, tables B6, B9, B12.

¹⁸⁰ See, e.g., John Van Reenen, Kieu-Trang Nguyen, Ralf Martin, Elias Einiö, & Antoine Dechezleprêtre, *Do Tax Incentives for Research Increase Firm Innovation? An RD Design for R&D*, NBER Working Paper 22405

<http://www.nber.org/papers/w22405> (finding evidence of a causal impact of research and development (R&D) tax incentives on innovation.); Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. HEALTH ECON. 1060, 1061 (2008) (demonstrating Tax credits can stimulate R&D); Frischmann, *supra* note 21, at 382 (finding tax incentives counterbalance innovative process market failures). *But see*, Robert Eisner, Steven H. Albert & Martin A. Sullivan, *The New Incremental Tax Credit for R&D: Incentive or Disincentive?*, 37 NAT'L TAX J. 171, 181 (1984) (reporting no positive impact between the research credit to R&D expenditures).

¹⁸¹ See Robert D. Atkinson, *Expanding the R&E Tax Credit To Drive Innovation, Competitiveness and Prosperity*, 32 J. TECH. TRANSFER 617, 619 (2007) (arguing all studies found investment of \$1 of research credit produces more than \$1 in R&D expenditures).

¹⁸² 26 U.S.C. § 41(e).

¹⁸³ 26 U.S.C. § 41(e)(6).

¹⁸⁴ It is calculated as the taxpayer's basic research payments over its qualified organization base period amount. The portion of the basic research payments which does not exceed the taxpayer's qualified organization base period amount is treated as contract expenses for purposes of the R&D tax credit, which can be claimed concurrent with the basic research credit. QOBPA is the sum of the taxpayer's minimum basic research amount and maintenance-of-effort amount. 26 U.S.C. § 41(e)(4) and (5). The base period is the three-year period ending with the tax year immediately preceding the taxpayer's first tax year.

¹⁸⁵ Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended at 26 U.S.C. § 45C). The cost of the basic credit was estimated to be around \$6.0 billion a year in 2010. CONGRESSIONAL RESEARCH SERVICE, TAX EXPENDITURES: COMPENDIUM OF BACKGROUND MATERIAL ON INDIVIDUAL PROVISIONS, UNITED STATES SENATE COMMITTEE ON THE BUDGET 89 (Dec. 2010).

smaller scope of patients and future “clients.”¹⁸⁶ Due to the limited size of the patient market for orphan drugs, the government provides, in addition to patents, special orphan-designated grants, expedited approval and waivers procedures, a 7-year marketing exclusivity protection from generics,¹⁸⁷ and additional tax benefits to assure pharmaceutical companies can recover their investments.¹⁸⁸

Previously scheduled to expire after 1987, Congress repeatedly extended the orphan drug tax credit and eventually made it permanent in 1997.¹⁸⁹ Following the U.S., other key markets also adopted similar orphan drug acts, most notably Japan in 1993 and the European Union in 2000. The Orphan Drug Act provided a tax credit for (then) 50 percent of domestic “qualified clinical testing expenses” incurred in the process of developing orphan drugs, as well as amended the FDA Act to include an exclusive period of promotion and marketing rights for such designated drugs.¹⁹⁰ It also allowed unused credit to be carried back three years and carried forward up to fifteen years following the year in which the credit was earned.¹⁹¹

The tax credit is available for human clinical testing to the extent the research is related to the use of a drug designated under the FDA to treat a rare disease or condition that influences a smaller portion of the general population.¹⁹² A rare disease or condition includes those affecting fewer than 200,000 people in the U.S., or affecting more than 200,000 in the U.S. but without reasonable prospects that such medication will be profitable, that is, its cost of development will be recovered from its sales in the U.S.¹⁹³

Scholars and professionals have noted that the Orphan Drug Act has been successful in achieving its goals by providing opportunities, incentivizing corporate investments, doubling the drugs available for rare diseases, and endorsing hundreds of new orphan drugs for clinical trials.¹⁹⁴ The Act spurred the development of lifesaving therapies for many rare disorders, such as cystic fibrosis, muscular dystrophy, and various pediatric cancers.¹⁹⁵ Moreover, strong patient advocacy, venture capital investments, industry cooperation, clinical advancements, and administrative

¹⁸⁶ For example, muscular dystrophy, Tourette's Syndrome, and Lou Gehrig's Disease. The use of the term “Orphan” refers to drugs for rare diseases and conditions that entail limited opportunities for pharmaceutical and biotechnology companies to undertake their development and production. See Orphan Drug Act, Pub. L. No. 97-414, section 1(b), 96 Stat. 2049, 2049 (1983) (providing an overview on the environment of research in the area of rare conditions and diseases).

¹⁸⁷ 21 U.S.C. § 360cc(a).

¹⁸⁸ Rachel E. Sachs, *Administering Health Innovation*, 39 CARDOZO L. REV. 1992, 2008 (2018).

¹⁸⁹ Rachel Sachs, *Delinking Reimbursement* (2018) (describing policymakers “clearly understand the potential benefits of implementing innovation-related policies through the FDA approval process.”)

¹⁹⁰ 26 U.S.C. § 45C; Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended at 21 U.S.C. section 360cc).

¹⁹¹ Taxpayer Relief Act of 1997, Pub. L. 105-34, § 604, 111 Stat. 788, 863 (1997). Any amount claimed under the orphan tax credit increases the base period for research expenses under the R&D tax credit and reduces the deduction otherwise available under immediate R&D expensing). 26 U.S.C. § 280C.

¹⁹² 21 U.S.C. § 45(c).

¹⁹³ 21 U.S.C. § 360bb.

¹⁹⁴ Nina J. Crimm, *A Tax Proposal To Promote Pharmacologic Research, To Encourage Conventional Prescription Drug Innovation and Improvement, and To Reduce Product Liability Claims*, 29 WAKE FOREST L. REV. 1007, 1074 (1994) (reviewing the success, limitation, and criticism on the Orphan Drug Act); U.S. Food & Drug Admin., Developing Orphan Products: FDA & Rare Disease Day 1-2 (2009), available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm107301.pdf> (reporting an increase of 300 treatments for orphan diseases receiving FDA approval in the 25 years following the enactment of the Orphan Drug Act enactment).

¹⁹⁵ Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. HEALTH ECON. 1060, 1061 (2008) (demonstrating that the Orphan Drug Act increased production of drugs for rare diseases); Developing Products for Rare Diseases & Conditions, U.S. Food & Drug Admin., <https://perma.cc/E3E7-X6V6> (“The program has successfully enabled the development and marketing of over 600 drugs and biologic products for rare diseases since 1983. In contrast, fewer than 10 such products supported by industry came to market between 1973 and 1983.”).

motivating forces have been considerably changing the scene of orphan drug research in the last few years. For instance, the Office of Orphan Products Development (OOPD) approved 89 new orphan designations in 2018 and 81 in 2019, the highest numbers annually since the passage of the Orphan Drug Act.¹⁹⁶ Every February, organizations mark the annual Rare Disease Day to raise awareness about the effects of such ailments on people's lives.¹⁹⁷ Scientific advances in rare diseases along with accelerated FDA review highlight policymakers' growing commitment to propel orphan drug development. Recent empirical studies demonstrated that receiving an orphan-drug designation provides, in and of itself, is a strong positive signal for potential investors.¹⁹⁸ Accordingly, the last few years also saw vast investment opportunities for pharmaceutical firms associated with orphan drugs in partnerships and corporate mergers and acquisitions.¹⁹⁹ Orphan drug credit claims increased from \$290 million in 2010²⁰⁰ to \$1.8 billion in 2020, with a projection of over \$4 billion in 2024.²⁰¹

Other academics, policymakers, and journalists have criticized the orphan drug laws for their effects on the price of drugs.²⁰² They have claimed that the orphan designation is overinclusive and harms pharmaceutical competition. Many drugs for rare diseases that have entered the market over the past few decades have become exceedingly profitable. Pharmaceutical firms were accused of reaping government financial and procedural benefits for orphan drug development while charging excessive prices for these medications.²⁰³ For example, AIDS medications, originally thought to be unprofitable, later turned out to be highly profitable due to their cost and marketing outside of the U.S.²⁰⁴ In 2015, several researchers from Johns Hopkins

¹⁹⁶ U.S. Food and Drug Administration, Total Number of Orphan Drug Approvals in the Month Requiring Exclusivity Determinations Fiscal Years 2018 and 2019, <https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=osmp&status=public&id=OSMP-OOPD-Number-orphan-drug-approvals-in-the-month&fy=2019>.

¹⁹⁷ See, e.g., FDA, Rare Disease Day 2020, <https://www.fda.gov/industry/orphan-products-development-events/rare-disease-day-2020#:~:text=%22Rare%20is%20many.&text=On%20February%2029%2C%202020%2C%20FDA,of%20which%20have%20n o%20treatment>.

¹⁹⁸ Kathleen L. Miller, *Do Investors Value the FDA Orphan Drug Designation?*, 12 ORPHANET J. OF RARE DISEASES 114, 115 (2017) (demonstrating stock prices increasing by 3.36% after the announcement of the orphan drug designation).

Philippe Gorry & Diego Useche, *Orphan Drug Designations as Valuable Intangible Assets for IPO Investors in Pharma-Biotech Companies*, (Nat'l Bureau of Econ. Research, Working Paper No. 24021, 2017), <https://www.nber.org/papers/w24021>. See also Dayton Misfeldt & James C. Robinson, *Orphan Diseases or Population Health? Policy Choices Drive Venture Capital Investments*, Health Aff.: Blog (July 21, 2017), <https://perma.cc/ZE4N-B6RH> (demonstrating venture capital companies growing interest in orphan disease treatments and connecting it to policy choices).

¹⁹⁹ David H. Crean, *Why Invest in Rare Diseases & Orphan Drugs?*, (2.19.2019) <https://pharmaboardroom.com/articles/investments-and-deal-activity-in-orphan-drug-products>.

²⁰⁰ U.S. Dep't of Treasury, Tax Expenditures, Table 19–1: Estimates of Total Income Tax Expenditures for Fiscal Years 2008–2014, available at <https://home.treasury.gov/policy-issues/tax-policy/tax-expenditures>, at 301.

²⁰¹ U.S. Dep't of Treasury, Tax Expenditures, Table 1: Estimates of Total Income Tax Expenditures for Fiscal Years S 2018–2028, available at <https://home.treasury.gov/policy-issues/tax-policy/tax-expenditures>, at 25.

²⁰² See, e.g., Sarah Jane Tribble, *Senator Grassley Launches Inquiry Into Orphan Drug Law's Effect on Prices*, NPR (Feb. 10, 2017), <https://www.npr.org/sections/health-shots/2017/02/10/514373480/sen-grassley-launches-inquiry-into-orphan-drug-laws-effect-on-prices> (stating that officials have become interested in revisiting Orphan Drug legislation); Nicholas Bagley, *Incidental Economist, The Benefits and Costs of Promoting the Development of New Orphan Drugs*, pt. 3 (2017), <https://theincidentaleconomist.com/wordpress/wp-content/uploads/2017/02/2.12-orphan-drug.pdf> (outlining the costs and problems surrounding Orphan Drug legislation).

²⁰³ Carolyn Y. Johnson, *High Prices Make Once-Neglected "Orphan" Drugs a Booming Business*, WASH. POST (Aug. 4, 2016), https://www.washingtonpost.com/business/economy/high-prices-make-once-neglected-orphan-drugs-a-booming-business/2016/08/04/539d0968-1e10-11e6-9c81-4be1c14fb8c8_story.html.

²⁰⁴ See LiHsien Rin-Laures & Diane Janofsky, *Recent Developments Concerning the Orphan Drug Act*, 4 HARV. J. L. & TECH. 269, 282–87 (1991). See also *Developing Products for Rare Diseases & Conditions*, FDA, <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm2005525.htm> (outlining the success of the

University urged the government to close orphan drug loopholes and prevent pharmaceutical companies from gaming the system.²⁰⁵ They claimed the majority of the best-selling drugs had enjoyed “orphan” designation in their nascent stages by initially listing only a single indication for the drug’s use, but past FDA approval ended up being marketed off-label for much more common conditions while inflating drug prices and hiking insurance premiums.²⁰⁶ Moreover, a recent study even demonstrated that, on the whole, certain “rare” diseases are not so uncommon and influence 25 to 30 million people in the U.S.²⁰⁷ As such, and with the combination of government fiscal and administrative benefits, they can become lucrative investments.²⁰⁸

On the other hand, tax practitioners criticized that the scope of the credit was very limited, as it only covered costs connected with human clinical testing rather than pre-clinical animal testing or research for the development of therapeutic compounds.²⁰⁹ The credit is restricted and does not cover basic research into the sources and causes of rare illnesses, such as preventative or genetic factors research. During the enactment of the Tax Cuts and Jobs Act in 2017, policymakers estimated that the orphan tax credit, at its current rate, would cost the government more than \$47 billion over the next decade.²¹⁰ Accordingly, the credit rate for the orphan drug credit was reduced to 25% for tax years beginning in 2018.²¹¹ With the reduction in the credit rate, the estimated revenue loss due to the orphan drug credit is projected to be around \$1.8 billion a year.²¹²

D. The Late Qualifying Therapeutic Discovery Project Credit (“QTDP credit”)

Enacted as part of the Patient Protection and Affordable Care Act of 2010,²¹³ the QTDP credit provided companies with 250 or fewer employees a 50 percent nonrefundable investment tax credit (up to a maximum credit of \$5 million per firm) for costs paid or incurred in qualifying therapeutic discovery projects.²¹⁴ The government allocated \$ 1 billion under the QTDP credit for

Orphan Drug Act). But see Johanne Bissonette, *Close-up on Rare Diseases and Orphan Drugs*, UNIVALOR, <http://www.univalor.ca/en/media/article/close-rare-diseases-and-orphan-drugs>, (mptomh that only 400 rare diseases out of the 7000-8000 rare diseases have an FDA approved treatment).

²⁰⁵ Martin Makary, “Orphan Drug” Loophole Needs Closing, *Johns Hopkins Researchers Say*, *JOHNS HOPKINS MEDICINE*, Nov. 19, 2015,

https://www.hopkinsmedicine.org/news/media/releases/orphan_drug_loophole_needs_closing_johns_hopkins_researchers_say#:~:text=Health%20experts%20at%20Johns%20Hopkins,In%20a%20commentary%20published%20Nov (citing commentary published at the American Journal of Clinical Oncology).

²⁰⁶ *Id.* (providing the example of the drug rituximab, originally approved to treat follicular B-cell non-Hodgkin’s lymphoma that affects 14,000 patients a year but later used for other types of cancer and organ rejection, and rheumatoid arthritis that affects 1.3 million Americans and becoming the 12th best seller drug in the U.S..).

²⁰⁷ David E.Fagnan, Austin A.Gromatzky, Roger M.Stein, Jose-MariaFernandez, and Andrew W. Lo, *Financing Drug Discovery for Orphan Diseases*, 19 *DRUG DISCOVERY TODAY* 533, 537 (2014).

²⁰⁸ *Id.* (The study utilized information from 28 nonclinical vagrant medication ventures at the National Institute of Health’s National Center for Advanced Translational Sciences (NCATS) to survey the advantages related with financing orphan drug claiming proper diversification may lead to 25% rates of return.).

²⁰⁹ See David M. Richardson, *The Orphan Drug Tax Credit: An Inadequate Response to an Ill-Defined Problem*, 6 *AM. J. TAX POL’Y* 135, 173-80 (1987) (discussing the disadvantages of the new credit limitation on the type of clinical testing).

²¹⁰ U.S. Dep’t of Treasury, Tax Expenditures FY2017, Table 2a. Estimates of Total Income Tax Expenditures for Fiscal Years 2016-2026, available at <https://home.treasury.gov/policy-issues/tax-policy/tax-expenditures>, at 27.

²¹¹ P.L. No. 115-97, 115th Cong., § 13401(a) (“Modification of Orphan Drug Credit”).

Zachary Brennan, *Senate, House Agree to Cut Orphan Drug Research Credit in Half in Tax Bill*, *Reg. Aff. Professionals Soc’y: Reg. Focus* (Dec. 18, 2017), <https://perma.cc/9UHZ-8VT8>; Katie Thomas & Sheila Kaplan, *Congress Weighs Repeal of Tax Credit for Rare Disease Drugs*, *N.Y. TIMES* (Nov. 8, 2017), <https://perma.cc/ARC9-96RD>.

²¹² U.S. Dep’t of Treasury, Tax Expenditures FY2021, Table 2a. Estimates of Total Income Tax Expenditures for Fiscal Years 2020-2029, available at <https://home.treasury.gov/policy-issues/tax-policy/tax-expenditures>, at 25.

²¹³ Section 9023, Qualifying Therapeutic Discovery Project, of the Patient Protection and Affordable Care Act, P.L. 111-148, added new section 48D to the Internal Revenue Code.

²¹⁴ Qualifying therapeutic discovery project expenses did not include any cost for remuneration for employees, interest expense, facility maintenance expenses, service cost. 26 U.S.C. § 48D (repeated 2018).

taxable years 2009 and 2010. The Secretary of Treasury acted in consultation with the U.S. Department of Health and Human Services to award certifications for qualified investments.²¹⁵ A “qualifying therapeutic discovery project” was defined as a research endeavor designed to develop a product, process, or therapy to diagnose, treat, or prevent diseases through pre-clinical activities, clinical trials, clinical studies, and research protocols, or by developing technology or products designed to diagnose diseases and conditions, including molecular and companion drugs and diagnostics, or to further the delivery or administration of therapeutics.²¹⁶

In order to claim the QTDP credit, companies had to go through a grant-like process. Firms had to apply to attain certification for qualifying investments and demonstrate that their project has reasonable potential to result in new therapies to treat areas of unmet medical need. That need could be to prevent, detect, or treat chronic or acute disease and conditions, to reduce long-term health care costs in the United States, or to significantly advance the goal of curing cancer within a 30-year period. Other factors that could help grant applicants were the potential to create and sustain high quality, high paying jobs in the U.S. and advance its competitiveness in the fields of life, biological, and medical sciences. Once granted, firms were able to elect to receive approved QTDP credit in the form of Treasury grants of 50 percent of the qualifying investment (not includible in gross income).²¹⁷

According to the IRS, the QTDP program awarded total grants of \$970 million and \$17 million in total tax credits.²¹⁸ The media reported that over 5,600 applications were filed ultimately awarding 4,606 projects from 2,923 companies deemed eligible. As a result, the most a company could receive for any one project was about \$244 thousands leaving firms disappointed for getting much smaller allotments than requested.²¹⁹ While vaccines research could have qualified under the QTDP credit, the absolute majority of companies receiving grants operated in the field of cancer, chronic diseases, and therapies to repair tissue and organ damage.²²⁰ Finally, the program concluded in December 31, 2013 and was formally repealed in the Consolidated Appropriations Act of 2018.²²¹

E. Patent Donations

Another form of R&D incentive somewhat grounded as a tax apparatus is deductible charitable contributions of intellectual property from for-profit firms to nonprofit organizations such as research institutions and universities. In addition to pursuing altruistic, reputational or other strategic goals, for-profit firms can support a non-profitable organization by transferring unused IP with a potential for stream of income in the future. Through patent donations, firms transfer

²¹⁵ Joint Committee Technical Explanation, JCX-18-10 (2018).

²¹⁶ *Id.*

²¹⁷ IRS Notice 2010-45 (describing the process by which taxpayers can apply to have a therapeutic discovery project certified as eligible for a credit or grant).

²¹⁸ Internal Revenue Service, Businesses, Small Business and Self-Employed, Qualifying Therapeutic Discovery Project Credits and Grants, <http://www.irs.gov/Businesses/Small-Businesses-&Self-Employed/Qualifying-Therapeutic-Discovery-Project-Credits-and-Grants>.

²¹⁹ Steven Overly, *Biotech Grants Stretched Thin*, WASH. POST (Nov. 8, 2010), at A10, (quoting NIH Director Francis S. Collins saying “It was an indication of the great opportunity and interest that there were so many applications received... Of course, with a \$1 billion total amount of money available and with so many of the applicants being judged as entirely appropriate for this program, it was not possible to make awards as large as \$5 million.”).

²²⁰ *Id.*

²²¹ The Qualifying Therapeutic Discovery Project credit was repealed H.R. 1625 the Consolidated Appropriations Act of 2018, P.L. 115-141 (2018).

indolent but conceivably valuable IP to universities and non-profit organizations capable of, or motivated to, develop it.

Large companies like Boeing have made patent donations on multiple occasions. In 2001, Boeing donated to the University of Pennsylvania IP related to a thermoplastic syntactic foam, a type of material Boeing initially developed to eliminate electromagnetic interference in antenna units mounted in aircraft wings. Research performed by University of Pennsylvania scientists on the heels of this patent donation subsequently led to the discovery that this material is bio-compatible and has structural properties similar to those of natural bone, which may render it useful for bone augmentation procedures.²²² The following year, Boeing donated a patent to Vanderbilt University covering particle-separation technology, originally designed for use in outer space and later utilized by Vanderbilt researchers for pharmaceutical nanotechnology.²²³ Subsequently, in 2003, Boeing donated microwave dehydration technology to Washington State University.²²⁴ The technology was originally developed to dry spacecrafts upon ocean landing, but Washington State University researchers were able to use it in R&D on additive-free food products.²²⁵ These are clear illustrations of innovation cycle progression by which a firm unable or uninterested in further developing its technology for additional downstream applications donates it forward to researchers that could successfully advance knowledge and technology diffusion in the pharmaceutical and related areas.

Procter & Gamble is another example of a conglomerate with established track record of donating its IP. In 2000, the firm donated 196 patents covering its COX-2 inhibitor technology—commonly known as “super aspirin”—to Vanderbilt University while providing additional funds for R&D and to cover expenses associated with patent maintenance for a period of three years.²²⁶ At the time, Procter & Gamble’s director of pharmaceuticals noted that the firm was creating more technology than it can possibly develop solely in-house.²²⁷ In 2003, Procter & Gamble donated patents covering a form of nanotechnology known as Cubosome to the Cincinnati Children’s Hospital, who subsequently used it in R&D on a synthetic vernix for coating premature infants.²²⁸

Since 1958, the Tax Code has allowed deductibility of intellectual property contributions in the like of those mentioned above, viewing intellectual property as merely a subcategory of intangible property.²²⁹ Yet, it was not until the late 1990s that firms began to widely utilize this tax benefit realizing they could save millions in tax liability by donating IP to non-profit organizations. Due to the ever-changing nature of intellectual property, there has not been an all-

²²² Boing Mediaroom, *Boeing Patent Donation to the University of Pennsylvania Could Help Treat Bone Disease and Injuries*, Oct. 15, 2001, <https://boing.mediaroom.com/2001-10-15-Boeing-Patent-Donation-to-the-University-of-Pennsylvania-Could-Help-Treat-Bone-Disease-and-Injuries>.

²²³ *Boeing Donates Electrophoresis Patent to Vanderbilt*, VAND. NEWS (Feb. 3, 2002), <https://news.vanderbilt.edu/2003/02/03/boeing-donates-electrophoresis-patent-to-vanderbilt-60112/>.

²²⁴ *Boeing donates patents; food processing could change*, WASH. ST. U. INSIDER (May 9, 2003), <https://news.wsu.edu/2003/05/09/boeing-donates-patents-food-processing-could-change/>.

²²⁵ *Id.*, *ib.*

²²⁶ Leigh Macmillan, *Procter & Gamble Patents to Spark New Drug Discovery*, REPORTER (Nov. 10, 2000), <https://reporter.newsarchive.vumc.org/index.html?ID=1269>.

²²⁷ *Id.*, *ib.*

²²⁸ *Cincinnati Children's Hospital Receives Cubosome Patent Donation from Procter & Gamble*, BIOTECH. PATENT NEWS (Sep. 2003), <http://bi.gale.com.ezp.slu.edu/global/article/GALE|A110537606/894ee293cf403ed7bf117f87bbd1de6?u=sain44199>.

²²⁹ It includes, but is not limited to computer software, Patents, inventions, formulae, processes, designs, patterns, trade secrets, or know-how, Copyrights and literary, musical, or artistic compositions, Trademarks, trade names, or brand names, Franchises, licenses, or contracts, Methods, programs, systems, procedures, campaigns, surveys, studies, forecasts, estimates, customer lists, or technical data, etc. See Internal Revenue Manual 4.48.5.1 (2020).

inclusive definition of such assets, but a guiding list of their common forms. Charitable contributions of qualified intellectual property can include patents, copyrights, trademarks, trade names, trade secrets, know-how, software, and other similar property.²³⁰ To be able to deduct the charitable intellectual property transfer, there needs to be a transfer of the taxpayer's entire interest in the intellectual property to the charity under written agreement that retain the donor's right to manufacture or use the product covered by the patent.²³¹ The transfer agreement has to identify the details of the transfer and acknowledge that the donor has not obtained any economic benefit.

Alas, there are complex issues related to assessing the value of innovation covered under intellectual property donations that harm their effectiveness. It remains a difficult task to transform speculative profits that depend on different future occasions into real present value. Thus, there is much potential for tax planning and abuse.²³² The higher the value claimed for the contributed intellectual property, the greater the tax benefit to the donor. At the same time, there might be little or no benefit to the charities, as many gifts of patents, copyrights, and trademarks turn out to be useless or create far less income than anticipated. Certain firms aggressively used this tactic by donating valueless patents using overinflated valuations to benefit from the charitable deduction. For example, in 1996 Dow Chemical donated to Case Western Reserve University over 10,000 patents and saved over \$40 million in maintenance fees and tax credits.²³³

After widespread abuse of inflating values of IP contributions, in 2004, Congress felt that assessing the actual revenue generated from such property—rather than the expected stream of income—would give a more precise estimate of what the charitable deduction is worth. It passed the American Jobs Creation Act of 2004 that added a rule that the deductible amount of the charitable contribution must be reduced by any long-term capital gain that would be realized if the property were sold at its fair market value at the time of the contribution. De facto, this change limits the charitable deduction for contribution of intellectual property to the donor's adjusted basis. Due to the fact that most intellectual property owners deduct developmental costs, research and experimental costs, or amortize their cost basis over the years, their adjusted basis most likely will be minimal if any; thus, they will not be eligible for significant (or any) deduction for their contribution of intellectual property. Accordingly, Congress followed with a rule allowing a contributors of intellectual property to charity to deduct a certain ratio of projected yearly income produced by such asset for up to 10 years on a sliding rate scale.²³⁴ This change was not significant but added more complexity, uncertainty, and tax controversy.

Today, there are still many complications related to the valuation of innovation rights, projection of income, and other beneficent and domain arrangement, which makes this tax incentive inefficient and costly. The post-2004 cost-basis limitation disincentivized and almost

²³⁰ 26 U.S.C. §170(e)(1)(B)(iii).

²³¹ 26 U.S.C. §170(f)(3); IRS Notice 2004-7.

²³² Teresa Riordan, *Patents; Some Corporations Take Generous Tax Write-Offs for Donated Patents, An Industry Gadfly Says*, NEW YORK TIMES (Mar. 17, 2003) (quoting concerns raised over many patent donations being worthless with overinflated appraisals for tax purposes); Cassell Bryan-Low, *Deductions for Patent Donations Draw Deeper Scrutiny from IRS*, WALL ST. J. (Oct. 7, 2003) (describing IRS agents questioning the legitimacy of the patent valuations).

²³³ Ron Layton & Peter Bloch, *Please Donate Patents on the Shelf; Tax benefits can be Focused for Greater Good*, Legal Times Magazine (Mar. 2004) https://iipi.org/wp-content/uploads/2010/07/IP_Donations.pdf (citing Rick Gross from Dow Industries describing this contribution "25 percent of our patents had no business value. We downsized the portfolio by over 10,000 patents and saved over \$40 million in five years. Additionally, the donation of unused intellectual property has resulted in millions of dollars of tax credits over the past six years.").

²³⁴ 26 U.S.C. §170(m). Tax years 1 and 2- deductible percentage of 100%, tax year 3- 90%, tax year 4-80%, tax year 5-70%, tax year 6- 60%, tax year 7- 50%, tax year 8- 40%, tax year 9- 30%, tax year 10- 20%, tax years 11 and 12- 10%. Id. In order to be eligible for such future charitable deduction the donor must provide a written notice to the charitable organization. §170(m)(8)(B).

diminished the volume of charitable gifts of intellectual property. Many scholars opined that the 2004 change took away entirely economic incentives for patent donations and left non-profit organizations to rely strictly on philanthropy and detached generosity of managers of for-profit organizations.²³⁵ This also likely hindered collaborative efforts between the private and public sector in developing innovations.²³⁶

To summarize this Part, current innovation tax incentives are complex, highly prone to abuse, and apply equally to innovation research done in all types of organizations. Even tax incentives specifically designed for pharmaceutical R&D such as Orphan Drug Credit the late QTDP have applied (and misused) to advance chronic diseases, thus prioritized the latter over vaccine development. Moreover, as will be further demonstrate next, these tax incentives were utilized and benefited mainly established firms with positive income. Small and start-up pharmaceutical companies with little or no positive income that sought to take advantage of the immediate deduction or the R&D and Orphan Drug tax credits had to carry forward these tax benefits to an indefinite point in time when they become profitable, if any. While there is no single best strategy to encourage scientific research for developing new vaccines, the next Part will propose a new framework and a fresh approach to channel funds into advancing human immunology and vaccine discovery in a more effective manner.

V. REDESIGNING TAX POLICY FOR VACCINE DEVELOPMENT

“The fair answer is: Does it have an impact? Yes. Is it the be-all, end-all? No.”

J.J. Finkelstein²³⁷

It is worthwhile at this point to recap the inefficiencies of developing pharmaceutical technologies for human immunotherapy prior to prescribing a proposal to tackle them. In our current day and age, there are numerous pathogens causing diseases for which there are no approved vaccines or therapies.²³⁸ Alas, vaccine development encompasses extreme uncertain conditions and unknowns about market effects, legal implications, competitive conditions, product pricing, and delayed commercialization. Recent anti-vaccination movements prefer relying on risk of infection or herd-immunization than paying for the price of the vaccine. Accordingly, vaccine development suffers from severe underinvestment. Pharmaceutical firms face long lags in harvesting returns on their vaccine research investments compared to ordinary investments in common drugs. Even the few firms that do pursue vaccine development face low return on investment because vaccines are typically a one-time-use product with low rate of repeat users. Specifically, the clinical trial, traditionally conducted in three phases of increasing size, are the

²³⁵ Bo Carlsson, Jeffrey Glass, Craig Nard & Richard Barrett, *Intellectual Property (IP) Management: Organizational Processes and Structures, and The Role of IP Donations*, 33 J. TECH. TRANSFER 549 (2008) (“generating good will, profiting from tax deductions and other financial benefits, and philanthropy were motives of the firms to donate their patents.”). But see *Tax Treatment of Patent Donations in a Post-Jobs Act World*, 18 HARV. J. L. & TECH. 295 (2004) (“By reducing the deduction granted from fair market value to a percentage of the donee’s income, the American Jobs Creation Act begins the realignment of the practice of patent donation with the public interest.”).

²³⁶ Nicole Ziegler et al., *Why Do Firms Give Away Their Patents for Free?*, WORLD PATENT INFORMATION xxx (2013) 1–7, <https://www.hiig.de/wp-content/uploads/2014/02/1-s2.0-S0172219013001592-main.pdf> (“Since a change of law regarding tax benefits through patent donations in 2004, the incentives for firms to donate moved away from mainly being financial-drive towards a combination of financial benefits and fostering innovation”).

²³⁷ J.J. Finkelstein, President and chief executive of RegeneRx remarking on his company’s experience with the QTDP credit in Overly, *supra* note 219.

²³⁸ See e.g. Stanley A. Plotkin et al., *Establishing a Global Vaccine-Development Fund*, 373 NEW ENGL. J. MED. 297, 298 (2015) (listing vaccine-preventable diseases for which there is no commercially available vaccine).

most cost-intensive than any other drug development process.²³⁹ In order to maintain protection of human subjects in research the FDA requires compliance, knowledge, and heavy investment in human capital with expertise in clinical administration, medical recruitment, HIPAA procedures and confidentiality, and scientific control processes that the public sector cannot provide on its own.²⁴⁰

For those reasons, the level of private spending on vaccine discovery falls short of the amount that is warranted by the social benefits of advancing human immunology. The total return to society from vaccine development and prevention of a widespread outbreak is much greater than the return on investment for the few pharmaceutical firms that do engage in such research.²⁴¹ As noted above, an outbreak may temporarily reduce or suspend some of these market inefficiencies, but we should be careful not to assume it solves them. If anything, the recent Covid-19 pandemic provided an extreme illustration of the importance of preparedness and prevention to the well-being of society and the economy.

Hence, government intervention is essential to drive the demand for scientific innovation in the immunology field. Public health imperatives prescribe robust vaccine development as the most cost-effective tool to prevent wide-spread and increased health costs. Society already spends abundant resources on R&D acknowledging its importance to spurring innovation. Alas, at present, current tax incentives used to spur R&D generally, and in the pharmaceutical context, fail to accord to differences between mainstream drugs and vaccines, or allocate efficiently resources for vaccine research. There exists, today more than ever, a stark justification to reassess and redirect such government intervention in more efficient ways by better targeting incentives for vaccine research and development.

In this Part we propose ways by which the tax system can be more redesigned more effectively in the vaccine context than direct subsidies. The tax system puts the choice of projects and progression into private hands with better knowledge and expertise to make such decisions than public health agencies. Next, we introduce specific ways by which policymakers can better employ the tax system via existing tax measures to increase preparedness and reverse insufficient levels of pre-outbreak vaccine research and development.

A. Prioritizing Underfunded Qualified Vaccine Discovery Projects

Today, even as epidemics and pandemic are projected to occur with increased frequency,²⁴² tax incentives for vaccine development are still perceived by most players in the pharmaceutical research arena as anecdotal and trivial.²⁴³ Taxation does not provide strong enough mechanisms to nudge companies towards making huge investment in time and money in therapeutic discoveries. Tax benefits provide good fortune the accounting firm may come upon at the end of the year, but it is far from affecting, or being factored as a meaningful part of, the decision to

²³⁹ See *supra* note 194 and accompanying text.

²⁴⁰ See, e.g., W. Nicholson Price II, *Making Do In Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 510-511 (2014) (describing the stages of undertaking new drug through three phases of expensive clinical trials); Jacob S. Sherkow, *Cancer's IP*, 96 N.C.L. REV. 297, 333 (2018) (noting clinical trials are expensive, arduous, multiyear affairs).

²⁴¹ On the uncertainty that is involved in developing innovation see generally, Eyal-Cohen, *Through the Lens of Innovation*, 43 FLA. ST. U. L. REV. 951, 978 (2016).

²⁴² See e.g. GAVI, 5 REASONS WHY PANDEMICS LIKE COVID-19 ARE BECOMING MORE LIKELY (Apr. 22, 2020), <https://www.gavi.org/vaccineswork/5-reasons-why-pandemics-like-covid-19-are-becoming-more-likely>

²⁴³ See *infra* note 237 and accompanying text.

engage in vaccine research efforts. However, it is possible, that if structured appropriately, the tax system may offer purposeful ex ante subsidies for vaccine research that can complement other ex post IP and non-IP incentives for vaccine innovation.

We begin with a general observation that we need to change the fact that the current tax system values investment in drugs that target common or chronic ailments over vaccine research.²⁴⁴ Drug development generally, and vaccines research specifically, are extremely costly activities. Yet, vaccine research endeavors yield limited profits compared to ordinary drugs thus suffer from severe underinvestment and amplified market uncertainty. We emphasize that by applying the same level of tax incentives to both traditional, technological, and pharmaceutical innovations to vaccine research is flawed. Treating all types of pharmaceutical research efforts the same under our tax system, fails to recognize the opposite effect occurs. Such equal treatment of investments with unequal returns pushes rational developers and investors away from vaccine research towards common and mainstream drugs or stirs them altogether in favor of investments in non-medical technological innovation.

Furthermore, recent tax changes that expanded and made the R&D credit permanent, yet at the same time, narrowed the orphan drug credit from 50% to 25% of clinical trials outlays worsened vaccines' position.²⁴⁵ Such reduction (made to prevent widespread abuse), in and of itself, further lowers the return-on-investment ratio on development of vaccines and rare diseases compared to ordinary diseases.²⁴⁶ Providing lower tax incentives to socially desired vaccine research that up-front holds less profit-potential nudges companies towards conventional drugs for widespread or common illnesses and frustrates the social goal of vaccine preparedness.

1. A Novel Proposal to Incentivize Vaccine Discovery: Tax Grants

To solve such discrepancies, we propose to increase available capital for vaccine research and its rate of return by adapting current tax incentives to desired levels of vaccine preparedness as they appear. We suggest a combination of ex ante apparatuses that combine tax and grant-like mechanisms in the form of tax incentives for predetermined list of qualified underfunded diseases.²⁴⁷ Vaccine research performed for emerging transmittable diseases on the list will deliver firms at the end of the year via their tax returns tax benefits without the need to apply. Increasing the level of funding channeled via tax incentives for vaccine discovery may be a balance against lowering the level of IP and non-IP incentives, and vice versa.

Such tax incentives should be provided to firms engaged in vaccine discovery regardless of their financial viability. As state above, current market inefficiencies present low incentives for vaccine R&D that discourage firms of all types, large or small, in pursuing such endeavor. Yet, emerging, smaller-scale life science companies often struggle more to secure financing as they present increased risk opportunities for investors. Research, clinical trials and regulatory review are cash-intensive and time-consuming, with the prospect of returns often years away. Vaccine

²⁴⁴ See *supra* notes 141-153 and accompanying text.

²⁴⁵ Modification of Orphan Drug Credit, Pub. L. No. 115-97, § 13401, 131 Stat. 2054, 2133-34 (Dec. 22, 2017).

²⁴⁶ See Rachel E. Sachs, *The Uneasy Case for Patent Law*, 117 MICH. L. REV. 499, 512 (2018) (describing this change as “the first instance of a Congressional walk-back since Congress began creating these incentives in the early 1980s”). See also Ryan Cross, Drug Company Earnings Outlook Bolstered by Tax Cuts and Repatriated Cash, Chem. & Eng'g News (Feb. 8, 2018), <https://cen.acs.org/articles/96/i7/Drug-company-earnings-outlook-bolstered.html>

²⁴⁷ See *infra* Part V.A.2.

research often presents even more reduced prospects of a return-on-investment. Accordingly, in order to maintain the financial and political feasibility of our proposal we suggest applying tax incentives for vaccine research in a gradual level. While larger, publicly traded pharmaceutical companies may have plenty of alternative sources of financing available, cash-strapped and startup pharmaceutical firms much more limited in their access to outside funding. The latter rely more heavily on immediate funding through internal sources and outside grants.

Our framework suggests providing tax incentives for vaccine research to all firms while delivering higher degree of tax benefits for private pharmaceutical firms with limited scope, scale, and size. We envision a tiered vaccine tax incentives system that will give vaccine developers an immediate reduction in their cost of vaccine research at the end of each tax year as opposed to rewards given to selective few via grants or prizes at the end of a successfully proven application process. Dependent on budget constraints, these tax incentives can be adjusted according to levels of vaccine preparedness needed in the U.S. based on world health conditions.

Past attempts to provide “tax-grant-like” incentives such as the late QTDP credit mentioned above proved there are small pharmaceutical firms willing and able to delve into research of neglected and acute diseases if only capital will be accessible. Nevertheless, the high demand for QTDP resulted in firms receiving much less funding than they requested in this “tax-grant-like” application. The focus on the grant-nature of the QTDP, as well as its cumbersome application process and broad list of qualified approved projects, were several reasons for its failure to provide effective and meaningful incentives for long-term pharmaceutical research.

We offer a simpler model. The central feature of our proposal lies in incorporating tax refundability. We propose making existing R&D and the Orphan tax credits refundable on a tiered basis for specifically designated list of underfunded diseases with communicable record. This will offer pharmaceutical firms for every dollar invested in vaccine research development up to 20 cents cash back pre-trial and up to 50 cents refund during human trial phase from the government at the end of the year regardless of their profitability status. Tax refundability is a main feature of our proposal due to its ability to instill greater equity in the market of tax incentives for innovation. While the value of deductions and credits depends on firms’ financial viability, refundable tax incentives are not contingent on where firms are situated in the tax brackets. Refundable tax incentives for predesignated underfunded vaccine research can play an instrumental role for capital-constrained firms in ex ante manner. Moreover, providing tax refunds avoids discrepancies in the integral value of tax benefits to firms with diverse applicable tax rates or those with net operating losses at the end of the year, such as startup or small pharmaceutical companies.

Take, for example, startup biotechnology company NewVax with no positive income that invested \$100,000 in designated vaccine research this year. NewVax will receive a check of \$20,000 at the end of the year after filing its tax return. On the other hand, publicly traded BigVax that invested the same amount could receive a benefit of only \$10,000 when filing its tax return, a smaller incentive but enough to be captured by managers and investors as increasing the return-on-investment in vaccine research. Once the human trial phase begins, for every dollar invested the government will offer a refund at the end of the year of 50 cents to NewVax and 25 cents to BigVax. The upshot of these tax benefits is that for every \$1 NewVax invests in pursuing vaccine research it immediately receives from the government 20 cents pre-trial and 50 cents during the human trial phase. BigVax will receive from the government only 10 cents pre-trial for every \$1 invested in vaccine research and 25 cents per \$1 invested during the human trial phase.

Restructuring the current R&D and Orphan drug credits as refundable for selective qualified underfunded vaccine research will provide firms with immediate subsidy within a short timeframe and cut the long-delayed rewards, that may (or may not) await them, at the end of the research and development process. It will guarantee that the public and the government, whose priority it is to encourage advance human immunology, vaccine discovery, and immunotherapy research for potentially critical infectious diseases, are indirect partners in this endeavor. Such mechanisms will have a similar effect to providing a grant to vaccine research but utilize the tax system to skip the application process. This will also improve competition in the private market for vaccines. There will not be an onerous submission process with limited available spots. All companies involved in qualified research in predetermined list of diseases will be eligible to receive the benefit based on actual investments reported in their tax return.

Searching for the vaccine discoveries or new therapeutic breakthroughs entails making many observations and studying inefficiencies, incorrect methods, or failed processes with the aim of improving them or creating new ones. Our proposal for prioritizing underfunded vaccine research via ex ante refundable tax credits and other complementing tax routes²⁴⁸ will further enhance knowledge spillover in the pharmaceutical field. We emphasize in our framework the notion that every form of genuine vaccine research (performed in the limited list of predesignated transmittable diseases) is valuable in providing scientific information to society on pathogen structures and mechanism, what therapeutic agent works (or does not work), rather than only rewarding selective developers that provide close-to-perfect therapies in a hasty manner solely with deadlines and rewards in mind.

The dissipation of costs of precuring knowledge spillover in vaccine research will be thus distributed through the tax system more equitably on all taxpayers as future benefactors of such knowledge. Claiming and benefiting from the proposed tax benefits will require firms to publish information on their scientific inquiries and preliminary results (while maintaining IP knowledge confidential similar to the case of grants and prizes) so to avoid duplication of research efforts. Accordingly, while the ex-ante tax incentives will increase the number of participant firms who are willing to risk the chance of reaching human immunology breakthroughs, at the same time, it will no longer render valueless investments in vaccine discoveries that came in second or third in place, or even failed. This approach is supported by prominent innovation scholars that have long considered failure as important as— and often an inseparable part of the process of attaining—breakthroughs and success.²⁴⁹

2. Administrating A List of Underfunded Emerging Infectious Diseases

The recent pandemic proved there is immense economic and social value to government investment in the future of vaccine research. Accordingly, policymakers should tailor tax rewards to advance and adjust priorities based on underfunded, rather than simply orphaned, vaccine research. In setting such priorities the government may be in an informational disadvantage relative to market actors on the substantial research involved in pathogens and pharmaceutical technology development. It may lack the ability to appraise potential projects, funding available

²⁴⁸ See *infra* Part V.B.

²⁴⁹ SCHUMPETER, JOSEPH A. SCHUMPETER, *The Theory of Economic Development* (1934), reprinted in THE ENTREPRENEUR: CLASSIC TEXTS BY JOSEPH A. SCHUMPETER 48-50 (Markus C. Becker et al. eds., 2011); KIRZNER, ISRAEL M. KIRZNER, COMPETITION AND ENTREPRENEURSHIP 51 (1973) (arguing that entrepreneurial failure is important in facilitating the innovation process).

for their development, and their benefits. Accordingly, our proposal suggests an advisory committee of domestic health and science organizations such as the FDA, CDC, NIH, will be charged with designating the list of underfunded vaccine research importance based on periodic evidence and monitoring of local occurrences, investments, and subsidies available around the world. To be clear, the special scientific advisory committee should not be engaged in the decisions of *who* gets the preferential vaccine tax treatment but *what* underfunded diseases are eligible to be on the list.

Using tax incentives allows the government to focus solely on the decision of setting vaccine priorities based on observed evidence and leaving the scientific decisions to the pharmaceutical developers. IRS agents should be required only to examine the input of predesignated vaccine research projects based on existing definition in the Tax Code of eligible research expenses. The output of R&D vaccine research process, whether effective new therapeutic breakthrough or not, will be appraised by the scientific community, the public, and the market. Adding a refundability feature to the current tax incentives for predesignated vaccine research can be an effective behavioral mechanism that could even allow tweaking current levels of innovation incentives such as modifying patent protection, grants, and prizes based on budgetary and public health priorities. As noted above and as in the current practice with government grants, policymakers should require firms to make knowledge from preferential tax treatment for qualified vaccine discovery projects available to the public to speed knowledge spillover and refrain from paying twice (or more) for the same knowledge procurement process.²⁵⁰

While bolstering the tax system as a locus for incentives to R&D may raise well-founded administrability concerns²⁵¹—as well as giving rise to resource-related considerations—we note here several features of our proposal that reduce the risk of overburdening the tax system and the IRS while administering our proposal. From a technology perspective, the type of innovation that our proposal seeks to incentivize is relatively simple—as evidenced by the recent Ebola, Zika and COVID-19 public health crises, vaccine development targeting these types of pathogens can occur on considerably expedited timelines. With the exception of one of the leading COVID-19 vaccine candidates (an mRNA vaccine developed by Moderna, which, if successful, would introduce a new form of vaccine technology)²⁵² many vaccines needed to prevent or mitigate large-scale public health crises borrow from pre-existing vaccine technology and components. For instance, the leading Zika vaccine candidate developed during the 2015-16 outbreak was adapted from a pre-existing vaccine developed by the same institution for a pathogen in the same viral family as Zika (the pathogen causing Japanese encephalitis).²⁵³

Seeing the relative simplicity and identifiability of the underlying list of predesignated vaccine technology, our proposal is more easily administrable than a proposal covering heterogeneous types of technology, or even the entire field of vaccine therapies as a whole. The tax incentives we propose can and should be explicitly restricted to research on predesignated vaccine-preventable transmittable diseases—diseases for which there are long-felt critical

²⁵⁰ For a comprehensive discussion of pay-twice arguments, see Rebecca E. Wolitz, *The Pay-Twice Critique, Government Funding, and Reasonable Pricing Clauses*, 39 J. LEG. MED. 177 (2019).

²⁵¹ See *infra* Part V.C.

²⁵² See MODERNA, *Moderna Advances Late-Stage Development of its Vaccine (mRNA-1273) Against COVID-19* (Jun. 11, 2020), <https://investors.modernatx.com/news-releases/news-release-details/moderna-advances-late-stage-development-its-vaccine-mrna-1273>

²⁵³ Rutschman, *Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine* 127 YALE L. J. FORUM 651, 654 (2018).

underinvestment, despite the enormous public health toll associated with their occurrence. Tailoring the tax-based incentive to this particular set of diseases furthers vaccine-specific research goals while implementing a compact incentives regime within the tax system.

The configuration of pre-selected diseases eligible for these incentives can be easily modeled after existing lists tracking either vaccine-preventable diseases for which there are no commercially available vaccines or lineups of infectious disease pathogens predicted to emerge in the near future. An example of the former are files found in the medical literature by leading scientist in the field of vaccinology.²⁵⁴ An example of the latter is offered by the World Health Organization list of pathogens expected to cause significant outbreaks in the short- and medium-term.²⁵⁵ There are also examples of directories of prize- or grant-eligible diseases in the United States' pharmaceutical innovation ecosystem: for instance, the priority review voucher program administered by the FDA that we surveyed in Part III²⁵⁶ was initially based on an index of voucher-eligible diseases created by Congress.²⁵⁷ The list was originally limited to 16 diseases, including Malaria, Cholera and Tuberculosis, and was later expanded to include other diseases like Ebola and Zika.²⁵⁸ Congress gave the FDA the authority to manage the list by adding "[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations."²⁵⁹ The FDA has used this authority to expand the directory of diseases, and has also solicited public recommendations on possible additions to it.²⁶⁰ Congress itself has intervened in this area, passing legislation that specifically added Ebola and Zika to the list during the 2014-15 and 2015-16 outbreaks, respectively.²⁶¹ Public health-oriented agencies in the United States—such as the FDA, CDC and NIH—are the most well-positioned to administer or to play an advisory role in regards to the list of tax benefits-eligible diseases in connection with meritorious vaccine research that we propose in this Article. Finally, an additional advantage of our vaccine tailored proposal is that it borrows from institutional and administrative features that exist already in our legal architecture and innovation tax policy apparatuses, which lowers learning, complexity, and compliance costs as will be further detailed in Part V.C.

B. Complementing Routes to Encourage Vaccine Collaboration Through the Tax System

1. Increasing Collaborations Around Basic Research

Covid-19 pandemic illustrated that the role of universities in developing vaccines could be much greater. Accordingly, the government may seek to further encourage collaborations in vaccine research between non-profit organizations and for-profit pharmaceutical firms by providing the latter with refundable basic research credit for underfunded designated vaccine research. At times, for-profit pharmaceutical firms may find it more efficient to outsource portions

²⁵⁴ See Plotkin, *supra* note 238.

²⁵⁵ WORLD HEALTH ORG., *supra* note 10, at 22 (2016).

²⁵⁶ See *supra* notes 124-126 and accompanying text.

²⁵⁷ See Rutschman, *The Priority Review Voucher Program at the FDA*, *supra* note 126, at 74 (providing an overview of the genesis and scope of the priority review voucher program).

²⁵⁸ *Id.*, at 78-79.

²⁵⁹ *Id.*, at 79. See also U.S. FOOD & DRUG ADMIN., TROPICAL DISEASE PRIORITY REVIEW VOUCHERS GUIDANCE FOR INDUSTRY (2016), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080599.pdf>, at 4.

²⁶⁰ U.S. FOOD & DRUG ADMIN., FDA-2008-N-0567 (Nov. 5, 2008), <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-N-0567-nhc.pdf>.

²⁶¹ Rutschman, *The Priority Review Voucher Program at the FDA*, *supra* note 257 at 87. See S.2917 - Adding Ebola to the FDA Priority Review Voucher Program Act; Public Law No: 113-233, Dec.16, 2014.

of basic research rather than engage in all intricate facets of the discovery process. Once initial scientific progress is made by the contracted non-profit, firms can then take that knowledge and commercialize it. Essentially, adding a refundable basic research tax incentive for vaccine R&D will even the level of benefits and allow firms to choose the most effective path to procure scientific knowledge, whether inhouse or subcontracting with non-profit, without losing the preferential tax treatment given to vaccine R&D under our proposal.

There is already a collaborative tradition in vaccine research during outbreaks of infectious diseases in which universities play a salient role. The recent COVID-19 outbreak illustrates this point: universities across the United States joined vaccine development projects as early as March 2020, from the University of Pittsburgh to the University of Texas to Colorado State University.²⁶² Outside the context of pandemics there are currently nine institutions—such as Emory and Saint Louis University—operating on a long-term basis as Vaccine and Treatment Evaluation Units (VTEUs).²⁶³ Our proposed framework can be used to further expand existing collaborative networks in the vaccine space. In particular, it incentivizes greater involvement of the non-profit sector in pre-clinical vaccine research through the tax credit given to firms in the private sector for contracting out basic vaccine research to non-profit entities.

The COVID-19 pandemic has illustrated how collaborations between industry and non-profit organizations deserve greater attention from an incentives perspective. For example, large pharmaceutical company Merck partnered with IAVI, a nonprofit scientific research organization,²⁶⁴ to use Merck-owned vaccine technology developed in response to the 2014-16 Ebola outbreak in research related to a COVID-19 vaccine candidate.²⁶⁵ Absent catalytic public health crises like COVID, however, industry-nonprofit collaborations are rarer in the vaccine R&D space. Yet, as the Merck/IAVI example shows, there are several types of vaccines that can be developed through adaptation of pre-existing vaccine technology.²⁶⁶

Ideally, this type of therapeutic research—which relies on relatively simpler and more well-understood forms of technology than many other types of vaccine research—should be incentivized during the pre-outbreak as strategic research and experimentation to increase our levels of preparedness.²⁶⁷ Recent history has nonetheless shown that most players in the private sector are fairly irresponsive to these needs before a large-scale outbreak occurs.²⁶⁸ Our proposal addresses this disjunction between preparedness needs and market-driven R&D strategies by

²⁶² See Lilah Burke, *The Race for a Vaccine*, INSIDE HIGHER ED. (Mar. 4, 2020), <https://www.insidehighered.com/news/2020/03/04/universities-role-race-develop-vaccine-coronavirus>.

²⁶³ See U.S. Nat'l Inst. Health, Vaccine and Treatment Evaluation Units (VTEU) (2015), <https://grantome.com/grant/NIH/272201300019I-0-27200001-1>. Although VTEUs receive public funding, they are involved in clinical trials for vaccine candidates resulting from public-private collaborations.

²⁶⁴ INTERNATIONAL AIDS VACCINE INITIATIVE (IAVI), About, <https://www.iavi.org>

²⁶⁵ Sam Meredith, *Merck in Collaboration to Develop Coronavirus Vaccine, with Clinical Trials to Start This Year*, CNBC (May 26, 2020), <https://www.cnbc.com/2020/05/26/coronavirus-merck-to-develop-vaccine-clinical-trials-to-start-later-this-year.html>

²⁶⁶ Other recent examples of this phenomenon include the U.S. Army's use of a Japanese encephalitis vaccine to develop a Zika vaccine candidate on an expedited R&D timeline. See e.g. Annette M. Boyle, *Army Research Produces Zika Vaccine Candidate in Record Time*, U.S. MED. (Aug. 2016), <http://www.usmedicine.com/agencies/department-of-defense-dod/army-research-produces-zika-vaccine-candidate-in-record-time>

²⁶⁷ See WORLD HEALTH ORG., *supra* note 10, at 20. See also Yaniv Heled et al., *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, __ J. L. BIOSCI. __ (2020).

²⁶⁸ AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS, *supra* note 13.

incentivizing players in the vaccine research ecosystem to more regularly partner with nonprofit institutions, and to do so before outbreak-induced vaccine races take place in a crowded R&D environment.

2. Incentivizing Patent Donations of Vaccine Technology

The key non-tax impetuses of patent donations are reducing costs through preserving research efforts, better management of intellectual property inventory, and saving maintenance fees. Companies like IBM with tens of thousands of patents tend to spend millions of dollars a year on maintenance fees.²⁶⁹ Some intellectual property may not be consistent with the firm's current technological mission, appropriate for licensing to third parties, or valuable in competitive markets. In those cases, patent donations can be an effective way to avoid having potentially valuable technologies sitting idle or abandoned when they do not fit with the firm's existing priorities. The deductibility of patent donations provides significant premium. Yet, by eliminating the financial benefit of charitable donations of intellectual property the current tax regime fails to incentivize socially desirable donations.²⁷⁰

If structured correctly, patent donations can become a catalyzer for vaccine innovation.²⁷¹ One way the government may encourage private-public collaborations is by modifying the current manner by which firms calculate the value of intellectual property relating to vaccine technology donated to obtain a charitable deduction. Rather than the formula used from 2004 restricting taxpayers to the cost basis of the donated intellectual property (usually trivial or zero), the government can revert to the pre-2004 rule that relied on the fair market value (FMV) of the donated intellectual property. Indeed, valuations are extremely subjective and appraisals of intellectual property are highly susceptible to manipulation especially in vaccine research where value of new therapeutics and developments are very hard to identify. Scholars have proposed a variety of solutions to prevent future abuse and overvaluation concerns such as structured reporting and clearer standards for valuation.²⁷² Others suggested qualified appraisal requirements, penalties on appraisers for valuation errors, heightened information requirements, and lengthening the statute of limitations.²⁷³

As noted above, there have been multiple instances in which patent donations served as an important tool for transfer of technology and knowledge spillover across industries.²⁷⁴ Yet, the charitable tax deductions of patent donations have suffered from a questionable past and complex present. Given the potential of patent donations as catalyst to vaccine research, we propose that the government experiment with a patent donation tax regime similar to the one in place before 2004 with appropriate new anti-abuse mechanisms in the field of vaccine R&D for underfunded

²⁶⁹ Layton & Bloch, *supra* note 233.

²⁷⁰ Xuan-Thao Nguyen & Jeffery A. Maine, *Giving Intellectual Property*, 39 U.S. DAVIS L. REV. 1721 (2006) (criticizing the 2004 amendment and calling for adopting of a Fair Market Value deduction for Patent donations.).

²⁷¹ Bo Carlsson, Jeffrey Glass, Craig Nard & Richard Barrett, *Intellectual Property (IP) Management: Organizational Processes and Structures, and The Role of IP Donations*, 33 J. TECH. TRANSFER 549 (2008) ("generating good will, profiting from tax deductions and other financial benefits, and philanthropy were motives of the firms to donate their patents.").

²⁷² Nicholas C. Tomlinson, *Tax Abuse Halting Progress? An Inside Look at Patent Donations and Their Tax Deductibility*, 35 SW. U. L. REV. 183 (2006) (explaining a study by Arthur Anderson in 1992 demonstrating the profitability of patent donations – catalyzed the practice by corporations.).

²⁷³ William A. Drennan, *Charitable Donations of Intellectual Property: The Case for Retaining the Fair Market Value Tax Deduction*, 2004 UTAH L. REV. 1045 92004) (proposing ways to lessen abuse in patent donations).

²⁷⁴ Xuan-Thao Nguyen & Jeffery A. Maine, *Giving Intellectual Property*, 39 U.S. DAVIS L. REV. 1721 (2006) (criticizing the 2004 amendment and calling for adopting of a Fair Market Value deduction for patent donations.).

diseases.

So far, the patent donation mechanism has been overlooked as a strategic tool in vaccine innovation policy—in spite of an early example of patent donations having occurred precisely in connection with vaccine technology, as a donation of involving a patent on a Malaria vaccine candidate was made to the World Health Organization in the 1990s.²⁷⁵ A study done shortly before the 2004 change interviewing industry, academics, and professionals concluded that most corporate donors and university recipients think tax incentives for patent donations have nonquantifiable benefits such as developing university-industry collaborations, increasing to inventor morale, and providing more research opportunities for faculty. The study concluded “what policy-makers need is more numbers, more facts, and more information about transactions so that the effectiveness of the program can be measured.”²⁷⁶

Experimenting with a new and improved patent-donation rule earmarked for a closed predesignated list of underfunded diseases should not also require highest complex and substantial valuation issues that the advisory committee comprised of FDA, CDC, NIH and other health science institutes cannot unravel. Such venturing with a small-scale of intellectual property donors and universities in the vaccine field may provide opportunities for learning and fine-tuning of IP valuation rules as well as empirical data needed for policymakers to decide whether there is enough economic benefit justifying revival or abandonment of this once momentous innovation incentive.³⁸⁷

C. Potential Problems

1. Abuse and Gamesmanship

We recognize that the creation of specialized incentives regimes can attract—and has engaged—players seeking to explore loopholes in the system by mislabeling activities as qualified R&D or minimizing R&D investment wherever possible. For instance, in the case of the FDA priority vouchers described above,²⁷⁷ the large Swiss pharmaceutical company Novartis was granted a voucher—designed to reward meritorious R&D—after obtaining FDA approval to market a combination therapy for Malaria that was already registered in 85 markets outside the United States, and which had been in use for the previous 10 years.²⁷⁸

In contrast with more transversal embodiments of incentives regimes such as the voucher program, ours is tailored to a very narrow list of predetermined underfunded infectious diseases and a specific set of biopharmaceutical technologies thus less prone to gamesmanship. It is possible to condition the tax incentives to cases in which a company is the first to develop a vaccine targeting a specific disease, which would ensure that significant levels of R&D would have to occur for the tax benefit to apply—modeled more as tax prizes rather than tax grants.

²⁷⁵ WORLD INTELL. PROP. ORG., SCIENTISTS WITH VISION: DR. MANUEL ELKIN PATARROYO (Sept. 2005), https://www.wipo.int/wipo_magazine/en/2005/05/article_0002.html

²⁷⁶ Layton & Bloch, *supra* note 233.

³⁸⁷ *But see* Natbony, *supra* note 174 (analyzing tax incentives for R&D); RinLaures & Janofsky, *supra* note 374 (discussing recent developments concerning Orphan Drug Act); Kenney, *supra* note 373 (discussing whether Orphan Drug Act inhibits innovation or creates unintended windfalls). [Check out this Scholarly criticism on R&D tax incentives].

²⁷⁷ *Supra*, Part III.C.

²⁷⁸ *See* Tatum Anderson, *Novartis Under Fire for Accepting New Reward for Old Drug*, 373 THE LANCET 1414, 1414 (2009).

Yet, even if the tax incentive is set more broadly—for instance, for vaccine research on incentive-eligible diseases the likelihood for gamesmanship is lower. Given the nature of the goods at stake, the same is true even in cases when the research and experimentation does not result in final approval of a vaccine. The types of vaccines needed to prevent and curb outbreaks of diseases like Zika or COVID-19 are relatively straightforward forms of technological discoveries with a predominantly preventative function.²⁷⁹ Unlike several other types of pharmaceutical products, a given vaccine is unlikely to address multiple conditions.

Consider the following scenario: Humira, the world's top blockbuster drug in the 2010's, has successively received cumulative market approval from regulatory agencies around the world for a broad range of conditions, from adult and juvenile forms of rheumatoid arthritis to multiple types of psoriasis and gastrointestinal diseases.²⁸⁰ A given vaccine cannot be deployed to target such a large swath of conditions.²⁸¹ As a primarily preventative, low-profit (if any), largely single-condition type of technology, vaccines serve limited purposes—albeit crucial from a public health perspective—and have fewer entry points into the regulatory ad hoc incentive system available to them. For those reasons, players willing to enter the vaccine R&D arena expect their return on investment to be inherently limited.²⁸² Between the relative simplicity of vaccine technology and the reduced prospects of profit-maximization, both motivation and opportunity for gamesmanship in this area are significantly lower than elsewhere in pharmaceutical innovation, even when factoring our proposed tax incentives.

2. Complexity

Intellectual property confers monopoly-like power to patent holders, enabling them to charge supra-competitive prices to consumers. Contingent upon demand elasticity, monopoly may create deadweight loss due to the fact that fewer customers will purchase the overpriced product.²⁸³ Similar to patents, cash awards, or any government intervention, taxation unavoidably involves deadweight loss as well. In the framework of imposed taxes, that loss may be created via higher product price to account for, and pass onwards to customers, the additional tax cost, which lowers market demand and creates considerable deadweight loss.²⁸⁴ In the tax incentives context,

²⁷⁹ See *supra* notes 252-253 and accompanying text.

²⁸⁰ See U.S. FOOD & DRUG ADMIN., HIGHLIGHTS OF PRESCRIBING INFORMATION (HUMIRA), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125057s2321bl.pdf. See generally Rutschman, *supra* note 60.

²⁸¹ We again note that our proposal expressly excludes any emerging forms of vaccine technology, such as the mRNA vaccine currently being developed being develop for COVID-19. It is also important to underscore that most vaccine R&D for the types of underfunded diseases contemplated in our proposal rely on standard, well-established forms of technology, not on cutting-edge technology. As of late June 2020, Moderna's mRNA vaccine was the sole R&D project among leading candidates relying on non-standard technology (in a universe of over 140 COVID-19 vaccine R&D projects). See MILKEN INST., COVID-19 TREATMENT AND VACCINE TRACKER, <https://covid-19tracker.milkeninstitute.org> (last accessed Jun. 23, 2020).

²⁸² Rutschman, *supra* note 39, at 742.

²⁸³ For a discussion on pricing Covid-19 vaccines see, e.g., Joseph Walker, *Covid-19 Drug Remdesivir to Cost \$3,120 for Typical Patient*, WALL ST. J. (Jun. 29, 2020), <https://www.wsj.com/articles/covid-19-drug-remdesivir-to-cost-3-120-for-typical-patient-11593428402> (discussing pricing plans for remdesivir); Katherine J. Wu, *Some Vaccine Makers Say They Plan to Profit From Coronavirus Vaccine*, N.Y. TIMES (Jul. 21, 2020), <https://www.nytimes.com/2020/07/21/health/covid-19-vaccine-coronavirus-moderna-pfizer.html> (noting Moderna, however, which has been granted \$483 million from the government to develop its product, made no promise to sell at reduced price); Arlene Weintraub, *Moderna's Rumored \$50-Plus Price on Covid-19 Vaccine Draws Ire as Company Touts New Animal Data*, FIERCE PHARMA (Jul. 29, 2020), <https://www.fiercepharma.com/pharma/moderna-s-rumored-50-plus-price-covid-19-vaccine-draws-ire-as-company-touts-new-animal-data> (comparing proposed price plans for Covid-19 vaccines).

²⁸⁴ See generally David A. Weisbach, *Line Drawing, Doctrine, and Efficiency in The Tax Law*, 84 CORNELL L. REV. 1627, 1656 (1999) ("The most efficient tax system raises the necessary revenue with the lowest deadweight loss.").

deadweight loss may be created due to externalities that arise from taxpayer's compliance and the organization of government.²⁸⁵ Regardless, our goal here is not to accurately estimate the cost of administering the tax mechanisms we proposed earlier. Rather, we aim to outline potential issues that may arise when offering and administering our proposal, while pointing to their narrower capacity in the vaccine context.

Similar to any tax scheme, employing tax incentives involves resources taxpayers devote to conform with tax laws.²⁸⁶ The more complex tax rules are, the higher the costs required to implement them. These compliance and implementation costs are not negligible and may consist of human, financial, intangible, and tangible capital required from both the IRS and taxpayers in applying the rules. They may include costs of completing tax forms, record keeping, reporting, auditing, monitoring, negotiating, advise-seeking, enforcing, and so on. Implementation costs that are too high may render certain tax incentives undesirable from a social normative significance.²⁸⁷

Another form of deadweight loss relates to organization of government that may derive from inefficient administrability or high enforcement costs. Scholars have argued that in the choice of optimal innovation-inducing strategies the organization of government dictates that cash transfers are generally superior to tax incentives.²⁸⁸ Subject-matter agencies possess higher specialization in technological and scientific matters than the IRS that lacks economies of scope in administration and enforcement and simpler intra-agency coordination in that field.²⁸⁹ For example, some of the intricacies of administering R&D tax incentives involve having to determine which expenses are experimental, laboratory-like, or related to information discovery.²⁹⁰ These actions consist of monitoring the technological progress over time, evaluating the R&D process, assessing the scientific or technological nature of the produce, dividing the production process between R&D (deductible) and non-R&D (non-deductible) parts and phases, etc.²⁹¹ These actions may commend scientific expertise the IRS does not possess and that is unrelated to its mission of collecting revenue in an efficient, equitable and simple manner.²⁹² These IRS determinations increase taxpayer uncertainty on attaining and relying on the tax benefit. It is possible, of course, to create more divisions within the IRS to better facilitate specialization in vaccine technology and

²⁸⁵ Frischmann, *supra* note 21, at 385 (stating "the tax system may have high administrative costs compared with other corrective mechanisms.).

²⁸⁶ See Rochelle Cooper Dreyfuss, *Response, Tailoring Incentives: A Comment on Hemel and Ouellette's Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 131, 137 (2014) (outlining compliance and enforcement costs).

²⁸⁷ See Jacob Nussim & Anat Sorek, *Theorizing Tax Incentives for Innovation*, 36 VA. TAX REV. 25, 41 (2017) (developing an organizational theory of implementation costs based on tax expenditures.). But see Shaun P. Mahaffy, *Note, The Case for Tax: A Comparative Approach to Innovation Policy*, 123 YALE L. J 812, 832 (2014) (discussing the advantages of tax credits lower administrative costs); Xuan-Thao Nguyen and Jeffrey A. Maine, *The History of Intellectual Property Taxation: Promoting Innovation and Other Intellectual Property Goals*, 64 SMU L. REV. 795 (2011) (comparing the benefits of utilizing tax v. IP as incentives for innovation).

²⁸⁸ Nussim & Sorek, *supra* note 287 at 57.

²⁸⁹ *Id.*

²⁹⁰ See Israel Klein, *Contemptuous Tax Reporting*, 2019 WIS. L. REV. 1161, 1208 (2019) (demonstrating that some managers use self-reporting of R&D expenditures in order to contemptuously inflate entitlement to R&D tax incentives).

²⁹¹ *Id.* at 1209.

²⁹² See Stephen E. Shay, J. Clifton Fleming, Jr., Robert J. Peroni, *R&D Tax Incentives: Growth Panacea or Budget Trojan Horse?*, 69 TAX L. REV. 419, 444 (2016) (claiming the tax credit leaves an open-ended evaluation process between the government and private parties).

pharmaceutical innovation, but this inevitably increases the intra-organizational costs of coordinating between the divisions.²⁹³

When applied to the context of predesignated underfunded vaccine research, our optimal choice of incentive level should compare the extent of the deadweight loss from compliance and organizational administrability from each apparatus (patents, grants, prizes and tax incentives). Certainly, assuring the R&D and orphan tax credits as well as basic research credit and patent donations would be available past administrative audit is a big hurdle.²⁹⁴ Their complexity and rate of controversy affect the deadweight loss created in applying and administering these innovation tax incentives. Yet, our proposal's limited application to a closed list of underfunded diseases governed by an expert advisory committee should resolve much of such controversies.

As far as organizational administrability, our proposed vaccine-inducing tax apparatuses directly relate to, complement activities within, and may benefit from, the IRS expertise.²⁹⁵ The IRS already observes, measures, and enforces input variables such as income, expenses, organizational choice, financial instruments, without the need for scientific or technological expertise. Indeed, the IRS has no knowledge of biopharmaceutical issues, nor should it have any, in administering vaccine research. Under our proposal, the IRS should have a non-discretionary, or marginally discretionary, administration of the proposed tax incentives. All it needs to do is apply, monitor, and audit the rules based on the discretion applied by the specialized health advisory committee in devising a list of predesignated underfunded diseases. In that sense, the tax incentives operate as grant-like in requiring fit of their nature (rather than their scope) with predigested list. Our proposed solution may also provide future insights in the contexts of inter-agency coordination, managing potential runaway costs, and experimenting with new practices of inducing socially desirable scientific and technological innovation.

3. Political Economy and Public Choice

Tax Scholars have relied on public choice theory to describe the effect of the political process on tax legislation.²⁹⁶ They claimed that tax subsidies are particularly susceptible for abuse by special interest groups because they offer political rent-extraction and rent-seeking opportunities.²⁹⁷ Some empirical scholarship reported politicians acting to reduce the tax burden of, and even exempt, the politically affluent from taxation at the expense of less influential

²⁹³ Nussim & Sorek, *supra* note 287, at 49. *But see* David M. Schizer, *Limiting Tax Expenditures*, 68 TAX L. REV. 275, 303 (2015) (arguing the government often lacks the expertise (and political independence) to choose technological winners in the non-tax context).

²⁹⁴ See CRS Report RL31181, *Research Tax Credit: Current Law and Policy Issues for the 114th Congress*, by Gary Guenther; and CRS In Focus IF10757, *The 2017 Tax Law (P.L. 115-97) and Investment in Innovation*, by Gary Guenther. Add cite to # of reported cases involving disputes under the R&D tax credits.

²⁹⁵ Nussim & Sorek, *supra* note 287, at 77 (admitting that certain "Innovation-inducing programs may be contingent, inter alia, on income or expenses, which are strongly related to IRS activities.").

²⁹⁶ See, e.g., Jennifer Brown, Katharine Drake & Laura Wellman, *The Benefits of a Relational Approach to Corporate Political Activity: Evidence from Political Contributions to Tax Policymakers*, 37 J. AM. TAX'N ASSOC'N 69 (2013).

²⁹⁷ See e.g., Rebecca M. Kysar, *The Sun Also Rises: The Political Economy of Sunset Provisions in the Tax Code*, 40 GA. L. REV. 335, 337 (2006) (describing temporary tax provisions as rent-extracting device for politicians to continue to receive rent payments); Theodore P. Seto, *Drafting a Federal Balanced Budget Amendment That Does What It Is Supposed to Do (and No More)*, 106 YALE L.J. 1449, 1465-66 (1997) (noting public choice theory plays a central role in providing opportunities for political players to remain relevant); Daniel Shaviro, *Beyond Public Choice and Public Interest: A Study of the Legislative Process as Illustrated by Tax Legislation in the 1980s*, 139 U. PA. L. REV. 1, 66-68 (1990) (claiming a key motive of certain tax legislation is rent extracting).

participants in the political process.²⁹⁸ The problem is arguably exacerbated in the context of innovation tax incentives because while there is bipartisan consensus on the need for such benefits there is limited knowledge about the extent of their output.²⁹⁹ This is due to the fact that developing innovations involves uninsurable and unmeasurable risks as well as little information on costs or prospective social value.³⁰⁰

The public choice argument that follows holds that the cross-party agreement on the need to encourage innovation coupled with much unknown about innovation outputs may create increased political opportunities for different market players to secure tax privileges at the expense of other taxpayers. As opposed to patents and awards that provide benefits at the end of a successful research and development process, tax legislation might create greater opportunities *ex ante* thus amplifies the efforts of lobbyists kept on retainer and congressional members to exchange rents in return to promoting innovation tax benefits.³⁰¹ Some academics go as far as calling for the repeal of such benefits for public choice concerns claiming genuine innovators and startup firms are seldom the beneficiaries of innovation subsidies.³⁰² They point to data on certain political pressures large corporation employ on Congress and the IRS in creating and interpreting innovation tax subsidies.³⁰³ They rely on the fact that the absolute majority of corporate R&D credit is claimed by large firms compared to start-up firms although *de facto* this benefit is not limited by input level.³⁰⁴

In the pharmaceutical innovation context though, nonpatent incentives may be prone to political influence, and drug companies may be reticent to innovate primarily in reliance on nonpatent incentives, if they are perceived as more likely to be revised downward.³⁰⁵ While these public choice concerns hold value, a normative justification for the use of tax incentives specifically for vaccine research is lacking. Our proposal is not to get rid of current intellectual property protection and cash transfers for vaccine research but to complement them with experimental framework that provides tax benefits to narrowly tailored list of underfunded diseases. Such limited list, in and of itself, significantly lowers that opportunities of political rent-seeking.

²⁹⁸ See, e.g., Raquel Alexander, Stephen Mazza & Susan Scholz, *Measuring Rates of Return for Lobbying Expenditures: An Empirical Case Study of Tax Breaks for Multinational Corporations*, 25 J.L. & POL. 401 (2009); Brian Kelleher Richter, Krislert Samphantharak & Jeffrey F. Timmons, *Lobbying and Taxes*, 53 AM. J. POL. SCI. 893 (2009).

²⁹⁹ See Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 139 (2000) (arguing the sources of innovation are unknown and differ by industry).

³⁰⁰ See generally, Schumpeter, *supra* note 16, at 258; KNIGHT, *supra* note 16, at 43-44 (noting uncertainty represents unknown and uninsurable future events).

³⁰¹ See Charles Delmotte, *The Case Against Tax Subsidies in Innovation Policy*, 48 FLA. ST. U. L. REV. 47, 53 (forthcoming 2020) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3564793 (“tax incentives allocate rewards via the political process. Given realistic assumptions about political opportunism, we can predict that they are subject to rent-seeking.”). But see LANDES & POSNER, *supra* note 20, at 14-15 (claiming concentrated investors interests affect the legislative process towards overprotection of patents.).

³⁰² Delmotte, *supra* note 301 at 47.

³⁰³ *Id.* n.230-231 citing to William Natbony, *Tax Incentives for Research and Development: An Analysis and a Proposal*, 76 GEO. L.J. 347, 407-415 (1987); Evan Wamsley, *The Definition of Qualified Research Under the Section 41 Research and Development Tax Credit: Its Impact on the Credit's Effectiveness*, 87 VA. L. REV. 165, 190-95 (2001); BRINK LINDSEY & STEVEN MICHAEL TELES, *THE CAPTURED ECONOMY: HOW THE POWERFUL ENRICH THEMSELVES, SLOW DOWN GROWTH, AND INCREASE INEQUALITY* (2017). But see Robert D. Atkinson, *Expanding the R&E Tax Credit to Drive Innovation, Competitiveness and Prosperity*, 32 J. TECH. TRANSFER 617, 623 (2007) (arguing in favor of expanding the R&D credit); Jennifer Venghaus, *Tax Incentives: A Means of Encouraging Research and Development for Homeland Security*, 37 RICH. U. L. REV., 1213, 1230 (proposing to utilize tax incentives to spur R&D for homeland security); Mahaffy, *supra* note 287 (calling for the utilization of tax incentives for innovation).

³⁰⁴ Some reasons for this phenomenon may including complexity, low salience, and lack of compliance resources.

³⁰⁵ Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 366 (2007).

Lastly, our proposal provides opportunities to reexamine optimal innovation incentives in a polity as a whole. With proper design, cash transfers for vaccine research can be restated as refundable tax incentives and produce superior *ex ante* results. The task of spurring biopharmaceutical research should not be allocated solely to patents, grants, prizes, vouchers, etc.. Innovation-inducing tax incentives for development of pathogens or pharmaceutical technologies should be utilized more widely by various government programs to increase likelihood of achieving optimal outcomes sooner and prior to commencement of an outbreak. Experimenting with such apparatuses can serve as a model and help rethink research incentives design to encompass different levels of IP and non-IP capacities while aiming to narrow each combination's complexity, abuse opportunities, and rent seeking.

VI. CONCLUSION

Vaccine research in emerging infectious diseases remains plagued by severe underinvestment that exposes both markets and health systems to significant social costs. The COVID-19 pandemic left the world in shockwave, unprepared for its extensive public health and economic toll. Pharmaceutical knowledge has always entailed vast positive externalities associated with information production. Yet, governments abruptly were forced to realize the social significance of procuring such knowledge in more robust ways. The pandemic has profoundly demonstrated the need to reconsider the conventional wisdom about the key role of IP incentives to the development of pathogens and technologies for rapidly transmitted diseases.³⁰⁶

Present laws do not provide adequate incentives designed to encourage investment in vaccine research in emerging infectious diseases. In fact, current innovation tax incentives that apply largely in homogenous ways to differentiated types of innovation achieve the opposite and push firms to prioritize technological research projects with higher commercialization value and repeated clienteles. By focusing on the case study of pharmaceutical innovations we hope to have established ways in which taxation can play a more dominant part in encouraging research in the vaccine space. The optimal nature of tax incentives for vaccine research should incorporate a normative choice not only between pharmaceutical versus mainstream innovation projects. A more robust tax framework holds promise to increase significantly *ex ante* rewards for research in the field of immunotherapy, thus encourage more market players to enter, compete, and collaborate in vaccine development that beholds high social value.

Our proposal also allows policymakers to distribute the social cost of vaccines on all taxpayers in a more just and equitable manner. Prioritizing research performed in a predesignated list of underfunded transmittable diseases works in a blind manner as opposed to cash-based direct incentives that may be influenced by the type of innovation, industry, costs, and location characteristics. Moreover, our suggestion for tiered refundable tax incentives and complementing routes introduces heterogeneity in application of tax incentives for innovation. As opposed to current deductions and credits, refundable tax incentives are not contingent on annual tax brackets

³⁰⁶ See generally Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 990 (1997) (providing an overview of the relationship between patents and inventive improvements). See also Hemel & Ouellette, *supra* note 81, at 327.

thus as such they prevent divergence in the built-in value of benefits to firms with different applicable rates or no positive tax liability at all such as startup or small life-science companies.

We proposed to experiment with limited-scope tax incentives for development of pathogens or pharmaceutical technologies to overcome underinvestment in this field by providing firms a higher rate of return when undertaking such research. After the dust settles on the current pandemic, policymakers will need to fine-tune the legal system to be better prepared the next one. Our framework provides a starting point for legal experimentation ahead of the next pandemic.

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