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Promoting Vaccine Innovation

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Promoting Vaccine Innovation

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As society grows to understand the need to promote innovation, policymakers try to employ an arsenal of policy tools, from traditional intellectual property ("IP") to newer tools such as grants, regulatory vouchers, and prizes. This Article argues that these frameworks crowd out certain types of investments in innovation projects that have a high social value. Vaccine innovation is a case in point. Despite the immense socioeconomic benefit of vaccines, existing policies have been limited in fostering investments in this space. This is because they fail to directly address the relevant bottleneck issues distinct to vaccine development.

This Article offers a policy measure especially apt at addressing this gap—tax law. Using properly designed tax instruments, policymakers can harness markets to produce innovation in a bottom-up manner. A key advantage of tax preferences for developing innovation is that they offer a superior mechanism of allocating risks and rewards while economizing on resources, administrative costs, regulatory capture, and informational problems.

The framework developed here offers a way forward in vaccine development, but also serves as a blueprint for interventions in other traditionally underfunded socially beneficial innovations. Critically, tax policies work synergistically with other policy measures, making them an important lever in the regulatory toolset—a vital measure for preparedness in the post-pandemic world.

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I. INTRODUCTION

The recent coronavirus pandemic has served as a powerful reminder of the critical role of vaccines in the contemporary world. Over 600 million people have been infected around the globe and over 6.5 million have died as of October 2022.[1] In the United States alone, there have been over 97 million reported infections and over one million deaths.[2] To put things in perspective, consider that these numbers vastly exceed the death toll of the Vietnam War,

[1] *COVID-19 Coronavirus Pandemic*, WORLDOMETER, https://www.worldometers.info/coronavirus/ [https://perma.cc/4VT8-8R4A].

[2] *COVID Data Tracker*, CDC, https://covid.cdc.gov/covid-data-tracker/#datatracker-home [https://perma.cc/3W9X-PP85].

and that the country is projected to face the economic consequences for years to come.[3]

The urgent demand for vaccines, nonetheless, shed renewed light on the crucial need for continuous and robust development of innovations that prevent and respond to large-scale public health crises. Pathogens such as coronaviruses are not new to the public health community.[4] They have been identified as top emerging pathogens likely to cause severe rapid outbreaks addressed in the World Health Organization reports as early as 2015.[5] But research and development ("R&D") on vaccines targeting coronaviruses was not a priority until the COVID-19 outbreak—and, even then, many companies were initially reluctant to develop COVID-19 vaccine candidates.[6]

Similarly, previous transnational outbreaks of infectious diseases such as Ebola and Zika (2014–2016) also demonstrated a clear need for a strong vaccine innovation infrastructure.[7] In the aftermath of the 2014–2016 Ebola outbreak, the World Health Organization characterized the infectious disease R&D status quo as one of critically lacking preparedness.[8] Yet, in spite of its considerable public health value and relative cost-effectiveness,[9] R&D for many vaccines

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[3] *The COVID-19 Economy's Effects on Food, Housing, and Employment Hardships*, CTR. BUDGET & POL'Y PRIORITIES (Nov. 10, 2021), https://www.cbpp.org/sites/default/files/8-13-20pov.pdf [https://perma.cc/585M-9LZZ]; *see Vietnam War U.S. Military Fatal Casualty Statistics*, NAT'L ARCHIVES, https://www.archives.gov/research/military/vietnam-war/casualty-statistics [https://perma.cc/42G5-DNCQ] (Aug. 23, 2022) (documenting total war casualties at 58,220).

[4] *See* WORLD HEALTH ORG., AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS 25 (May 2016), https://cdn.who.int/media/docs/default-source/blue-print/an-randd-blueprint-for-action-to-prevent-epidemics.pdf?sfvrsn=f890ab4e_1&download=true [https://perma.cc/6345-ZLMV].

[5] *See id.* at 22 (listing MERS Co-V and SARS as emerging infectious "diseases to be urgently addressed").

[6] *See* Ana Santos Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. U. J.L. & POL'Y 167, 169, 174–75 (2021) [hereinafter Rutschman, *Vaccine Race*]; *see also* Ana Santos Rutschman, *The Mosaic of Coronavirus Vaccine Development: Systemic Failures in Vaccine Innovation*, COLUM. J. INT'L AFFS. ONLINE (Mar. 21, 2020) [hereinafter Rutschman, *Mosaic*], https://jia.sipa.columbia.edu/online-articles/mosaic-coronavirus-vaccine-development-systemic-failures-vaccine-innovation [https://perma.cc/P68A-P4VA]; PETER LOFTUS, THE MESSENGER: MODERNA, THE VACCINE, AND THE BUSINESS GAMBLE THAT CHANGED THE WORLD 8–10 (2022) (describing the case of the Moderna COVID-19 vaccine).

[7] *See, e.g.*, *2014–2016 Ebola Outbreak in West Africa*, CDC, https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html [https:// perma.cc/XS2Y-D87B] (Mar. 8, 2019); Morgan Hennessey, Marc Fischer & J. Erin Staples, *Zika Virus Spreads to New Areas—Region of the Americas, May 2015–January 2016*, 65 MORBIDITY & MORTALITY WKLY. REP. 55, 56–57 (2016), https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6503e1.pdf [https://perma.cc/K3KS-8KWG].

[8] *See generally* Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200 (2018) [hereinafter Rutschman, *IP Preparedness*]; WORLD HEALTH ORG., *supra* note 4.

[9] *See infra* Part II.A.

targeting emerging pathogens is often intermittent or insignificant.[10] Public health preparedness for outbreaks of infectious diseases is critical in maintaining health and economic wellbeing. It requires persistent *ex ante* investment in vaccine innovation targeting pathogens associated with emerging,[11] lesser known,[12] or "non-mainstream"[13] diseases. How can we get there more effectively absent a humanitarian and economic crisis?

As the world closely follows the continued development and rollout of the race for vaccines,[14] as well as other therapeutics,[15] and their efficacy in tackling new viral mutations such as the delta and omicron variants,[16] the limitations of the current innovation policy landscape become readily apparent.[17] Typically,

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[10] *See generally* Massinissa Si Mehand, Farah Al-Shorbaji, Piers Millett & Bernadette Murgue, *The WHO R&D Blueprint: 2018 Review of Emerging Infectious Diseases Requiring Urgent Research and Development Efforts*, 159 ANTIVIRAL RSCH. 63 (2018).

[11] In the case of COVID-19, the disease was 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 2002, but not with SARS-CoV-2. *Coronaviruses*, U.S. NAT'L INST. ALLERGY & INFECTIOUS DISEASES, https://www.niaid.nih.gov/diseases-conditions/coronaviruses [https://perma.cc/RP7V-8BDB] (Mar. 22, 2022).

[12] For example, Zika was identified for the first time in 1947, but it was not until the 2015–2016 outbreak that some of the most of severe effects of Zika infection were reported. *See generally The History of Zika Virus*, WORLD HEALTH ORG. (Feb. 7, 2016), https://www.who.int/news-room/feature-stories/detail/the-history-of-zika-virus [https://perma.cc/3MJV-MQ3H].

[13] This is the case for different types of diseases, including the group known as "neglected tropical diseases," traditionally endemic to the Global South and which have generally failed to attract sizable R&D interest, partly due to profitability concerns on the part of R&D players whose business models rely primarily on return on investment approaches. *See Neglected Tropical Diseases*, NAT'L INST. ALLERGY & INFECTIOUS DISEASES, https://www.niaid.nih.gov/research/neglected-tropical-diseases [https://perma.cc/U5Q8-XQKM] (July 11, 2016); Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. ONLINE 170, 172–79 (2020) [hereinafter Rutschman, *Intellectual Property*].

[14] *See, e.g.*, *The COVID-19 Vaccine Race*, GAVI (Jan. 12, 2022), https://www.gavi.org/vaccineswork/covid-19-vaccine-race [https://perma.cc/9NVL-R7GR].

[15] *See, e.g.*, J.H. Beigel et al., *Remdesivir for the Treatment of Covid-19—Final Report*, 383 NEW ENG. J. MED. 1813, 1814 (2020); Stephanie Soucheray, *FDA Approves Pfizer's COVID-19 Pill for Emergency Use*, CTR. FOR INFECTIOUS DISEASE RSCH. & POL'Y (Dec. 22, 2021), https://www.cidrap.umn.edu/news-perspective/2021/12/fda-approves-pfizers-covid-19-pill-emergency-use [https://perma.cc/C67T-Y878].

[16] *See, e.g.*, Ralph S. Baric, *Emergence of a Highly Fit SARS-CoV-2 Variant*, 383 NEW ENG. J. MED. 2684, 2684 (2020); *Update on Omicron*, WORLD HEALTH ORG. (Nov. 28, 2021), https://www.who.int/news/item/28-11-2021-update-on-omicron [https://perma.cc/D78R-AFPB].

[17] *See, e.g.*, Andrew Joseph, *Scientists Are Monitoring a Coronavirus Mutation That Could Affect the Strength of Vaccines*, STAT (Jan. 7, 2021), https://www.statnews.com/2021/01/07/coronavirus-mutation-vaccine-strength/ [https://perma.cc/PC98-U62V] (describing recently identified mutations in the pathogen causing COVID-19); *see also* Patricia J. Zettler,

lawmakers and policymakers regard the IP and patent system as the default legal tool to spur investment in risky, non-rivalrous, and resource-intensive research endeavors.[18] Non-IP policies such as grants, prizes, vouchers, or insurance reimbursement, have progressively been recognized as other measures to encourage discoveries.[19] This Article argues that these frameworks crowd out other motivations to pursue innovation projects with high social value. The case study of vaccine innovation illustrates this point.[20] It reveals that albeit an important and cost-effective tool to lessen the socio-economic impact of widespread diseases, existing innovation levers do not address central idiosyncratic hurdles of vaccine research.[21]

This Article aims to fill this gap. We argue that tax law can help promote socially beneficial innovation. Tax policy can provide important functions and achieve superior allocation, incentivization, and distributive outcomes in a bottom-up manner. The characteristics of tax incentives—most importantly the mobilization of private-sector players through flexible commitment of their economic resources[22]—render them especially well-suited as stimulants of private investment in traditionally underfunded areas. Simply put, tax incentives provide market players (including capital-constrained and young firms) instant *ex ante* benefits, and consequently, remove extrinsic barriers to developing innovations in predesignated areas.[23] They leave subject-matter decisions such as the nature of individual projects, the priority given to each study, and resources devoted to every undertaking to private firms with better knowledge and expertise.[24] Moreover, the wide incidence of tax incentives delivers a more equitable distribution of the cost of research borne by other taxpayers that socially benefit from such knowledge goods.[25]

Using vaccine R&D as a case study, we argue that the market-based characteristics of tax instruments make them especially well-suited to promote vaccine innovation *ex ante* and increase community preparedness, which to date has never been explored. We demonstrate that, when designed properly, the tax system offers a unique advantage—the ability to harness public tools to

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Micah L. Berman & Efthimios Parasidis, *Drug and Vaccine Development and Access*, *in* ASSESSING LEGAL RESPONSES TO COVID-19, at 163, 163–66 (Burris et al. eds., 2020).

[18] *See, e.g.*, Henry G. Grabowski, Joseph A. DiMasi & Genia Long, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFFS. 302, 302–03 (2015).

[19] *See infra* notes 111–13 and accompanying text.

[20] *See generally* Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729 (2019).

[21] *See infra* Part III.E.

[22] *See generally* Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents—Prizes Debate*, 92 TEX. L. REV. 303, 321–26 (2013) (surveying the role of tax incentives in R&D).

[23] *See id.* at 336.

[24] *See id.* at 307–08.

[25] *See* Robert D. Atkinson, *Expanding the R&E Tax Credit to Drive Innovation, Competitiveness and Prosperity*, 32 J. TECH. TRANSFER 617, 619 (2007).

overcome problems distinctive to vaccine research. The latter includes research on emerging infectious diseases—a group of diseases that includes coronaviruses and other pathogens predicted to cause outbreaks in the near future.[26] Within that category, scarce resources, higher administrative costs, regulatory capture, and informational problems are some illustrative hurdles.

Based on this insight, we develop a novel framework for vaccine innovation that combines IP and other non-IP policy tools. Creating a mix of heterogenous and pliable forms of strategies to spur vaccine innovation is in line with what Professors Hemel and Ouellette have termed "innovation policy pluralism."[27] Likewise, we argue that innovation policies should make further use of the tax system, not only as an incentive mechanism and a source of government spending, but also as an allocation and distributional mechanism that can be internalized by all market participants.

The Article proceeds as follows. Part II describes the need for sustained levels of vaccine innovation. Part III outlines traditional policy frameworks—developed mainly through IP channels, as well as non-IP policies such as grants, prizes, vouchers, and other types of incentives. It points to misalignments of these innovation strategies and their anecdotal aptitude when it comes to spurring meaningful vaccine innovation. This can be attributable to the failure of these policies to attend to the idiosyncratic features of vaccine research. Part IV outlines the past and present universe of tax incentives for innovation, as well as their operation and flaws in the vaccine-specific context. This Part further demonstrates an anomaly—current design of tax schemes serves a contrary goal—they nudge market players away from vaccine research and towards ordinary drug development and mainstream technological projects. Accordingly, Part V lays out a new framework to better promote vaccine innovation. It proposes combining IP and other non-IP instruments with tax policy that prioritizes qualified vaccine discovery projects designated by a special health advisory committee. After surveying the potential benefits and concerns involving such a proposal, including abuse and gamesmanship, complexity, and political economy considerations, the Article proves such framework can deliver simpler, more equitable, and administrable outcomes.

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 vaccine innovations for emerging diseases.[28] We demonstrate that from economic efficiency and distributional justice points of view, governments ought to employ tax policy to spread the cost of developing vaccine innovations on all market participants (including countries) that will benefit from them. The

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[26] *See* WORLD HEALTH ORG., *supra* note 4, at 11, 12, 22 (listing emerging infectious "diseases to be urgently addressed" and noting a "lack of R&D preparedness" for emerging infectious diseases likely to translate into elevated public health costs).

[27] *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544, 549 (2019).

[28] *See generally* Rutschman, *IP Preparedness*, *supra* note 8.

Article initiates the discussion around the underexplored role of tax law in optimal design of vaccine innovation incentives and the distribution of their cost. At a broader level, it contributes to pluralistic approaches to innovation policy[29] and provides an adaptable blueprint for future work on other strategies to promote innovation in traditionally underfunded areas.

II. THE IMPORTANCE OF VACCINE INNOVATION

The pace at which outbreaks of infectious diseases occur have increased significantly over the past century.[30] The World Health Organization defines these diseases as those "caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one person to another."[31] Increased travel and other by-products of globalization have rendered the spread of these pathogens much faster and unencumbered than ever before.[32] Scientists anticipate that the continued growth of the world population, coupled with the expansion of urban centers and climate change, will continue to accelerate the pace at which infectious outbreaks occur.[33]

One of the central tenets of public health approaches to the prevention and management of public health crises is the idea of "preparedness."[34] The Centers for Disease Control and Prevention ("CDC") define preparedness as the "ability of communities to prepare for, withstand, and recover from public health incidents in both the short and long term."[35] Public health preparedness, thus, encompasses two distinct, yet intertwined, dimensions: the development of capabilities that allow a given community to *prevent* or lessen the burden of a

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[29] *See generally* Hemel & Ouellette, *supra* note 27.

[30] *See, e.g.*, Meera Senthilingam, *Seven Reasons We're at More Risk Than Ever of a Global Pandemic*, CNN (Apr. 10, 2017), https://www.cnn.com/2017/04/03/health/pandemic-risk-virus-bacteria [https://perma.cc/HTW2-SKWX]; Michaeleen Doucleff & Jane Greenhalgh, *Why Killer Viruses Are on the Rise*, NPR (Feb. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/02/14/511227050/why-killer-viruses-are-on-the-rise [https://perma.cc/L9P4-VY8X].

[31] *See Infectious Diseases*, WORLD HEALTH ORG. REG'L OFF. FOR THE E. MEDITERRANEAN, http://www.emro.who.int/health-topics/infectious-diseases/index.html [https://perma.cc/WS7N-A9ZZ].

[32] *See, e.g.*, Julia Belluz, *4 Reasons Disease Outbreaks Are Erupting Around the World*, VOX (May 31, 2016), https://www.vox.com/2016/5/31/11638796/why-there-are-more-infectious-disease-outbreaks [https://perma.cc/C4JK-HFV4]; Bahar Gholipour, *What 11 Billion People Mean for Disease Outbreaks*, SCI. AM. (Nov. 26, 2013), https://www.scientificamerican.com/article/what-11-billion-people-mean-disease-outbreaks [https://perma.cc/2E4Z-54YL].

[33] *See generally* Belluz, *supra* note 32.

[34] *See, e.g.*, *Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health*, CDC, https://www.cdc.gov/cpr/readiness/capabilities.htm [https://perma.cc/APS9-4RAY] (Jan. 25, 2021) [hereinafter CDC, *Public Health Emergency*].

[35] *Id.*

public health crisis; and the development of capabilities that allow the community to adequately *respond* to the onset of a public health crisis.[36]

These two types of capabilities—and their operation through both preventative and responsive pathways—require public health actors to achieve seemingly intractable goals typical to the development of innovation products.[37] They must act under the veil of uncertainty while formulating and executing plans designed to address future events without knowing which type of pathogens will cause outbreaks, the characteristics of the diseases to be targeted, and the evolution of the diseases throughout an outbreak.[38]

The recent pandemic has provided the most recent illustration of this challenge. Until late 2019, the pathogen at the root of this disease, a coronavirus known as SARS-CoV-2, was unknown to the scientific community.[39] How can the scientific and public health communities prepare for a disruptive agent that may be an entirely new pathogen?

Public health preparedness often answers this question through reliance on proximate knowledge. While the SARS-CoV-2 pathogen may be new, it is related to a large family of viruses that are genetically interrelated.[40] Scientists have studied this and other viral families for rather long periods of time, and there is often technology developed in connection with one pathogen that can be adapted or improved upon to create effective drugs or vaccines targeting a *related* pathogen or parts of it.[41] SARS-CoV-2, for example, is related to other coronaviruses, such as SARS-CoV, the SARS coronavirus that caused an outbreak between 2002 and 2004,[42] and MERS-CoV,[43] the coronavirus causing Middle East respiratory syndrome ("MERS"), which reported cases of the disease from 2012 onwards.[44]

Scientific knowledge has also evolved to the point in which it is possible to predict many of the pathogen families likely to trigger outbreaks in the short-

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[36] *See id.*

[37] *See generally id.*

[38] *See, e.g.*, Stephen S. Morse et al., *Prediction and Prevention of the Next Pandemic Zoonosis*, 380 LANCET 1956, 1959, 1963 (2012).

[39] *See supra* note 11 and accompanying text.

[40] *See* Eriko Padron-Regalado, *Vaccines for SARS-CoV-2: Lessons from Other Coronavirus Strains*, 9 INFECTIOUS DISEASE & THERAPY, 255, 255–56 (2020); *supra* note 11 and accompanying text.

[41] *See infra* notes 456–58 and accompanying text on the mRNA technology.

[42] *Frequently Asked Questions About SARS*, CDC, https://www.cdc.gov/sars/about/faq.html [https://perma.cc/Z6NA-ZPQZ] (May 3, 2005); *see also Severe Acute Respiratory Syndrome (SARS)*, CDC, https://www.cdc.gov/sars/index.html [https://perma.cc/F2CW-EYJM] (Dec. 6, 2017).

[43] *Middle East Respiratory Syndrome Coronavirus (MERS-CoV)*, WORLD HEALTH ORG. (Aug. 5, 2022), https://www.who.int/news-room/fact-sheets/detail/middle-east-respiratory-syndrome-coronavirus-(mers-cov)? [https://perma.cc/2PJ2-LHKV].

[44] *Middle East Respiratory Syndrome Coronavirus (MERS-CoV)*, WORLD HEALTH ORG., https://www.who.int/health-topics/middle-east-respiratory-syndrome-coronavirus-mers#tab=tab_1 [https://perma.cc/8LDJ-EL65].

and medium-term.[45] In the wake of the 2014–2016 Ebola outbreak, the World Health Organization published a list of the emerging pathogens most likely to cause outbreaks in the near future.[46] Diseases caused by coronaviruses were placed in the highest priority category.[47] The SARS-CoV-2 outbreak in 2019 was the third in the twenty-first century caused by a pathogen in the coronavirus family, after SARS (2002–2004) and MERS (2012–present).[48]

Public health preparedness capitalizes on proximate innovation knowledge, however imperfect, to devise proactive strategies to prevent or lessen the burden of emerging infectious diseases.[49] Among these strategies are the development, stockpiling, and distribution of innovations in known virus families.[50] Vaccine innovations operate largely as preventatives: their goal is to trigger a protective reaction in the human body that impedes or mitigates the onset of disease.[51] As such, vaccination is often described as one of the most cost-effective social tools, both for preventative purposes and for responding to escalating public health crises, such as an epidemic or a pandemic.[52]

In its 2016 report on emerging pathogens, the World Health Organization noted that there was a generalized lack of "R&D preparedness" for vaccines and drugs needed to address the public health challenges posed by these pathogens.[53] Not enough resources are being committed to research and development of innovations in this area.[54] R&D on vaccines, in particular, is chronically underfunded for reasons we explore later in this Article.[55] In this sense, we face a paradoxical suboptimal investment in socially valuable innovation even though scientists have been able to provide reliable predictive frameworks.[56]

As the recent pandemic has demonstrated, outbreaks can have a corrective function and increase investment in vaccine innovations, albeit towards one

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[45] WORLD HEALTH ORG., *supra* note 4, at 6, 21–22.

[46] *Id.* at 6, 22. WHO publishes a list of top emerging diseases likely to cause major epidemics. *Id.* at 22.

[47] *Id.* at 22.

[48] *Timeline: WHO's COVID-19 Response*, WORLD HEALTH ORG., https://www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline [https://perma.cc/G9RR-XLH8]; Padron-Regalado, *supra* note 40, at 256.

[49] *See* CDC, *Public Health Emergency*, *supra* note 34.

[50] *See generally* WORLD HEALTH ORG., *supra* note 4.

[51] *See generally Understanding How COVID-19 Vaccines Work*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html [https://perma.cc/83XZ-LTEM] (Sept. 16, 2022).

[52] *See, e.g.*, F.E. Andre et al., *Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide*, 86 BULL. WORLD HEALTH ORG. 140, 141–43 (2008).

[53] WORLD HEALTH ORG., *supra* note 4, at 5–6.

[54] *See, e.g.*, *id.* at 16.

[55] *See infra* Part III. *See generally* Rutschman, *Intellectual Property*, *supra* note 13 (exploring the characteristics of vaccine products that render them tendentially less attractive to funders when compared to other types of health goods).

[56] *See infra* notes 61–67 and accompanying text; WORLD HEALTH ORG., *supra* note 4, at 6.

specific type of pathogen.[57] At this point, however, this is operating in catch-up mode, having fewer resources on which to draw from as vaccine developers use preexisting technology and adapt it to an emerging pathogen—or, as noted below, a significant mutation of a known pathogen.[58]

General preparedness principles postulate a different agenda.[59] They prescribe continuous robust investment in the knowledge goods that can best minimize the impact of an outbreak—and, ideally, prevent it.[60] Failing to conform to these principles, particularly in the area of vaccines, may entail significant public health and economic costs, as described in the following sections.

A. *The Social Value of Public Health Preparedness*

Many disease pathogens can be targeted by a vaccine.[61] The use of existing vaccines can be directly linked to death and disease avoidance, as well as to significant reductions in social and health costs.[62] The most recent estimates from the World Health Organization indicate that, on average, current vaccination practices help prevent between 3.5 to 5 million deaths every year.[63] And although savings associated with the non-production of an event are notoriously hard to estimate, several studies have highlighted the positive externalities associated with broad administration of vaccines.[64]

In the United States, for instance, a study published in 2014 calculated that administering routine childhood vaccines to around 4 million infants would prevent 42,000 early deaths and 20 million cases of disease.[65] The non-occurrence of death and disease would save the United States $13.5 billion in net direct costs, a category that includes both the provision of medical treatment and the provision of nonmedical services, such as the costs entailed by providing special education to disabled children.[66] Additionally, the same study found that administration of routine vaccines would also produce the United States $68.8

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[57] *See generally* Rutschman, *IP Preparedness*, *supra* note 8, at 1259.

[58] *See Could a Vaccine Candidate for SARS Also Prevent COVID-19?*, PATH (May 7, 2020), https://www.path.org/articles/could-vaccine-candidate-sars-also-prevent-covid-19/ [https://perma.cc/SPJ9-9PUV]; *infra* Part II.B.

[59] *See* CDC, *Public Health Emergency*, *supra* note 34.

[60] *See id.*

[61] *See, e.g.*, Stanley A. Plotkin, Adel A.F. Mahmoud & Jeremy Farrar, *Establishing a Global Vaccine-Development Fund*, 373 NEW ENG. J. MED. 297, 298 (2015) (describing vaccine-preventable diseases).

[62] *See Vaccines and Immunization*, WORLD HEALTH ORG., https://www.who.int/health-topics/vaccines-and-immunization#tab=tab_1 [https://perma.cc/SZ2S-X6SN]; Fangjun Zhou et al., *Economic Evaluation of the Routine Childhood Immunization Program in the United States, 2009*, 133 PEDIATRICS 577, 577 (2014).

[63] *Vaccines and Immunization*, *supra* note 62.

[64] *See, e.g.*, Zhou et al., *supra* note 62, at 577–78.

[65] *Id.* at 580.

[66] *Id.* at 577–78, 580.

billion in net savings in societal costs, a category encompassing productivity losses and opportunity costs, such as missed wages.[67]

The examples above relate to situations in which vaccine innovations have been developed and are available to indicated populations. In the case of some of the emerging pathogens at the root of large public health crises, there may be no vaccine readily available.[68] That was the case with the recent pandemic, during which vaccines were developed in record time but while placing a tremendous toll on both public health and economic systems around the world.[69]

Preparedness frameworks are critical to prevent potentially high public health and economic costs. Although society was put on notice, research targeting pathogens in the coronavirus family was lacking in the period leading to the pandemic.[70] Conversely, in the case of other infectious diseases, there was, on average, a modicum of vaccine research before outbreaks.[71] For instance, that was the case of the 2014–2016 Ebola outbreak, in which a viable vaccine candidate was developed years before the outbreak but remained in storage due to lack of commercial interest.[72]

B. *Changing Playing Field: Viral Mutations and Vaccine Races*

The response to epidemics and pandemics is further complicated by the circumstance of viral mutation.[73] Many types of viruses—for instance, RNA viruses like the one causing COVID-19—continue to evolve as they spread among human populations.[74] While scientists are familiar with this phenomenon, these mutations are difficult to predict, and so is their impact on the efficacy of vaccines designed to target pre-mutation versions of a

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[67] *Id.*

[68] *See, e.g.*, Lilah Burke, *Race for a Vaccine*, INSIDE HIGHER ED (Mar. 4, 2020), https://www.insidehighered.com/news/2020/03/04/universities-role-race-develop-vaccine-coronavirus [https://perma.cc/F2JU-7MTN] (explaining that no vaccine existed when COVID-19 emerged in 2020); *see also* Plotkin, Mahmoud & Farrar, *supra* note 61, at 298 (listing vaccine-preventable diseases in need of a vaccine).

[69] *See* Burke, *supra* note 68.

[70] WORLD HEALTH ORG., *supra* note 4, at 22; *cf. Could a Vaccine Candidate for SARS Also Prevent COVID-19?*, *supra* note 58 (describing some levels of pre-COVID-19 R&D on SARS and MERS vaccines).

[71] *See generally* Rutschman, *IP Preparedness*, *supra* note 8, at 1218–22.

[72] *Id.* at 1221–22.

[73] *See, e.g.*, Baric, *supra* note 16, at 2684–85; Joseph, *supra* note 17.

[74] EUR. CTR. FOR DISEASE PREVENTION & CONTROL, RAPID INCREASE OF A SARS-COV-2 VARIANT WITH MULTIPLE SPIKE PROTEIN MUTATIONS OBSERVED IN THE UNITED KINGDOM 6 (Dec. 2020), https://www.ecdc.europa.eu/sites/default/files/documents/SARS-CoV-2-variant-multiple-spike-protein-mutations-United-Kingdom.pdf [https://perma.cc/T83X-H78N].

pathogen.[75] This contributes to the high uncertainty of developing vaccine innovations.

COVID-19 illustrated this problem, with more aggressive variants of the virus—such as delta and omicron.[76] At the time of writing, some existing vaccines are expected to be effective against some of these variants (such as delta and omicron), but it is impossible to predict whether they will be effective against as-of-yet unknown variants.[77] In the worst case scenario, later-emerging variants of a pathogen may spread faster, be harder to diagnose, cause either milder or more severe symptoms, and lead to situations in which the human body is irresponsive (or not as responsive) to the administration of existing vaccines.[78] Such fast-paced mutational conditions accentuate further the need for *ex ante* and incessant investment in vaccine innovation.

Failure to dedicate appropriate resources to vaccine research ahead of pandemics and epidemics compromises preparedness strategies. In Part III, we explore the specific characteristics of vaccine innovations that have traditionally made them less attractive to researchers and investors.[79] But we note here that failures to properly promote vaccine innovation before large public health crises unfold need to be understood not merely as market inefficiencies (or quasi-market failures) but as shortcomings that affect preparedness frameworks. It disturbs the ability to prevent and respond to the spread of infectious diseases, exacerbates the resulting toll on public and individual health, and upsets economies in the affected regions, and potentially the world.[80] Unfortunately, as we demonstrate next, the current landscape of innovation policies is ineffective in addressing the idiosyncratic features of vaccines and overcome lack of preparedness in this area.

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[75] *See, e.g.*, Elisabeth Mahase, *Covid-19: What New Variants Are Emerging and How Are They Being Investigated?*, 372 BRIT. MED. J. 1, 1 (2021), https://www.bmj.com/content/bmj/372/bmj.n158.full.pdf [https://perma.cc/QWF5-H3YM].

[76] *See, e.g.*, Eric J. Rubin, Lindsey R. Baden & Stephen Morrissey, *Audio Interview: Covid-19 Vaccination and the Omicron Variant*, NEW ENG. J. MED. (Dec. 30, 2021), https://www.nejm.org/doi/full/10.1056/NEJMe2120098 (on file with the *Ohio State Law Journal*); Baric, *supra* note 16, at 2684–86.

[77] *See, e.g.*, Rubin, Baden & Morrissey, *supra* note 76; Baric, *supra* note 16, at 2686; *SARS-CoV-2 Variant Classifications and Definitions*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html [https://perma.cc/PE22-N4HV] (Apr. 26, 2022); Ewen Callaway, *Delta Coronavirus Variant: Scientists Brace for Impact*, 595 NATURE 17, 17 (2021); Donato Paolo Mancini & John Burn-Murdoch, *How Effective Are Coronavirus Vaccines Against the Delta Variant?*, FIN. TIMES (July 9, 2021), https://www.ft.com/content/5a24d39a-a702-40d2-876d-b12a524dc9a5 [https://perma.cc/NUY5-LW3W].

[78] *See generally* Baric, *supra* note 16.

[79] *See infra* Part III.

[80] *See generally* Zhou et al., *supra* note 62.

III. CURRENT INNOVATION POLICIES

A. *Intellectual Property*

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.[81] These discussions are often fueled by the concern that some types of goods, albeit welfare enhancing, might fail to attract sufficient funding and interest from the private sector.[82] This concern is furthered by the fact that at the same time, the public sector alone cannot see them through from early research stages to manufacturing and commercialization.[83]

As Kenneth Arrow has explained, private companies are likely to invest less than is socially optimal in risky endeavors without a mechanism that counterbalances uncertainty (real or perceived) associated with research and discovery processes because they cannot fully appropriate the benefits of the product of innovation and because of increasing returns in use.[84] Such unwillingness or inability to bear unknown risks associated with developing innovations "will give rise to a nonoptimal allocation of resources, in that there

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[81] *See generally* FRANK H. KNIGHT, RISK, UNCERTAINTY, AND PROFIT 40–42 (Dover 2006) (1921) (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., 1st 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* 1 (Fed. Trade Comm'n Bureau Econ., Working Paper No. 51, 1982), https://www.ftc.gov/system/files/documents/reports/role-risk-aversion-allocation-resources-invention/wp051.pdf [https://perma.cc/WG5F-A7UC] (debating the different views on underinvestment in innovation).

[82] Because they are knowledge-intensive, these goods are often described as non-rivalrous and non-excludable. *See generally* Joseph E. Stiglitz, *Knowledge as a Global Public Good*, *in* GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 308 (Inge Kaul, Isabelle Grunberg & Marc A. Stern eds., 1999). Non-rivalrous goods can be consumed by multiple users without a reduction in their quantity or quality. *Id.* at 309. Users of nonexcludable 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. *Id.* at 309–10.

[83] *See* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 623 (1962).

[84] *Id.* at 610–19. *But see* Jack Hirshleifer, *The Private and Social Value of Information and the Reward to Inventive Activity*, 61 AM. ECON. REV. 561, 561 (1971) (arguing that the private value of an invention can exceed its social value, leading to an overinvestment in research).

will be discrimination against risky enterprises as compared with the optimum," Arrow vindicates.[85]

Against this background, patent systems are viewed primarily as a way to cure market failures of underinvestment in technical and scientific areas.[86] Absent patent protection, scholars have noted that the price of products will be reduced to the "marginal cost of copying," deterring any type of investment in developing unprotected non-rivalry innovation.[87] The dominant worldview depicts patents as incentive mechanisms, designed to promote investment in areas that might remain underfunded without the conferral of a legal right that enables the patent holder to enjoy some form of market exclusivity for a certain period of time.[88]

How does patent law relate to incentives for developing vaccine innovation? According to the prevailing IP narrative, both the main function and justification for the existence of the modern patent system is to tend to problems related to market prospectivity.[89] It maintains a would-be rational investor will likely shy away from allocating resources to a particular innovation project if the anticipated market for an invention is not deemed large or profitable enough to recoup costs and/or turn a profit.[90] Under this logic, patents become especially relevant as catalysts to vaccine innovation when there is a misalignment between the value and the cost of socially desirable goods.

Indeed, commentators often point out that nowhere is this misalignment more evident than in the case of pharmaceutical and biopharmaceutical

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[85] Arrow, *supra* note 83, at 611–12.

[86] We employ the expression "market failure" in this Article to refer to situations in which certain types of inefficiencies lead to suboptimal investment in R&D on socially valuable goods. *See generally* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 37–41 (2003) (discussing the economic theory underlying patents and the risk of underinvestment as prices reduced to marginal cost of copying). *See also* Madhavi Sunder, *IP*^{3}, 59 STAN. L. REV. 257, 283 (2006) ("Market failure is cited as the *raison d'etre* 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) ("Fair use will revolve less around market failure, and more around the idea of favoring certain classes of users with a statutory privilege.").

[87] LANDES & POSNER, *supra* note 86, at 40; *see also* Gideon Parchomovsky & Peter Siegelman, *Towards an Integrated Theory of Intellectual Property*, 88 VA. L. REV. 1455, 1459 (2002) ("In a competitive market the price will be driven down to the marginal cost of copying."); Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347, 349 (2000) ("[I]nnovation 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.").

[88] *See, e.g.*, ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 11, 13 (6th ed. 2012).

[89] *See* Rutschman, *IP Preparedness*, *supra* note 8, at 1214.

[90] *Id.* at 1213–15.

innovation.[91] Pharmaceutical markets have long been considered as one of the areas of prime application of patent-as-incentives theory.[92] Taken as a whole, pharmaceutical research tends to occur over timelines that are on average considerably longer than in other areas.[93] Scientific complexity and uncertainty often renders R&D processes unpredictable, increasing the risk of failure.[94] The pharmaceutical industry is heavily regulated, a phenomenon which—while not exclusive to such industry—further increases the cost of producing innovations.[95] Accordingly, the risk of market inefficiency in the form of

[91] *Id.* at 1216–17; *see also* Richard A. Posner, *Why There Are Too Many Patents in America*, ATLANTIC (July 12, 2012), https://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725 [https://perma.cc/6HFF-Z4EZ] (calling the pharmaceutical industry "the poster child for the patent system"). The word "pharmaceutical" is used in different contexts, but primarily refers to products meeting colloquial, scientific, and regulatory definitions of medicines and drugs. *See, e.g.*, *Medicines*, WORLD HEALTH ORG., https://www.who.int/topics/pharmaceutical_products/en/ [https://perma.cc/XH7D-M8LY]. "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). Malgorzata Kesik-Brodacka, *Progress in Biopharmaceutical Development*, 65 BIOTECH. & APPLIED BIOCHEMISTRY 306, 306 (2018). Because this Article focuses primarily on problems arising in the vaccine 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 Industry (Biologics)*, FDA, https://www.fda.gov/vaccines-blood-biologics/resources-you-biologics/industry-biologics [https://perma.cc/L7KC-ERLC] (Oct. 12, 2022) (providing an overview of biologics for regulatory purposes); *Vaccines, Blood & Biologics*, FDA, https://www.fda.gov/vaccines-blood-biologics [https://perma.cc/T2ZR-ZZPC].

[92] 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, 441, 451 (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, 316, 324 (2012) (examining economic justification for "the existence of a different patentability regime for inventions of methods for treatment and diagnostic methods").

[93] For instance, in the case of vaccines, the complete R&D arc lasts, on average, over a decade. *See, e.g.*, INT'L FED'N PHARM. MFRS. & ASS'NS, THE COMPLEX JOURNEY OF A VACCINE: THE STEPS BEHIND DEVELOPING A NEW VACCINE 2–5 (July 2019), https://www.ifpma.org/wp-content/uploads/2019/07/IFPMA-ComplexJourney-2019_FINAL.pdf [https://perma.cc/5M3R-Z3N9]; *Vaccine Testing and the Approval Process*, CDC, https://www.cdc.gov/vaccines/basics/test-approve.html [https://perma.cc/834W-6B8M] (May 1, 2014) (describing the stages of vaccine development and regulatory review and approval).

[94] *See generally* Petra Oyston & Karen Robinson, *The Current Challenges for Vaccine Development*, 61 J. MED. MICROBIOLOGY 889 (2012) (listing both scientific and financial challenges associated with vaccine development).

[95] *Id.* at 891; *Laws, Regulations, Policies and Procedures for Drug Applications*, FDA, https://www.fda.gov/drugs/development-approval-process-drugs/laws-regulations-policies-and-procedures-drug-applications [https://perma.cc/T2HX-HTYR] (Dec. 4, 2014); *Development & Approval Process (CBER)*, FDA, https://www.fda.gov/vaccines-blood-biologics/development

underinvestment in developing socially beneficial innovations is often depicted as heightened in connection with pharmaceutical products more than it is elsewhere in the innovation ecosystem.[96]

But even if patent-protected, certain types of disease categories have long been known to fare poorly in attracting investments based on prospects of return on investment.[97] Small, seasonal, or otherwise temporally-limited markets have long been known not to attract sustained interest and funding from the private sector.[98] Accordingly, innovators often rely on support for basic research from the public sector, philanthropic funding, or a combination thereof.[99] Examples of such diseases include neglected tropical and communicable diseases prevalent in tropical and subtropical climates.[100] Chagas disease, Leishmaniasis,[101] and orphan diseases (defined in the United States as affecting fewer than 200,000 patients) such as Lou Gehrig's disease, Tourette Syndrome, and rare childhood cancers, are just some illustrations.[102]

-approval-process-cber [https://perma.cc/S3XC-Q4ZZ] (Jan. 27, 2022) (collectively providing an overview of the regulatory review and approval process to which different types of pharmaceutical drugs are subjected before entering the market).

[96] *See generally* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 370–71 (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 contributing to the value of new drugs).

[97] Rutschman, *IP Preparedness*, *supra* note 8, at 1209–10.

[98] Rutschman, *Intellectual Property*, *supra* note 13, at 177; *see also* Rutschman, *IP Preparedness*, *supra* note 8, at 1225–26 (exploring the temporal limitations of vaccine markets for certain infectious diseases).

[99] Rutschman, *IP Preparedness*, *supra* note 8, at 1225–26 (exploring the funding profile of vaccine R&D, highlighting the primacy of public funding); *see, e.g.*, Sarah Murray, *Philanthropists Play a Crucial Role in Developing Vaccines*, FIN. TIMES (May 21, 2020), https://www.ft.com/content/847a9052-6847-11ea-a6ac-9122541af204 [https://perma.cc/J7KU-GFCM].

[100] *See* WORLD HEALTH ORG., *supra* note 4, at 5.

[101] *Control of Neglected Tropical Diseases*, WORLD HEALTH ORG., https://www.who.int/teams/control-of-neglected-tropical-diseases [https://perma.cc/UEY9-L6EJ]. *See generally* Alberto E. Paniz-Mondolfi et al., *Concurrent Chagas' Disease and Borderline Disseminated Cutaneous Leishmaniasis: The Role of Amiodarone as an Antitrypanosomatidae Drug*, 4 THERAPEUTICS & CLINICAL RISK MGMT. 659 (2008).

[102] *About GARD*, NAT'L CTR. ADVANCING. TRANSLATIONAL SCIS., https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases [https://perma.cc/99KY-PYNA]; *Rare and Orphan Diseases*, NAT'L CONF. STATE LEGISLATURES (Feb. 16, 2021), https://www.ncsl.org/research/health/rare-and-orphan-diseases.aspx [https://perma.cc/C29N-6VYC]; *see, e.g.*, *Amyotrophic Lateral Sclerosis*, NAT'L CTR. ADVANCING TRANSLATIONAL SCIS., https://rarediseases.info.nih.gov/diseases/5786/amyotrophic-lateral-sclerosis [https://perma.cc/A7F4-TJCP] (Nov. 8, 2021) (acknowledging that Amyotrophic Lateral Sclerosis (ALS) is also known as Lou Gehrig's Disease); Rishi S. Kotecha, Ursula R. Kees, Catherine H. Cole & Nicholas G. Gottardo, *Rare Childhood Cancers—an Increasing Entity Requiring the Need for Global Consensus and Collaboration*, 4 CANCER MED. 819, 820–21 (2015)

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.[103] These types of diseases are characterized by markets where the misalignment between IP policies and public health goals is often apparent, with very few players willing to engage in R&D absent a catalyst such as a pandemic.[104] To mitigate some of the market inefficiencies traditionally felt in these areas, few commentators and policymakers have focused on newer approaches to promoting pharmaceutical innovation that rely on non-IP incentives such as grants, prizes, vouchers, etc., as a complement to existing patent frameworks.[105]

B. *Grants*

The idea of non-IP incentives has coexisted with patent frameworks from the inception of the IP system in the United States.[106] Fritz Machlup and several other researchers have traced the idea of non-IP incentives in the United States back to James Madison's proposal of a premium system as the primary mechanism to encourage and reward innovation.[107] Today, non-IP incentives

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(discussing the types of rare childhood cancers that would benefit from a global consensus and research approach); *Tourette Syndrome*, NAT'L CTR. ADVANCING TRANSLATIONAL SCIS., https://rarediseases.info.nih.gov/diseases/7783/tourette-syndrome [https://perma.cc/6BHY-U87N] (Nov 8, 2021).

[103] *See* Rutschman, *IP Preparedness*, *supra* note 8, at 1224–43 (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 S. Kesselheim & Kevin Outterson, *Improving Antibiotic Markets for Long Term Sustainability*, 11 YALE J. HEALTH POL'Y L. & ETHICS 101, 103 (2011); Kevin Outterson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Intellectual Property Law*, 67 U. PITT. L. REV. 67, 69 (2005).

[104] *See* Rutschman, *supra* note 20, at 740–42 (2019) (describing vaccine manufacturer attrition from the mid-twentieth century onwards).

[105] *See* Hemel & Ouellette, *supra* note 27, at 551; OHE CONSULTING, 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? 8, 46 n.10 (2005); *see, e.g.*, Aaron S. Kesselheim & Kevin Outterson, *Fighting Antibiotic Resistance: Marrying New Financial Incentives to Meeting Public Health Goals*, 29 HEALTH AFFS. 1689, 1689, 1691–92 (2010); Michael J. Burstein, *Patent Markets: A Framework for Evaluation*, 47 ARIZ. ST. L.J. 507, 507–08 (2015) (criticizing the notion of patent markets as perfect innovation catalyst).

[106] STAFF OF S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 15 (Comm. Print 1958) (prepared by Fritz Machlup) ("Proposals for systems of prizes and bonuses to inventors, as alternatives to patents, are almost as old as the patent system.").

[107] *Id. See generally* Craig Allen Nard & Andrew P. Morriss, *Constitutionalizing Patents: From Venice to Philadelphia*, 2 REV. L. & ECON. 223, 299–304 (2006); Tyler T. Ochoa & Mark Rose, *The Anti-Monopoly Origins of the Patent and Copyright Clause*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 909, 922–28 (2002).

have come to be understood as innovation levers, complementary to the patent system,[108] playing an important role in the innovation policy landscape.[109] The Federal Government disburses the overwhelming majority of innovation funding through the grant system.[110] 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."[111]

The current preference for the grant model has been criticized on several accounts,[112] with some commentators suggesting that incentives mechanisms operating *ex post*, such as prizes, should absorb a greater share of public funding.[113] 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.[114] 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.[115] His study emphasizes the peer review process as important in allocative decisions.[116] This process includes formal and informal accountability mechanisms such as reporting

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[108] *See generally* Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, 2 INNOVATION POL'Y & ECON. 51 (2002); Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1001–02 (2014); Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525 (2001).

[109] Hemel & Ouellette, *supra* note 27, at 551–52; *see also* Joshua D. Sarnoff, *Government Choices in Innovation Funding (with Reference to Climate Change)*, 62 EMORY L.J. 1087, 1089 (2013) (noting that in spite of the relevance of government funding, we continue to "lack any clear theory or good comparative empirical analyses from which to determine the best *form* of deploying such massive amounts of government money").

[110] *See infra* note 111 and accompanying text.

[111] Hemel & Ouellette, *supra* note 22, at 361. Hemel and Ouellette further note that several states also provide R&D funding for universities and other research facilities. *Id.* at 321. *But see* Heidi Ledford, Sara Reardon, Emiliano Rodríguez Mega, Jeff Tollefson & Alexandra Witze, *Trump Seeks Big Cuts to Science Funding—Again*, NATURE (Mar. 11, 2019), https://www.nature.com/articles/d41586-019-00719-4 [https://perma.cc/RAF8-PCUF] (illustrating fluctuations in the amount of public funding available for basic research).

[112] *See generally* W. Nicholson Price II, *Grants*, 34 BERKELEY TECH. L.J. 1, 9–15 (2019) (reviewing the grant system in the United States and offering systemic critiques).

[113] *See, e.g.*, Jonathan H. Adler, *Eyes on a Climate Prize: Rewarding Energy Innovation to Achieve Climate Stabilization*, 35 HARV. ENV'T. L. REV. 1, 28–35 (2011) (making the case for a shift in government funding from climate change-related research from grants to prizes); *see also infra* note 143 and accompanying text.

[114] Price, *supra* note 112, at 6.

[115] *Id.* at 7.

[116] *Id.*

apparatuses and reputational concerns for repeat applicants.[117] Thus, the risk shouldered by the granting institution often translates into valuable social benefits, including the disclosure of confidential negative knowledge surrounding the invention.[118]

In the field of vaccines, one of the most prestigious awards—the Michelson Prize—in spite of its blurred terminology, is in fact a grant.[119] It is awarded to encourage new investigators under thirty-five years old "who are applying disruptive concepts and inventive processes to advance human immunology, vaccine discovery, and immunotherapy research for major global diseases."[120] Housed under the "Human Immunome Project," a decade-long, transnational and multi-party research partnership modeled after the "Human Genome Project,"[121] the initiative was created as a response to the growing scientific and infrastructural challenges in immunology and vaccine innovation.[122] Its goal is to accelerate research on new vaccines, alongside diagnostics and treatments.[123] While highly prestigious and relevant in the scientific discipline(s) it covers, the Michelson Prize also speaks to the general limitations of these models. The awards are made to individuals as opposed to research projects, and their amount—$150,000 as of the 2021 edition[124]—is far from substantial. The award itself is to some extent conditioned by the existence of, and funding for, the awarding entity—the Human Immunome Project.[125] 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 developing vaccine innovations. These limitations further illustrate a greater need for innovation

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[117] *Id.*

[118] *Id.*

[119] *Michelson Prizes*, HUM. IMMUNOME PROJECT, https://www.humanimmunomeproject.org/michelsonprizes [https://perma.cc/P2PE-LTJG] (noting that awards are made to proposals for the application of "disruptive concepts and inventive processes to advance human immunology, vaccine discovery, and immunotherapy research for major global diseases" (emphasis omitted)). Note, the Human Immunome Project was previously named the "Human Vaccines Project."

[120] *Id.* (emphasis omitted).

[121] *The Human Genome Project*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/human-genome-project [https://perma.cc/JG8P-BYAB] (Sept. 2, 2022); Stacey L. Wooden & Wayne C. Koff, The Human Vaccines Project*: Towards a Comprehensive Understanding of the Human Immune Response to Immunization*, 14 HUM. VACCINES & IMMUNOTHERAPEUTICS 2214, 2214–15 (2018); *Pioneering a New Era of Human Health*, HUM. IMMUNOME PROJECT, https://www.humanimmunomeproject.org/the-project/ [https://perma.cc/32HT-346V]; Pedro Romero et al., *The Human Vaccines Project: A Roadmap for Cancer Vaccine Development*, 8 SCI. TRANSLATIONAL. MED. 1, 1 (2016), https://www.science.org/doi/pdf/10.1126/scitranslmed.aaf0685? [https://perma.cc/HSB7-DFGC].

[122] *Michelson Prizes*, *supra* note 119.

[123] *Pioneering a New Era of Human Health*, *supra* note 121.

[124] *Michelson Prizes*, *supra* note 119.

[125] *See id.*; *Pioneering a New Era of Human Health*, *supra* note 121.

policies that work with market-driven approaches, such as the framework we propose in Part V.[126]

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 research.[127] As of March 2021, for instance, there were thirty-one open grant funding opportunity announcements from the National Institute of Allergy and Infectious Diseases ("NIAID").[128] In addition to regular support for vaccine research through their grant systems, NIAID, NIH, and other federal agencies also provide funding during public health crises like the recent one.[129] Yet, while the total amount of federal grants offered to pharmaceutical innovations is considerable, the amount granted to facilitate vaccine innovation is not significant enough to tilt the scale towards vaccine research compared to mainstream pharmaceutical and technological innovations in the pre-pandemic setting through traditional patents.[130]

C. *Prizes*

Even though they receive only a small fraction of public-sector funding,[131] non-IP incentives systems based on prizes have long enjoyed favor among many commentators looking for complementary levers to IP in innovation policy landscape.[132] Before patents grew into the default incentives regime for scientific and technical innovation, prizes were used often across different fields of science.[133] Perhaps the most famous example is that of prizes offered in the

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[126] *See infra* Part V.

[127] *See, e.g.*, *Vaccines*, NAT'L INST. ALLERGY & INFECTIOUS DISEASES, https://www.niaid.nih.gov/research/vaccines [https://perma.cc/EU8A-JL5B] (Aug. 13, 2020) (providing an overview of NIAID's role in funding vaccine R&D).

[128] *Opportunities & Announcements*, NAT'L INST. ALLERGY & INFECTIOUS DISEASES, https://www.niaid.nih.gov/grants-contracts/opportunities? [https://web.archive.org/web/20210329162710/https://www.niaid.nih.gov/grants-contracts/opportunities?combine=vaccine&search=vaccine].

[129] *See, e.g.*, *BARDA and Sanofi Prepare for Studies of COVID-19 Vaccine*, MED. COUNTERMEASURES, https://www.medicalcountermeasures.gov/newsroom/2020/psc-sanofi-recombinant/ [https://perma.cc/PRS6-8N9R] (Apr. 15, 2020); *see also* ANTHONY S. FAUCI, OVERVIEW OF COVID-19 AND THE RESEARCH RESPONSE (June 2020), https://acd.od.nih.gov/documents/presentations/06112020_Fauci.pdf [https://perma.cc/5A3L-8ZUX].

[130] *See* Hemel & Ouellette, *supra* note 22, at 360–61.

[131] *See supra* note 109 and accompanying text.

[132] *See, e.g.*, Roin, *supra* note 108, at 1001; Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 976 (2012); Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 119 (2003); Michael Kremer & Heidi Williams, *Incentivizing Innovation: Adding to the Tool Kit*, 10 INNOVATION POL'Y & ECON. 1, 1 (2010).

[133] Roin, *supra* note 108, at 1020–22; *see also* Kapczynski, *supra* note 132, at 973; Michael J. Burstein & Fiona E. Murray, *Innovation Prizes in Practice and Theory*, 29 HARV. J.L. & TECH. 401, 402–03 (2016) (claiming prizes are important levers in innovation policy goals and solving uncertainty and information asymmetries).

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.[134]

Today, examples of prizes for technical and scientific innovation can be found in the public[135] and private[136] 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 research,[137] 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.[138] If set by the government, prizes are subject to "risks of politicization, rent-seeking, and mismanagement."[139] Moreover, because the sum and terms of the rewards are set *ex ante*, prizes are also subject to problems of under and overevaluation.[140] Finally, prizes set by institutions in both the public and the private sectors are subject to budgetary and other financial constraints.[141]

Consequently, traditional prizes are much less frequently deployed in vaccine innovation systems.[142] They are nonetheless routinely theorized both by scholars and professionals outside academia.[143] While greater attention and resources directed towards vaccine research is desirable, prizes offered as a public health crisis unfolds are an intrinsically limited incentives mechanism.

Most recently, prizes have been proposed as a way to bolster research on vaccines while the pandemic unfolds.[144] In an allusion to the longitude prizes

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[134] Burstein & Murray, *supra* note 133, at 403; *Origins of the Longitude Prize*, LONGITUDE PRIZE, https://longitudeprize.org/the-history/ [https://perma.cc/33YP-SQS4].

[135] *See, e.g.*, OFF. SCI. & TECH. POL'Y, EXEC. OFF. OF THE PRESIDENT, IMPLEMENTATION OF FEDERAL PRIZE AUTHORITY: FISCAL YEAR 2015 PROGRESS REPORT 5 (Aug. 2016), https://obamawhitehouse.archives.gov/sites/default/files/fy2015_competes_prizes_report.pdf [https://perma.cc/KU3Q-AQGW] (describing greater public-sector investment in inducement prizes).

[136] *See, e.g.*, Alan MacCormack, Fiona Murray & Erika Wagner, *Spurring Innovation Through Competitions*, MIT SLOAN MGMT. REV., Fall 2013, at 25, 27 (describing the value of competition facilitated by the 2010 Progressive Insurance Automotive X-Prize, which awarded $10 million to the development of a vehicle with breakthrough energy efficiency).

[137] *See, e.g.*, *Mega-Prizes in Medicine: Big Cash Awards May Stimulate Useful and Rapid Therapeutic Innovation*, 68 MED. HYPOTHESES 1, 2–3 (2007), https://pubmed.ncbi.nlm.nih.gov/17052861/ [https://perma.cc/8LT3-PSQS].

[138] *See* Hemel & Ouellette, *supra* note 22, at 326–28.

[139] *Id.* at 327.

[140] *Id.* at 327–28.

[141] *Cf. id.* at 312.

[142] *See supra* note 109 and accompanying text.

[143] *See* James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANNALS HEALTH L. 155, 155–56 (2009) (proposing four possible embodiments of prize models for vaccines and other types of drugs).

[144] *See, e.g.*, Daniel Hemel & Lisa Larrimore Ouellette, *Want a Coronavirus Vaccine, Fast? Here's a Solution*, TIME (Mar. 4, 2020), https://time.com/5795013/coronavirus-

described previously,[145] Chris Callaghan has suggested a "Longitude Prize" for vaccines of "many billions of pounds" that would be funded through contributions collected by the World Health Organization or the United Nations.[146] Outbreak-spiked funding for vaccine research has historically been short-lived and limited by shifting financial dynamics and the political economy.[147] 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.[148]

Hemel and Ouellette have proposed "a large cash prize" for the successful 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."[149] Yet, 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 vaccines[150]—which can also be addressed in other forms by the legal system[151]—they do not address the fundamental shortcomings of incentives to

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vaccine-prize-challenge/ [https://perma.cc/XNX8-BZLT]; Chris Callaghan, *Would a Longitude Prize Speed Production of a Covid-19 Vaccine?*, TIMES HIGHER EDUC. (Mar. 28, 2020), https://www.timeshighereducation.com/blog/would-longitude-prize-speed-production-covid-19-vaccine [https://perma.cc/533Z-9J7R].

[145] *See supra* note 111 and accompanying text. The allusion further references the revival of the Longitude Prize in the United Kingdom in 2014. 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/ [https://perma.cc/7N5W-BCYA].

[146] Callaghan, *supra* note 144.

[147] Rutschman, *IP Preparedness*, *supra* note 8, at 1225–26, 1259–60 (noting how outbreak-spiked funding is often lost on short-lived R&D projects and tends to shrink fairly quickly).

[148] *See, e.g.*, Amy Maxmen, *Why Did the World's Pandemic Warning System Fail When COVID Hit?*, NATURE (Jan. 23, 2021), https://www.nature.com/articles/d41586-021-00162-4 [https://perma.cc/E3AA-NPWK]; Paige Winfield Cunningham, *The Health 202: WHO Has Stumbled Repeatedly in Communicating About the Coronavirus*, WASH. POST (June 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/ [https://perma.cc/TY7T-DB3Y]; Paul LeBlanc, *Fauci Voices Support for World Health Organization After Trump Terminates US Relationship*, CNN, https://www.cnn.com/2020/06/11/politics/fauci-world-health-organization-coronavirus/index.html [https://perma.cc/7UA7-48RC] (June 11, 2020).

[149] Hemel & Ouellette, *supra* note 144.

[150] *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/ [https://perma.cc/63TR-UKLS].

[151] *See generally, e.g.*, Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV. 57 (2022). *See also, e.g.*, Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH 275, 275 (2016).

vaccine research before an outbreak takes place. Without any meaningful prize system in place, a few months into the pandemic there were well over one hundred different vaccine research projects,[152] as well as more than two hundred drugs being considered for therapeutic purposes.[153] Unfortunately, these policy levers—patents, grants and prizes—have not been successful in instigating sustainable interest in vaccine innovation in the pre-crisis setting.

D. *Regulatory and Reimbursement Schemes*

A strand of legal literature focusing on innovation law and policy has progressively added to the traditional roster, non-IP incentives that operate specifically in pharmaceutical industry.[154] 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.[155] These include the awarding of market and data exclusivities to first market entrants,[156] which prevent the FDA from approving follow-on drugs for certain periods of time.[157] This confers a de facto monopoly-like position to drug manufacturers who gain FDA approval for first-of-its-kind drugs.[158]

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[152] A few months after the beginning of the pandemic, in late-June 2020, some sources put the number of vaccine-specific COVID-19 R&D projects around 130, while others reported over 160 projects. *See, e.g.*, WORLD HEALTH ORG., DRAFT LANDSCAPE OF COVID-19 CANDIDATE VACCINES—JUNE 29, 2020 (2020), https://www.who.int/docs/default-source/coronaviruse/novel-coronavirus-landscape-covid-19 [https://perma.cc/5Z4J-FECB]. As of early 2022, there are 114 COVID-19 vaccines in clinical trials. Jonathan Corum, Carl Zimmer, Jonathan Corum, Sui-Lee Wee & Matthew Kristofferson, *Coronavirus Vaccine Tracker*, N.Y. TIMES, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html [https://web.archive.org/web/20200610095640/https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html] (June 10, 2020) (identifying that researchers "are developing more than 125 vaccines against the Coronavirus").

[153] *COVID-19 Treatment and Vaccine Tracker*, MILKEN INST., https://covid-19tracker.milkeninstitute.org/#treatment_antibodies [https://perma.cc/4AAV-VG6N] (Aug. 19, 2022) (listing over 230 R&D projects as of June 10, 2020). As of early 2022, there were over 600 products on this list (between therapeutics and vaccines). *Id.*

[154] *See generally, e.g.*, Eisenberg, *supra* note 96; Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299 (2015); David B. Ridley, Henry G. Grabowski & Jeffrey L. Moe, *Developing Drugs for Developing Countries*, 25 HEALTH AFFS. 313 (2006).

[155] *See generally* Eisenberg, *supra* note 96.

[156] *Id.* at 365–66. There are also market exclusivities available to some follow-on innovators. *Id.* Follow-on innovators can be either sponsors of generic versions of small-molecule drugs, or sponsors of biosimilar versions of large-molecule drugs. *See generally* Daniel J. Nam, *Patent and Regulatory Exclusivities: The Two Keys Driving Generic and Follow-on Market Availability*, U.S. PHARMACIST GENERIC DRUG REV., June 2016, at 6 (discussing follow-on innovation and the FDA's discretion to award market exclusivity).

[157] *See* Eisenberg, *supra* note 96, at 387–88 (defining follow-on innovators). *See generally* Nam, *supra* note 156.

[158] *See generally* Heled, *supra* note 154.

Market and data exclusivities are independent of the status of patent protection.[159] Yaniv Heled has emphasized how these FDA-administered exclusivities constitute "regulatory competitive shelters."[160] He also noted that these types of exclusivities are "limited almost exclusively to FDA regulation."[161] They reflect how pharmaceutical market players can take advantage of (and even abuse) some forms of incentives that are not available in other technical and scientific areas.[162]

Another type of incentive mechanism used by the FDA is the priority review voucher system.[163] The FDA encourages pharmaceutical companies to engage in research on traditionally underfunded diseases by offering review vouchers to sponsors of novel drugs in this area.[164] The vouchers can then be redeemed to expedite regulatory review of an unrelated drug—in practice, a drug targeting a mainstream disease[165]—by the same sponsor, or sold to a competitor.[166] The system covers vaccine-preventable infectious diseases like Ebola and Zika, as well as other neglected tropical diseases.[167] The transferability option of the voucher system naturally has made it highly susceptible to gamesmanship and

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[159] *Frequently Asked Questions on Patents and Exclusivity*, FDA, https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity [https://perma.cc/62X2-9NLU] (Feb. 5, 2020).

[160] *See* Heled, *supra* note 154, at 300.

[161] *Id.* at 353.

[162] For a critique of (overly) cumulative layers of incentives in the pharmaceutical and biopharmaceutical space, see for example Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 424 (2012).

[163] *See generally* Ridley, Grabowski & Moe, *supra* note 154, at 313 (proposing the voucher system); Michael Mezher, Zachary Brennan & Alexander Gaffney, *Regulatory Explainer: Everything You Need to Know About FDA's Priority Review Vouchers*, REGUL. AFFS. PROS. SOC'Y (Feb. 25, 2020), https://www.raps.org/regulatory-focus/news-articles/2017/12/regulatory-explainer-everything-you-need-to-know-about-fdas-priority-review-vouchers (on file with the *Ohio State Law Journal*).

[164] *See, e.g.*, Mezher, Brennan & Gaffney, *supra* note 163; *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., Summer 2017, at 71, 82.

[165] Rutschman, *supra* note 164, at 85 n.97 (critiquing the effect of the voucher system to reinforce its use for mainstream therapies).

[166] *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 [https://perma.cc/2MSW-7T9A]; 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/ [https://perma.cc/7SCT-DU4D] (noting the progressive decline in value after record high set in 2015).

[167] CTR. DRUG EVALUATION & RSCH. AND CTR. BIOLOGICS EVALUATION & RSCH., FOOD & DRUG ADMIN., U.S. DEP'T HEALTH & HUM. SERVS., TROPICAL DISEASE PRIORITY REVIEW VOUCHERS: GUIDANCE FOR INDUSTRY 3–4 (Oct. 2016), https://www.fda.gov/media/72569/download [https://perma.cc/3QUD-6LTU].

abuse.[168] Pharmaceutical companies can obtain vouchers in underfunded research but utilize the special expedited review in research of unrelated profitable drugs.[169]

Elsewhere in the administrative state, Rachel Sachs and others have made the case that insurance reimbursement, such as through the Medicare[170] and Medicaid[171] programs, should also be considered part of IP policy.[172] They demonstrated that such insurance programs can serve as a form of incentive to pharmaceutical research by promising consistent demand (albeit at lower prices) for vaccines.[173]

Similarly, other federal programs such as the Vaccines for Children Program ("VFC") enable the CDC to buy recommended vaccines at discount prices.[174] These vaccines are then made available through state, local, and territorial health departments or agencies to VFC providers at no cost for eligible populations.[175] The VFC program covers Medicaid-eligible, uninsured, and underinsured children, as well as American Indian and Alaska Native children.[176] The program is restricted to childhood vaccines recommended by the Advisory Committee on Immunization Practices,[177] which constitutes the backbone of official vaccination schedules.[178] Vaccines typically needed during a pandemic—which tend to align with the spectrum of neglected diseases—fall outside the VFC program.[179] Similarly, some adult vaccines are covered by state

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[168] *See* Rutschman, *supra* note 164, at 85–86.

[169] *Id.* at 72.

[170] *See generally* Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75 (2020).

[171] Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 193–08 (2016).

[172] *See generally id.*; Lemley, Ouellette & Sachs, *supra* note 170, at 75.

[173] *See* Sachs, *supra* note 171, at 207–08.

[174] *Vaccines for Children Program (VFC)*, CDC, https://www.cdc.gov/vaccines/programs/vfc/index.html [https://perma.cc/RG5W-CXHM] (Oct. 24, 2022).

[175] *Quality of Care Vaccines*, MEDICAID, https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/quality-of-care-vaccines/index.html [https://perma.cc/2EJ6-WNSJ].

[176] *Vaccines for Children Program (VFC)*, *supra* note 174.

[177] ADVISORY COMM. ON IMMUNIZATION PRACS., ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES POLICIES AND PROCEDURES 1 (June 2022), https://www.cdc.gov/vaccines/acip/committee/downloads/Policies-Procedures-508.pdf [https://perma.cc/AK2F-TMAV].

[178] CTRS. FOR DISEASE CONTROL & PREVENTION, RECOMMENDED CHILD AND ADOLESCENT IMMUNIZATION SCHEDULE 1 (2022) [hereinafter CHILDHOOD IMMUNIZATION SCHEDULE], https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf [https://perma.cc/6MT2-JLV9].

[179] *See, e.g.*, *Vaccines for Children Program vs. CDC COVID-19 Vaccination Program*, CDC, https://www.cdc.gov/vaccines/covid-19/vfc-vs-covid19-vax-programs.html [https://perma.cc/H34H-78L2] (Apr. 8, 2022) (explaining the separation between the VFC program and CDC Covid-19 Vaccination Program Provider Program).

Medicaid programs,[180] but coverage is significantly more limited when compared to the VFC program.[181]

Lastly, at the international level, there are procurement mechanisms to buy and distribute vaccines in developing countries.[182] 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.[183] Currently, Gavi supports seventeen different types of vaccines in varying ways.[184] 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.[185] Alas, these collaboration initiatives provide limited profit opportunities (if any) to participant pharmaceutical firms.[186]

Following outbreaks, and in response to a widely recognized lack of sufficient levels of research in the vaccine space, an international public-private partnership dedicated to supporting vaccine innovation in underfunded public health areas—the Coalition for Epidemic Preparedness Innovations or CEPI—emerged in 2017.[187] 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.[188]

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[180] *Quality of Care Vaccines*, *supra* note 175.

[181] *Compare* SARA ROSENBAUM, ALEXANDRA STEWART, MARISA COX & ALEXIS LEE, THE EPIDEMIOLOGY OF U.S. IMMUNIZATION LAW: MEDICAID COVERAGE OF IMMUNIZATIONS FOR NON-INSTITUTIONALIZED ADULTS 6 (Nov. 2003), https://publichealth.gwu.edu/departments/healthpolicy/DHP_Publications/pub_uploads/dhpPublication_5F6FC614-5056-9D20-3D48DB88 4F5C18C8.pdf [https://perma.cc/2HRC-KZ7K], *with* CHILDHOOD IMMUNIZATION SCHEDULE, *supra* note 178.

[182] *See* GAVI, A ROADMAP FOR THE FUTURE: COUNTRY-OWNED DECISIONS IN VACCINE PROCUREMENT 2 (Mar. 2018), https://www.gavi.org/sites/default/files/document/country-owned-decisions-roadmap---public-summarypdf.pdf [https://perma.cc/P9V8-8YRG] (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 immunisation among its people").

[183] *About Our Alliance*, GAVI, https://www.gavi.org/our-alliance/about [https://perma.cc/8D4F-5C84] (Dec. 21, 2022).

[184] *Vaccine Support*, GAVI, https://www.gavi.org/programmes-impact/types-support/vaccine-support [https://perma.cc/G65R-BBAE] (Nov. 29, 2022).

[185] *Id.*

[186] *GAVI's Business Model*, GAVI, https://www.gavi.org/our-alliance/operating-model/gavis-business-model [https://perma.cc/FK5A-DPC9] (Nov. 19, 2020).

[187] *A World in Which Epidemics and Pandemics Are No Longer a Threat to Humanity*, COAL. EPIDEMIC PREPAREDNESS INNOVATIONS, https://cepi.net/about/whyweexist/ [https://perma.cc/C4MP-F42L]; *see also* Rutschman, *Intellectual Property*, *supra* note13, at 181–85.

[188] COAL. FOR EPIDEMIC PREPAREDNESS INNOVATIONS, PRELIMINARY BUSINESS PLAN 2017–2021, at 12 (Nov. 2016), https://cepi.net/wp-content/uploads/2019/02/CEPI-Preliminary-Business-Plan-061216_0.pdf [https://perma.cc/GYU2-J43G] ("In the event that a vaccine developed with CEPI support does develop economic value, agreements between CEPI and

Yet, while CEPI has become a valuable player in the vaccine arena, it has a limited number of affiliated actors and restricted budget. Thus, the partnership contribution to the vaccine research pipeline is too small to have a significant effect on vaccine preparedness.

In the next part, we discuss the upshot of innovation policies in the vaccine context. We demonstrate how IP's monetary payoffs "crowd out" other motivations that might lead researchers to pursue the projects with the highest social value, such as basic vaccine research that lack immediate commercial applications. In other words, the incentive function of current IP and non-IP mechanisms is insufficient in the case of vaccine innovation.

E. *Crowding Out Vaccine Innovation*

Predominant economic narratives of intellectual property as a system of incentives essential to innovation have been gradually nuanced in scholarly literature and commentary.[189] The development of new vaccines is of strategic importance from a scientific and public health point of view. Nevertheless, a host of other factors—according to these intellectual property narratives—render investments in these socially valuable goods unattractive.[190] Such factors include, but are not limited to, high R&D costs, lengthy R&D timelines, scientific complexity and associated risk of failure, cost of regulatory review, potential emergence of new pathogenic variants, and, in some cases, potentially limited patient populations for a particular drug.[191] Given the particularities of vaccine innovation, we elaborate here on specific embodiments of vaccines and illustrate the shortcomings of IP and non-IP incentives for biopharmaceutical innovation in crowing out vaccine innovation. Thus, we highlight the

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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.").

[189] *See generally, e.g.*, LANDES & POSNER, *supra* note 86; Paul J. Heald, *A Transaction Costs Theory of Patent Law*, 66 OHIO ST. L.J. 473 (2005); ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 2 (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, 1539 (2017) (describing vaccine R&D processes that do not rely predominantly on IP frameworks); Eisenberg, *supra* note 96, at 347–48 (noting the existence of additional incentives mechanisms in the regulatory apparatus outside of patents and the particular role of the Food and Drug Administration as a catalyst for R&D in the pharmaceutical space); *see also generally* WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (1969); 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, which are based on efficient management frameworks and/or the goal of limiting overuse of information).

[190] *See* LANDES & POSNER, *supra* note 86, at 20–21.

[191] *See, e.g.*, Eisenberg, *supra* note 96, at 346.

importance of combining other non-IP policies to achieve superior preparedness frameworks in public health.[192]

Vaccines constitute a special illustration of biopharmaceutical innovations. While enormously important from a public health perspective, they are less attractive as commodified goods: vaccines offer very limited prospects for single-patient repeated use; demand wanes quickly as outbreaks begin to diminish; and pathogens mutate quickly, often reducing the efficacy of newly developed vaccines.[193] From a market-driven perspective, vaccine technology is often considered as one of the least appealing areas for investment in innovation.[194]

For market players motivated strictly or primarily by economic considerations, the prospects of return on investment tend to be considerably less in the area of vaccines compared to other types of pharmaceutical innovations.[195] Professor Yochai Benkler explains that motivation crowding out theory predicts that when monetary rewards to an activity are low, we might witness a negative effect of crowding out social motivation and other monetary incentives to engage in such activity.[196] Indeed, current IP and non-IP policies for biopharmaceutical research are instrumental to solve the crowding out effect in the case of vaccine innovation.[197]

Unlike existing blockbuster drugs[198] or drugs treating mainstream diseases, such as heart or autoimmune conditions,[199] vaccines have several idiosyncratic

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[192] *See infra* Part V.

[193] *See* Rutschman, *Intellectual Property*, *supra* note 13, at 173–74.

[194] Michael Kremer & Christopher M. Snyder, *Why Are Drugs More Profitable Than Vaccines?* 1 (Nat'l Bureau of Econ. Rsch., Working Paper No. 9833, 2003), https://www.nber.org/system/files/working_papers/w9833/w9833.pdf [https://perma.cc/ARH4-L75Y] (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).

[195] Rutschman, *Intellectual Property*, *supra* note 13, at 175–76.

[196] YOCHAI BENKLER, THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM 92–99, 115 (2006) (discussing motivation crowding out theory).

[197] *Id.* at 115.

[198] Rutschman, *IP Preparedness*, *supra* note 8, at 1207–13.

[199] The term "mainstream" is used here 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." *See* Mike Ward, *The 4 Trends Affecting Blockbuster Drug Status*, OUTSOURCED PHARMA (Jan. 25, 2022), https://www.outsourcedpharma.com/doc/the-trends-affecting-blockbuster-drug-status-0001 [https://perma.cc/P36K-4NSW]. 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 Rowley, *Pfizer's Lipitor: The Blockbuster Drug that Almost Wasn't*, HUFFPOST (Dec. 30, 2011), https://www.huffpost.com/entry/pfizers-lipitor-the-block_n_1176252 [https://perma.cc/XN3Q-KS6T]; 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/ [https://perma.cc/9TVR-GLF5].

features that inherently hamper commercialization and restrict possibilities of monetization.[200] First, they are primarily deployed to prevent a transmittable disease—a positive outcome in public health terms, but one whose economic impact is much harder to assess, as well as to reconcile with squarely for-profit business models.[201] Once vaccines successfully bring outbreaks under control, their effectiveness creates a false sense of security that the disease is "a matter of the past" all the while decreasing public awareness for the necessity of continuous vaccination to prevent transmission.[202] As opposed to vaccines for highly transmittable diseases that are developed concurrent to studying isolated outbreaks of the pathogen, drug treatments are often sold after the firm has already obtained ample information on the probability of contracting the illness.[203]

Moreover, mainstream drugs consumed over long periods of time or in multiple doses over a period of years provide a steady income per individual drug.[204] Conversely, vaccines often provide limited possibilities of limited consumption: one dose is frequently enough to generate long-term immunity,[205] and even when booster doses are required, they are still few and far between.[206] Once vaccines become widely used and prevent the spread of the disease, they reduce demand for the product along with revenue.[207] Lastly, although it is socially preferable to prevent epidemics, some people have been choosing—depending on their health situation, social exposure, and severity of the disease—to forgo vaccination as part of anti-vaccine ideology.[208] In recent

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[200] Rutschman, *IP Preparedness*, *supra* note 8, at 1207–13.

[201] *See* Rutschman, *Intellectual Property*, *supra* note 13, at 173.

[202] *See id.* at 173–74.

[203] Kremer & Snyder, *supra* note 194, at 6.

[204] Rowley, *supra* note 199; Keown, *supra* note 199.

[205] A few vaccines require repeat or boost dosages due to 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 What Vaccines Are Recommended for You*, CDC, https://www.cdc.gov/vaccines/adults/rec-vac/index.html [https://perma.cc/D34E-UELU] (Mar. 30, 2022) (listing recommended vaccines by age group, including vaccines that do not require booster doses). *But see* 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/ [https://perma.cc/7KLX-L8DR] (challenging the notion that a booster is even necessary for tetanus); *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 [https://perma.cc/HK6C-PTFW] (challenging the timeline for tetanus boosters).

[206] Rutschman, *supra* note 13, at 173–74.

[207] *See* Kremer & Snyder *supra* note 194, at 13–14.

[208] Donya Khalili & Arthur Caplan, *Off the Grid: Vaccinations Among Homeschooled Children*, 35 J.L. MED. & ETHICS 471, 474 (2007) (discussing the varying reasons—religion, government mistrust, mistrust of the premise of vaccines—that discourage parents from vaccinating their children).

years, the anti-vaccination movement has been on the rise.[209] Anti-vaccine or vaccine-questioning individuals may free ride others via herd immunity—rather than paying the prices (monetary and other) of vaccination.[210]

Moreover, even in the case of vaccines against emerging infectious disease pathogens for which there appears to be a market, quick pathogenic mutation may lessen—or raise concerns about—the effectiveness of a vaccine developed earlier in the outbreak, prior to the emergence of a variant of concern.[211] This, in turn, may in some cases lead to less demand for vaccine doses than originally predicted. Current IP and non-IP policies have not been successful in increasing the motivation of firms with excess capacity to engage in vaccine research.[212] We believe that the specific characteristics of vaccines as commodified goods—in particular the limited number of potential users and uses[213]—make current IP and non-IP mechanism imperfect incentives for vaccine innovation. The dynamics of vaccine innovation models structured around current allocation and incentives mechanisms are thus often in tension with public health imperatives, which prescribe preparedness and affordability through a robust and continuous R&D.[214]

Considering that vaccines are generally regarded as one of the most cost-effective means of preventing a disease and lessening its socioeconomic burden,[215] underinvestment in vaccine innovation also produces significant undesirable social effects.[216] Lacking or insufficient vaccines are bound to result in high costs to health systems dealing with outbreaks of vaccine-preventable

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[209] *See, e.g.*, Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J.L. & PUB. POL'Y 537, 543 n.23 (2010) (discussing the roots of the anti-vaccine movement opposing compulsory vaccination on grounds of personal autonomy as well as fear of injury).

[210] 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*, 2020 U. ILL. L. REV. 233, 245 ("[S]ome 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.").

[211] *See, e.g.*, Carl Zimmer, *New Virus Variant Stokes Concern but Vaccines Still Likely to Work*, N.Y. TIMES, https://www.nytimes.com/2021/11/26/health/omicron-variant-vaccines.html [https://perma.cc/N98S-9XEE] (Nov. 30, 2021).

[212] Rutschman, *supra* note 13, at 172–77.

[213] *See id.* at 173.

[214] *See, e.g.*, Mehand, Al-Shorbaji, Millet & Murgue, *supra* note 10, at 63.

[215] *See supra* note 51–52 and accompanying text; Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, 7 TEX. A&M J. PROP. L. 110, 112 (2021).

[216] *See The Impact of COVID-19 on Employment and Jobs*, ORG. ECON. CO-OP. & DEV., https://www.oecd.org/employment/covid-19.htm [https://perma.cc/75LQ-PMRV] (hosting policy briefs detailing the wide variety of economic, employment, social, income, health and personal effects the COVID-19 pandemic has had on individuals).

diseases while slowing economic growth and upsetting employment.[217] The recent pandemic thrust this aspect of the economic impact of preparedness frameworks (or lack thereof) into mainstream debates, associating it with the biggest blow to the U.S. economy since the Great Depression.[218]

The current IP and non-IP incentives framework, in its transversal and largely technology-agnostic architecture,[219] has so far proved an imperfect catalyst for vaccine innovation, especially in the case of neglected or orphan diseases.[220] As such, predominant policy models, which remain IP-centric,[221] have historically led to a scenario of pronounced underinvestment in the development of new vaccines.[222] 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.[223] In public health terms, this market inefficiency translates into suboptimal 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.[224] Other non-IP incentives used in an attempt to solve these inefficiencies in vaccine research have had marginal success in improving vaccine preparedness.[225]

Set side by side with pharmaceutical and other technological innovation, current allocation and incentive mechanisms perpetuate a lower market

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[217] *See generally id.*; *The Impact of COVID-19 on Health and Health Systems*, ORG. ECON. CO-OP & DEV., https://www.oecd.org/health/covid-19.htm [https://perma.cc/4TMK-XGTN].

[218] *The Impact of COVID-19 on Employment and Jobs*, *supra* note 216.

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

[220] *See supra* notes 98–102 and accompanying text.

[221] Vaccine R&D 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 20, at 732–33. 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 AFFS. (May 19, 2020), https://www.foreignaffairs.com/articles/world/2020-05-19/drugs-and-vaccines-are-coming-whom [https://perma.cc/T4BY-3JAZ].

[222] *See supra* notes 193–96 and accompanying text; Frederick Chen & Flavio Toxvaerd, *The Economics of Vaccination*, 363 J. THEORETICAL BIOLOGY 105, 105–06 (2014) (noting that the "market for vaccinations is widely believed to be characterized by market failures" but demonstrates conditions in which equilibrium non-optimality may be obtained).

[223] *See* Rutschman, *IP Preparedness*, *supra* note 8, at 1246.

[224] WORLD HEALTH ORG., *supra* note 4, at 6, 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 Health Organization noted with regard to the 2014–2016 Ebola outbreak, "[t]here were no vaccines, no treatments, few diagnostics, and insufficient medical teams and trained responders." *Id.* at 6.

[225] *See* Rutschman, *IP Preparedness*, *supra* note 8, at 1216–17.

motivation for vaccine research.[226] Compared to ordinary drugs, vaccines for diseases that do not reoccur are deemed relatively less profitable.[227] For example, in 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 $8.23 billion and $8.19 billion, respectively.[228] All top ten best-selling drugs registered in 2017 over $6 billion in sales individually.[229] 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 world's best-selling vaccine, known as Prevnar 13 targeting pneumococcal disease,[230] generated $5.69 billion in revenue, a number that is projected to increase modestly by 2024 to $5.76 billion.[231] Gardasil, a vaccine targeting the human papillomavirus (HPV),[232] came in second in the United States market at $2.38 billion in 2017.[233] The fourth and fifth best-selling vaccines in 2017 were already under the $2 billion threshold.[234]

These vaccines are listed on official recommended child and adolescent vaccination schedules (routine vaccinations) and thus enjoy relatively stable markets with predictable and sustained demand over time.[235] It is important to note that the majority of vaccines against infectious disease pathogens generate significantly lower revenues than these best-selling vaccines alluded to above.[236] Accordingly, the National Academy of Sciences has reported "radical change[s]" over the last few decades in the vaccine supply system.[237] While more than twenty-five private firms produced vaccines for the U.S. market in

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[226] *See* Rutschman, *Intellectual Property*, *supra* note 13, at 175–77.

[227] *See* COAL. FOR EPIDEMIC PREPAREDNESS INNOVATIONS, *supra* note 188, at 7.

[228] Mark Terry, *Drum Roll, Please! Top 10 Bestselling Drugs in the U.S.*, BIOSPACE (May 21, 2018), https://www.biospace.com/article/drumroll-please-top-10-bestselling-drugs-in-the-u-s-/ [https://perma.cc/5JFF-6GFS]; *see also* Ana Santos Rutschman, *Regulatory Malfunctions in the Drug Patent Ecosystem*, 70 EMORY L.J. 347, 351 (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 elsewhere).

[229] Terry, *supra* note 228.

[230] *Pneumococcal Conjugate VIS*, CDC, https://www.cdc.gov/vaccines/hcp/vis/vis-statements/pcv13.html [https://perma.cc/95RW-88JT] (Feb. 4, 2022).

[231] Matej Mikulic, *Top 5 Global Vaccine Products Based on Revenue 2017 and 2024*, STATISTA (July 27, 2022), https://www.statista.com/statistics/314566/leading-global-vaccine-products-by-revenue/ [https://perma.cc/7WPG-HRBH].

[232] *Human Papillomavirus (HPV) Vaccine*, CDC, https://www.cdc.gov/vaccinesafety/vaccines/hpv-vaccine.html [https://perma.cc/8CDK-8BJC] (Sept. 9, 2020).

[233] Mikulic, *supra* note 231.

[234] *Id.*

[235] CHILDHOOD IMMUNIZATION SCHEDULE, *supra* note 178.

[236] INST. OF MED. OF THE NAT'L ACADS., FINANCING VACCINES IN THE 21ST CENTURY: ASSURING ACCESS AND AVAILABILITY 107 (2003) (reporting severe erosion in the private vaccine supply system).

[237] *Id.* at 1.

the last thirty years, currently only five companies produce all routinely recommended vaccines.[238]

Non-routine vaccines tend to fare much worse in terms of market performance.[239] This is the case for vaccines when there are outbreaks of infectious diseases that are (or used to be) infrequent in countries in the developed world, such as the Ebola outbreak in 2014–2016 and the Zika outbreak in 2015–2016.[240] 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.[241] And yet, before the outbreak suddenly and temporarily spiked demand for these vaccines, R&D of these vaccines had come to a standstill.[242] 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.[243]

Business models dependent on the monetization of IP rights and the paucity of current non-IP incentives landscape present high inefficiencies when applied to vaccines.[244] Consequently, there remains a large disjunction between public health needs and investment in vaccine innovation, creating suboptimal levels of preparedness. This prompts us to consider underused levers in the non-IP incentives landscape. Next, we explore the role of tax law in spurring investment in pharmaceutical innovation, more specifically, in the vaccine research domain.

IV. PAST AND PRESENT INNOVATION TAX SCHEMES

We now turn our attention to tax policy for two reasons: first, within the innovation literature—and, more broadly, within the legal literature—tax incentives have received far less attention than other incentives frameworks.[245] Second, and more importantly, reliance on the tax system offers a significant advantage over other types of non-IP incentives, which require greater shares of *ex ante* set-asides for the incentive to be disbursed and passed along to market players.[246] Set by the public sector, tax incentives create an enabling framework that is self-incorporated by private sector players and investors.[247] They leverage private information from market actors to establish innovation

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[238] *Id.*

[239] *See* Rutschman, *supra* note 215, at 112–13.

[240] *See generally* Rutschman, *IP Preparedness*, *supra* note 8, at 1209–12.

[241] *Id.* at 1242.

[242] 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 [https://perma.cc/9WYA-XG6X].

[243] *Id.*; Rutschman, *IP Preparedness*, *supra* note 8, at 1222.

[244] *See* Rutschman, *Intellectual Property*, *supra* note 13, at 173–74; Rutschman, *IP Preparedness*, *supra* note 8, at 1216–17.

[245] *See* Hemel & Ouelette, *supra* note 27, at 551–52.

[246] *See id.* at 553; *supra* note 105 and accompanying text.

[247] *See* Hemel & Ouelette, *supra* note 27, at 553.

payoffs.[248] In this sense, they constitute a public policy tool that takes advantage of market forces and maintains market actors' flexibility, without relying on set funding from pre-existing, limited budgets.

It is important to note that in focusing on tax policy, our point is not that tax incentives are preferable or comparatively superior to other forms of non-IP incentives. Rather, we join recent scholarship calling for innovation policy pluralism.[249] We argue that in the vaccines for transmittable diseases area, tax law has been ignored or underused efficiently to stimulate innovations. We contend that tax policies can and should be tailored in ways that further innovation policy landscape, in particular those that are closely aligned with the pursuit of superior vaccine preparedness and other public health imperatives.

At present, there are several tax apparatuses that are available for companies conducting research, including but not limited to pharmaceutical research.[250] Immediate expensing provides a faster way to recover the cost of investment in innovation. The Research and Experimentation credit ("R&D credit")[251] offers companies a direct reduction in their tax bills in return for increasing spending on in-house research.[252] The Basic Research credit ensures that companies receive the same benefit as the latter when they outsource scientific investigations and collaborating with universities.[253] The Orphan Drug Credit aims to alleviate some of the development costs of drugs for rare diseases at the clinical trial phase.[254] Finally, Patent Donations provide a charitable deduction for intellectual property donated to nonprofit organizations.[255]

As this Part will reveal, these existing incentives displace motivations for vaccine research and are poorly designed to address the idiosyncratic features of vaccine development. The tax system's current one-size-fits-all approach de facto disincentivizes vaccine preparedness by nudging firms away from vaccine

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[248] *See id.* at 555–56.

[249] *See generally id.*

[250] *See, e.g.*, I.R.C. § 179.

[251] In this Article, the terms "research and development" and "research and experimentation" are used interchangeably although the latter is more restrictive than the former and does not necessarily specify immediate commercial applications. The term "research and experimentation" tracks back to immediate expensing under I.R.C. § 174; 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).

[252] Atkinson, *supra* note 25, at 618.

[253] *See infra* Part IV.B.

[254] *See infra* Part IV.C.

[255] This Article focuses on tax provisions relating to pharmaceutical innovation and does 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) (discussing extensive literature on taxation of intangibles); Xuan-Thao Nguyen & Jeffrey A. Maine, *Equity and Efficiency in Intellectual Property Taxation*, 76 BROOK. L. REV. 1 (2010) (reviewing and criticizing tax rules relating to patents, copyrights, and trademarks).

innovation projects with high social value and toward mainstream pharmaceutical and technological innovations. Moreover, while these incentives might contribute to the growth of private research enterprise, they have been criticized for mainly rewarding large pharmaceutical firms that make use of the benefits whilst spiking drug prices and insurance premiums.[256]

A. *Recovery of R&D Investments*

A fundamental rule in tax law is that the cost of doing business incurred while creating or developing an asset with useful life extending beyond the taxable year is "capitalized" ("amortized" in the case of intangibles), i.e. deducted over time.[257] Nevertheless, the Internal Revenue Code ("Tax Code") provides taxpayers with a faster way to recover their costs relating to research and development.[258] In the past, companies could elect to fully expense qualified intangible investments (such as research and experimentation equipment) or deduct them over a period of five to ten years.[259] The policy is often termed "immediate" or "full" expensing.[260] 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[261]—most taxpayers opted to deduct such expenses immediately rather than incrementally depreciate them over a number of years.[262] In that manner, immediate expensing improves the attractiveness of qualified R&D investments by their increasing the rate of return.[263] Yet, companies with substantial short-term losses such as small and startup companies with no positive income to offset against the immediate deduction

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[256] *See infra* notes 319–22 and accompanying text.

[257] I.R.C. §§ 167, 263.

[258] Internal Revenue Code of 1954, Pub. L. 83-591, § 174, 68A Stat. 3, 66 (codified as amended at I.R.C. § 174).

[259] I.R.C. § 174(a), (b).

[260] ROBERT BELLAFIORE, TAX FOUND., NO. 635, AMORTIZING RESEARCH AND DEVELOPMENT EXPENSES UNDER THE TAX CUTS AND JOBS ACT 2 (Feb. 2019), https://files.taxfoundation.org/20190204170826/Amortizing-Research-and-Development-Expenses-under-the-Tax-Cuts-and-Jobs-Act-FF635.pdf [https://perma.cc/63TE-ARM4].

[261] *See* John Schmidt, *How Inflation Erodes the Value of Your Money*, FORBES, https://www.forbes.com/advisor/investing/what-is-inflation/ [https://perma.cc/YL36-5DH5] (Aug. 5, 2022).

[262] I.R.C. § 179. For the history of the immediate expensing, see Mirit Eyal-Cohen, *Lessons in Cyclical Fiscal Activism*, 48 CONN. L. REV. 873, 875–78 (2016) (reviewing the history of certain investment tax incentives and the reasons for their persistence).

[263] The Tax Code defines qualified research and experimentation expenses eligible for immediate expensing as those used for testing in the exploratory or lab setting related to the development or improvement of a product. Treas. Reg. § 1.174-2(a) (as amended in 2014). Some examples include wages of employees engaged in R&D, expenses to update and maintain research facilities, equipment utilized for experimentation or trials, etc. *See id.*

likely do *not* benefit as much from this preference compared to larger and established firms.[264]

Scholars have debated the efficiency of immediate and accelerated capital recovery policies.[265] They questioned their efficacy in furthering government goals to generate economic stimulus by increasing the positive net present value of designated investments.[266] Some have argued that immediate expensing as a general rule (not just for intangibles R&D investments) represents bad policy and a hefty subsidy[267] without special public merit.[268] Others have noted expensing encourages a waste of capital by promoting ineffective investments that, absent the tax benefit, would not have been made.[269] They called policymakers' attention to the scope, efficacy, and desirability of such investments when taken primarily for tax savings purposes.[270]

Indeed, in recent legislation, the government expended the application of bonus depreciation for tangible property to all taxpayers but, starting in 2022, eliminated that benefit for intangible R&D expensing, requiring such expenditures to be amortized ratably over several years.[271] This change has drawn bipartisan opposition.[272] The Tax Foundation estimated that full expensing of R&D investments has the potential of increasing the economy by 0.15% creating additional 30,600 full-time jobs.[273] Many warned such changes threaten to disrupt the future of innovation in the United States and may drive science and discovery activities offshore to Europe and China.[274]

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[264] *Id.*; I.R.C. §§ 174(f)(2), 59(e). Moreover, some companies might choose to defer the deduction to mitigate the effect of the alternative minimum tax adjustment for research expenditures. I.R.C. § 56(b)(2).

[265] *See, e.g.*, Rebecca N. Morrow, *Accelerating Depreciation in Recession*, 19 FLA. TAX REV. 465, 488–90 (2016).

[266] *See, e.g.*, *id.* (arguing that the data is mixed on whether these policies achieved their stated intent).

[267] *See* BELLAFIORE, *supra* note 260, at 4 (estimating the effect of the policy is an annual $8.43 billion in revenue).

[268] On the history of the immediate expensing rule, see generally Eyal-Cohen, *supra* note 262 (comparing the historical circumstances for creating immediate expensing and other tax policies).

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

[270] *See generally id.*

[271] Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, § 13206, 131 Stat. 2054, 2111 (codified as amended I.R.C. § 174) ("TCJA"); I.R.C. § 174(a)(1)-(2).

[272] *See* Xuan-Thao Nguyen & Jeffrey A. Maine, *Attacking Innovation*, 99 B.U. L. REV. 1687, 1689–93 (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 innovation); Press Release, U.S. Rep. Mike Kelly, Ways & Means Republicans Reintroduce Legislating Supporting Treatments and Cures for Healthier Future (Apr. 19, 2022), https://kelly.house.gov/media/press-releases/kelly-ways-means-republicans-reintroduce-legislation-supporting-treatments-and [https://perma.cc/H679-5JXW].

[273] BELLAFIORE, *supra* note 260, at 3260.

[274] *See, e.g.*, Nguyen & Maine, *supra* note 272, at 1692.

Additionally, we point to the problem of making available a superior cost recovery rule to the development or improvement of *any* product, regardless of its public necessity, positive (or negative) spillovers, or social value.[275] This wide application may disturb other motivations that lead firms to pursue research projects with highest social value but prolonged development period and limited commercial application. Such is the case of vaccine innovation. Not only do current cost recovery rules lack incentives to engage in research, let alone vaccine innovation, but they also tend to nudge taxpayers towards other tangible investment activities.[276] These rules address none of the distinct vaccine development characteristics, which aside from high uncertainty and non-rivalry affecting all innovation endeavors, also implicate restricted monetarization, high regulatory oversight, and lack of recurrent use.[277]

B. *Credits for Increasing Research Efforts*

In 1981, Congress added a temporary research credit to stimulate private research and experimentation in technological discoveries and reverse a decline in private sector R&D during those years.[278] The R&D credit was not necessarily geared toward medicinal research.[279] It benefited from large endorsement by leaders from the high-tech, integrated circuits, telecommunications, and computer industries thus enjoyed wide bipartisan support.[280] Not surprisingly, over several decades, the credit endured multiple renewals, extensions, and retroactive extensions until it became permanent in 2015.[281]

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[275] I.R.C. § 168(k) was made availableby the TCJA. *Supra* note 271; *See* Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, § 13201, 131 Stat. 2054, 2105 (codified as ameneded I.R.C. § 168).

[276] *See* Rutschman, *Intellectual Property*, *supra* note 13, at 177.

[277] *See id.*

[278] Economic Recovery Tax Act of 1981, Pub. L. No. 97–34, § 221, 95 Stat. 172, 241–49 (adding § 44F to the Tax Code); STAFF OF JOINT COMM. ON TAX'N, 97TH CONG., GENERAL EXPLANATION OF THE ECONOMIC RECOVERY TAX ACT OF 1981, at 119 (Comm. Print 1981) (reporting civilian research to GNP ratio is 1.5%, compared with 1.9% for Japan and 2.3% for West Germany).

[279] STAFF OF JOINT COMM. ON TAX'N, 97TH CONG., GENERAL EXPLANATION OF THE ECONOMIC RECOVERY TAX ACT OF 1981, at 140 (Comm. Print 1981).

[280] Mirit Eyal-Cohen, *Unintended Legislative Inertia*, 55 GA. L. REV. 1193, 1245–46 (2021) (describing the history of the research credit that was created as part of a cluster of temporary provisions to allow flexible legislation).

[281] The R&D credit been extended sixteen times, of which seven times were retroactive extensions. GARY GUENTHER, CONG. RSCH. SERV., RL31181, FEDERAL RESEARCH TAX CREDIT: CURRENT LAW AND POLICY ISSUES 4, 27–29 (2022). In 2015, President Obama signed into law the Protecting Americans from Tax Hikes Act of 2015, Pub. L. No. 114-113, § 121, 129 Stat. 3041, 3049, that made the credit permanent. Eyal-Cohen, *supra* note 280, at 1269 n.449. For a detailed legislative history of the acts extending the R&D credit, see *id.* at 1273–75.

As its title specifies, the R&D credit applies only to incremental research expenditures, aiming to nudge firms to increase their average research expenses rather than rewarding them for research undertaken regardless of the tax savings.[282] To achieve this ambitious endeavor, the R&D credit provides up to 20% dollar-per-dollar reduction against the taxpayer tax liability.[283] Nevertheless, claiming the credit involves complicated calculations.[284] It requires calculating "qualified research expenses"[285] and multiplying the company's historical "fixed-base percentage"[286] by average annual gross receipts for the preceding four taxable years.[287] For start-up companies with fewer than three years of gross receipts there exists a modified calculation.[288]

Much of the R&D credit's ineffectiveness derives from its high intricacy.[289] Considerable confusion further stems from rules added later to limit punishment of firms that maintain a solid but nonetheless steady research record,[290] to avoid benefiting companies that increase their research spending after establishing a

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[282] Economic Recovery Tax Act of 1981 § 221.

[283] I.R.C. § 41(a).

[284] *See* sources cited *infra* notes 290–92.

[285] I.R.C. § 41(b)(1). Contract research expenses are limited to 65% of any amount paid to any person (other than an employee of the taxpayer) for qualified research. I.R.C. § 41(b)(3)(A). Expenses are ineligible if they involve routine data collection, routine quality-control testing, social science research, grant-funding research, or research conducted outside the United States. I.R.C. § 41(d)(4).

[286] I.R.C. § 41(c)(1). 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. I.R.C. § 41(c)(2). The credit's statutory rate was initially set at 20% 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. Tax Reform Act of 1986, Pub. L. No. 99-514, § 231(c)(1), 100 Stat. 2085, 2173 (1986) (current version at I.R.C. § 41); ALEX MURESIANU & GARRETT WATSON, TAX FOUND., NO. 759, REVIEWING THE FEDERAL TAX TREATMENT OF RESEARCH & DEVELOPMENT EXPENSES 3 (Apr. 2021), https://files.taxfoundation.org/20210413140116/Reviewing-the-Federal-Tax-Treatment-of-Research-Development-Expenses.pdf [https://perma.cc/87CW-4EJ7].

[287] I.R.C. § 41(c)(1). The fixed-base percentage is a historical percentage denoting the company's total "qualified research expenses" over total gross receipts. I.R.C. § 41(c)(3)(A).

[288] I.R.C. § 41(c)(3)(B). The calculation is multifaceted, starting from a fixed-base percentage of 3% and thereafter gradually transitioning to a fixed-base percentage based on actual R&D. I.R.C. § 41(c)(3). *See generally* Catherine Fazio, Jorge Guzman & Scott Stern, *The Impact of State-Level R&D Tax Credits on the Quantity and Quality of Entrepreneurship* (Nat'l Bureau of Econ. Rsch., Working Paper No. 26099, 2019), https://www.nber.org/system/files/working_papers/w26099/w26099.pdf [https://perma.cc/7UVR-MDAS] (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).

[289] *See, e.g.*, MURESIANU & WATSON, *supra* note 286, at 11 (noting one of the R&D credit's biggest flaws is its complexity, which "may limit the ability of firms, particularly smaller firms, to access its benefits").

[290] I.R.C. § 41(c)(3)(C) ("In no event shall the fixed-base percentage exceed 16 percent.").

base period,[291] and to permit companies to elect a simpler way to calculate the credit.[292] Alas, these noteworthy objectives add numerous convoluted features to the R&D credit that make it hard to comply, administer, and enforce.[293] In addition, in order to narrow misuse, gaming, or overclaiming, the R&D credit contains several limitations on "double dipping" in conjunction with other benefits.[294] The R&D credit also comes with a high tax price tag.[295] Yet, due to the difficulty in evaluating innovation output and tracing it to R&D spending, little is known about the effects of such incentives in *actually* spurring innovation.[296]

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[291] I.R.C. § 41(c)(2) (providing that at a minimum, the base amount is no less than 50% of the qualified research expenses for that year).

[292] Firms can elect to use an alternative simplified manner to calculate the R&D credit as 14% of "qualified research expenses for the taxable year as exceeds 50% of the average qualified research expenses" for the three preceding taxable years. I.R.C. § 41(c)(4)(A). If the taxpayer has no qualified research expenses in any of three preceding taxable years, the alternative simplified credit rate is 6% of qualified research expenses. I.R.C. § 41(c)(4)(B).

[293] *See* MURESIANU & WATSON, *supra* note 286, at 9–10 (discussing issues relating to the administration and compliance of the R&D credit).

[294] For example, the credit is not available for research funded via government or private grants. I.R.C. § 41(d)(4)(H). Moreover, companies claiming the credit cannot "double dip;" thus, they must reduce immediate expensing & the Orphan Drug Credit for the credit. I.R.C. § 280C(c)(1).

[295] The Joint Committee on Taxation estimates that in 2020, the federal government will lose $12.9 billion in tax revenues by reason of the R&D credit. *See* STAFF OF THE JOINT COMM. ON TAX'N, JCX-55-19, ESTIMATES OF FEDERAL TAX EXPENDITURES FOR TAX YEARS 2019-2023, at 24 (2019).

[296] Over the years, studies on the correlation between the R&D tax credit and R&D spending have been mixed. *See, e.g.*, *National Patterns of R&D Resources: 1994*, NAT'L SCI. FOUND. tbls. B6, B9, B12 (Sept. 14, 1995), https://www.nsf.gov/statistics/archive-goodbye.cfm?p=http://www.nsf.gov/statistics/s2194/ [https://perma.cc/CP27-PYSE] (to navigate to tables B6, B9 and B12: Appendix B. Detailed Statistical Tables >>National Totals >> B-6: "Sources of funds for basic research, by sector: 1953–94," B-9: "Sources of funds for applied research, by sector: 1953–94," B-12: "Sources of funds for development, by sector: 1953–94") (supporting the renewal of the credit for its contribution to a positive research growth trend); Antoine Dechezleprêtre, Elias Einiö, Ralf Martin, Kieu-Trang Nguyen & John Van Reenen, *Do Tax Incentives for Research Increase Firm Innovation? An RD Design for R&D* (Nat'l Bureau of Econ. Rsch., Working Paper No. 22405, 2016), https://www.nber.org/system/files/working_papers/w22405/w22405.pdf [https://perma.cc/NC4F-ETPE] (finding evidence of a causal impact of R&D tax incentives on innovation); Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. HEALTH ECON. 1060, 1061 (2008) ("Tax credits can stimulate R&D."); Frischmann, *supra* note 87, at 382 ("[T]ax incentives counterbalance innovative process market failures."); Atkinson, *supra* note 25, at 619 (arguing almost all recent studies found the investment of $1 of research credit produces more than $1 in R&D expenditures). *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 and R&D expenditures).

Lastly, when Congress enacted the R&D credit, it also created the Basic Research Credit.[297] The Basic Research Credit offers for-profit firms a similar credit for payments made to nonprofit organizations for collaborative research.[298] The definition of basic research entails domestic original study for the development of scientific knowledge not having an explicit commercial objective.[299] Qualified basic research payments must be made to an educational or tax-exempt organization pursuant to a written agreement.[300] The Basic Research Credit calculation is different from the general R&D credit, which adds yet more complexity to an already intricate incentive system and increases hurdles for new and smaller firms trying to secure these benefits.[301] By enacting the Basic Research Credit the government aimed to encourage firms to collaborate around primary research that has no initial profitable objective in hope that later on that knowledge will continue to be developed and commercialized.[302]

Although not geared specifically towards pharmaceutical firms, about thirteen percent of firms claiming the R&D and Basic Credits have been from that industry.[303] At the same time, these measures are not designed specifically to address the explicit challenges involving vaccine innovation. Substantially lower revenues, no repeat customers, limited price margins, as well as extensive expenses and lags for clinical trials to ensure mass production safety are not well attended to by these measures.[304] As a result, the R&D and Basic Credits do not improve the attractiveness of investments in vaccine research and even

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[297] I.R.C. § 41(e).

[298] I.R.C. § 41(e)(6).

[299] William Natbony, *The Tax Incentives for Research and Development: An Analysis and a Proposal*, 76 GEO. L.J. 347, 397 (1987).

[300] *Id.* at 396–98 (discussing the credit in the context of federal budget constraints).

[301] The Basic Research Credit 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. I.R.C. § 41(e)(1). The Qualified Organization Base Period Amount ("QOBPA") is the sum of the taxpayer's minimum basic research amount and maintenance-of-effort amount. I.R.C. § 41(e)(3). The base period is the three-year period ending with the tax year immediately preceding the taxpayer's first tax year. I.R.C. § 41(e)(7)(B).

[302] *See* Shay, Fleming & Peroni, *supra* note 251, at 444 (detailing the purpose of subsidies for inducing basic research and noting it is not substantial enough for private-sector participants).

[303] 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%). *SOI Tax Stats—Corporation Research Credit*, https://www.irs.gov/statistics/soi-tax-stats-corporation-research-credit [https://perma.cc/9RYA-LB72] (scroll to "Table 2: Corporations Claiming a Credit, by Manufacturing Subsector"; click "2013" hyperlink).

[304] *See* Rutschman, *Intellectual Property*, *supra* note 13, at 172–79.

discourage undertaking it by providing the same inducements to the more common curative treatments and everyday technological innovations.

C. *Orphan Drug Credit*

The R&D and Basic tax Credits as well as the capital recovery rules are tax mechanisms that apply to all types of investments in innovation.[305] An apparatus designed specifically to encourage an explicit category of pharmaceutical research was created in 1983 in the Orphan Drug Act.[306] The Act provided a credit for expenditures related to human clinical testing (the most expensive stage)[307] for rare diseases[308] or conditions that influence a smaller portion of the general population.[309] A rare disease or condition includes those affecting fewer than 200,000 people in the United States, or affecting more than 200,000 in the United States but without reasonable prospects that such medication will be profitable, that is, its cost of development will not be recovered from its sales in the United States[310]

The credit's main purpose is to spur research on rare disorders and uncommon ailments that lack commercial pharmaceutical sponsorship (i.e., "orphaned") due to their smaller scope of patients and prospective "clients."[311] When enacted, the Orphan Drug Act provided a credit for (then) 50% of clinical testing expenses incurred in the process of developing orphan drugs.[312] The Act

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[305] *See supra* Part II.A–II.B; *cf.* Orphan Drug Act, Pub. L. No. 97-414, § 1(b), 96 Stat. 2049, 2049–57 (1983) (codified as amended in scattered sections of 26 U.S.C).

[306] Orphan Drug Act § 1(b).

[307] *See, e.g.*, Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20, 25–26 (2016); Orphan Drug Act, Pub. L. No. 97-414, § 4(a), 96 Stat. 2049, 2053 (1983) (codified as amended at I.R.C. § 28, renumbered § 45C); *see also* I.R.C. § 45C(2). The cost of the Basic Credit was estimated to be around $6.0 billion a year in 2010. STAFF OF S. COMM. ON THE BUDGET, 111TH CONG., TAX EXPENDITURES: COMPENDIUM OF BACKGROUND MATERIAL ON INDIVIDUAL PROVISIONS 89 (Dec. 2010) (prepared by the Congressional Research Service).

[308] I.R.C. § 45(C)(d)(1)(A).

[309] I.R.C. § 45(C)(d)(1)(B).

[310] *See supra* note 102 and accompanying text.

[311] For example, muscular dystrophy, Tourette syndrome, and Lou Gehrig's disease. *See supra* note 102 and accompanying text; *Duchenne Muscular Dystrophy*, NAT'L CTR. ADVANCING TRANSLATIONAL SCIS., https://rarediseases.info.nih.gov/diseases/6291/duchenne-muscular-dystrophy [https://perma.cc/FYK7-YBNB] (Nov. 8, 2021). 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 § 1(b) (providing an overview on the environment of research in the area of rare conditions and diseases).

[312] I.R.C. § 45C; Orphan Drug Act, Pub. L. No. 97-414, § 2(a), 96 Stat. 2049, 2049–53 (1983) (codified as amended at 21 U.S.C. § 360cc). It also allowed unused credit to be offset by past and future tax liability through carryback and carryforward features. Richard Chueng, Jillian C. Cohen & Patricia Illingworth, *Orphan Drug Policies: Implications for the United*

also amended the FDA Act to include an exclusive period of promotion and marketing rights for such designated drugs.[313] Such policies are complemented with additional non-IP measures such as special orphan-designated grants, expedited approval and waivers procedures, and a seven-year marketing exclusivity protection from generics.[314]

Scholars and professionals have noted that the Orphan Drug Act has been successful in spurring the development of lifesaving therapies for over 600 drugs and biologic products for rare diseases such as cystic fibrosis, muscular dystrophy, and various pediatric cancers.[315] Scientific advances in rare diseases along with accelerated FDA review highlight policymakers' growing commitment to propel orphan drug development.[316] Recent empirical studies demonstrated that receiving an orphan drug designation provides, in and of itself, a strong positive signal for potential investors.[317] Accordingly, the last few years also saw vast investment opportunities for pharmaceutical firms associated with orphan drugs in partnerships and corporate mergers and

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States, Canada, and Developing Countries, 12 HEALTH L.J. 183, 185 (2004) (explaining that the Orphan Drug Act permitted carryback three years and carry forward up to fifteen years).

[312] *See, e.g.*, 21 U.S.C. § 360ee(a) (establishing the scope of the tax credit).

[313] *See, e.g.*, 21 U.S.C. § 360cc(a). *See generally* Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2351–52 (2018) ("[P]olicymakers clearly understand the potential benefits of implementing innovation-related policies through the FDA approval process.").

[314] Rachel E. Sachs, *Administering Health Innovation*, 39 CARDOZO L. REV. 1991, 2008–12 (2018).

[315] 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, 1074–75 (1994) (reviewing the successes limitations, and criticisms of the Orphan Drug Act); Yin, *supra* note 296, at 1061 (demonstrating that the Orphan Drug Act increased production of drugs for rare diseases); NAT'L ORG. FOR RARE DISORDERS, ORPHAN DRUGS IN THE UNITED STATES: AN EXAMINATION OF PATENTS AND ORPHAN DRUG EXCLUSIVITY 3 (2021), https://rarediseases.org/wp-content/uploads/2021/03/NORD-Avalere-Report-2021_FNL-1.pdf [https://perma.cc/MH6C-28RA].

[316] *See, e.g.*, Isabella Cueto, *'A Golden Age': Long Neglected in Medicine, Rare Kidney Diseases See a Surge in Research*, STAT (Aug. 23, 2022), https://www.statnews.com/2022/08/23/rare-kidney-disease-research-igan/ [https://perma.cc/9VTQ-GV6C].

[317] Kathleen L. Miller, *Do Investors Value the FDA Orphan Drug Designation?*, 12 ORPHANET J. RARE DISEASES 4 (2017), https://ojrd.biomedcentral.com/articles/10.1186/s13023-017-0665-6 [https://perma.cc/H456-5UNB] (demonstrating stock prices increasing by 3.36% after the announcement of orphan drug designation); Philippe Gorry & Diego Useche, *Orphan Drug Designations as Valuable Intangible Assets for IPO Investors in Pharma-Biotech Companies* 15, 17 (Nat'l Bureau of Econ. Rsch., Working Paper No. 24021, 2017), https://www.nber.org/papers/w24021 [https://perma.cc/DR6N-9C3W]; Dayton Misfeldt & James C. Robinson, *Orphan Diseases or Population Health? Policy Choices Drive Venture Capital Investments*, HEALTH AFFS. (July 21, 2017), https://www.healthaffairs.org/do/10.1377/forefront.20170721.061150 [https://perma.cc/ZE4N-B6RH] (demonstrating venture capital companies growing interest in orphan disease treatments and connecting it to policy choices).

acquisitions.[318] Why, then, has this apparatus been futile in promoting vaccine innovation?

Other academics, policymakers, and journalists have criticized orphan drug laws for their effects on the price of drugs.[319] Pharmaceutical firms were accused of reaping government financial and procedural benefits for orphan drug development while charging excessively high prices for these medications to recuperate their investment.[320] 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 United States[321] Several researchers from Johns Hopkins University claimed that systematically best-selling drugs enjoy "orphan" designation in their nascent stages by initially listing only a single indication for the drug's use but, after FDA approval, end up being marketed off-label for much more common conditions with inflated prices.[322]

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[318] *See* David H. Crean, *Why Invest in Rare Diseases & Orphan Drugs?*, PHARMA BOARDROOM (Feb. 19, 2019), https://pharmaboardroom.com/articles/investments-and-deal-activity-in-orphan-drug-products [https://perma.cc/YJY7-G89A].

[319] *See, e.g.*, Sarah Jane Tribble, *Sen. 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 [https://perma.cc/NR4N-SWJD] (stating that officials have begun investigating the effects of the Orphan Drug legislation); Nicholas Bagley, The Benefits and Costs of Promoting the Development of New Orphan Drugs (Feb. 12, 2017) (unpublished manuscript), https://theincidentaleconomist.com/wordpress/wp-content/uploads/2017/02/2.12-orphan-drug.pdf [https://perma.cc/R7YQ-GJS9] (outlining the costs and problems surrounding Orphan Drug legislation).

[320] *See* 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 [https://perma.cc/3VHN-2XFS].

[321] *See* Li-Hsien Rin-Laures & Diane Janofsky, *Recent Developments Concerning the Orphan Drug Act*, 4 HARV. J.L. & TECH. 269, 280–87 (1991); DARRELL M. WEST & JAKE SCHNEIDER, MEASURING REVENUE STREAMS AND PROFITABILITY FOR HIV DRUGS 5–7 (Apr. 2018), https://www.brookings.edu/wp-content/uploads/2018/04/measuring-revenue-streams-and-profitability-for-hiv-drugs_final.pdf [https://perma.cc/JG42-NPTP].

[322] *'Orphan Drug' Loophole Needs Closing, Johns Hopkins Researchers Say*, JOHNS HOPKINS MED. (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 [https://perma.cc/U56T-SE4U] (providing the example of the drug rituximab, originally approved to treat follicular B-cell non-Hodgkin's lymphoma—which affects 14,000 patients a year—but later marketed for other types of cancer, organ rejection, and rheumatoid arthritis—becoming the 12th best-selling drug in the United States); *see also* David E. Fagnan, Austin A. Gromatzky, Roger M. Stein, Jose-Maria Fernandez & Andrew W. Lo, *Financing Drug Discovery for Orphan Diseases,* 19 DRUG DISCOVERY TODAY 533, 534 (2014) ("Today, this once-ignored category of diseases commands a market worth nearly US$90 billion annually and is believed to serve more than twice the number of all US cancer patients—at least 25 million Americans are afflicted with one of almost 7000 recognized rare diseases. Clearly as a collective, rare diseases are not rare at all.").

Regardless, expenses related to innovation are unable to qualify for the Orphan Drug Credit as they are incurred in developing therapeutics for transmittable diseases that likely affect more than 200,000 people.[323] Moreover, the scope of the credit is very limited.[324] The Orphan Drug Credit applies to offset only costs incurred in connection with human clinical testing rather than pre-clinical animal testing or research for the development of therapeutic compounds.[325] Furthermore, in the most recent tax reform the scope of the orphan drug credit was further limited in light of the expansion of a related tax preference—the R&D credit.[326]

D. *The Late Qualifying Therapeutic Discovery Project ("QTDP") Program*

During 2009–2010 the U.S. government experimented with a new tax approach by allocating $1 billion toward the QTDP program.[327] The QTDP program provided companies with 250 or fewer employees a 50% nonrefundable investment credit (up to a maximum credit of $5 million per firm) or a nontaxable grant for costs paid or incurred in a "qualifying therapeutic discovery project."[328] The latter was research performed through pre-clinical or clinical studies to develop therapies for acute diseases or unmet medical needs.[329] Such needs 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 offering better early stage cancer treatments.[330]

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[323] I.R.C. § 45C(b), (d).

[324] *See* David M. Richardson, *The Orphan Drug Tax Credit: An Inadequate Response to an Ill-Defined Problem*, 6 AM. J. TAX POL'Y 135, 176 (1987) (discussing the limited nature of what qualifies as a "rare disease" or "condition" which effectively limits the scope of the act).

[325] *See id.* at 173 (discussing the limits on the type of clinical testing to which the credit may apply).

[326] Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, § 13401, 131 Stat. 2054, 2133 (reducing the Orphan Drug Credit to 25%); STAFF OF JOINT COMM. ON TAX'N., 115TH CONG., GENERAL EXPLANATION OF PUBLIC LAW 115–97, at 209 (Comm. Print 2018); 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 [https://perma.cc/8RJ4-2F55].

[327] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 48D, 9023, 124 Stat. 119, 877–78 (2010).

[328] Qualifying therapeutic discovery project expenses did not include any cost for remuneration for employees, interest expense, facility maintenance expenses, service cost. *Id.* at 877–80; I.R.C. § 48D (repealed 2018).

[329] Patient Protection and Affordable Care Act § 9023.

[330] *See, e.g.*, Austin Frakt, *Why Preventing Cancer Is Not the Priority in Drug Development*, N.Y. TIMES (Dec. 28, 2015), https://www.nytimes.com/2015/12/29/upshot/why-preventing-cancer-is-not-the-priority-in-drug-development.html [https://perma.cc/3HTD-

To claim the QTDP benefits, companies had to go through a rather extensive application process. Firms had to apply to attain certification for qualifying their investments and demonstrate that their project had potential to result in new therapies.[331] Other factors that could help grant applicants were the potential "to create and sustain . . . high quality, high-paying jobs in the United States" and advancement of competitiveness "in the fields of life, biological, and medical sciences."[332] Once approved, the Secretary of the Treasury granted certification awards for qualified investments in consultation with the U.S. Department of Health and Human Services ("HHS").[333]

Indeed, much of the QTDP program's shortcoming laid in its (over) ambitious scope and multifaceted grant procedures.[334] The media reported over 5,600 applications were filed, with ultimately 4,606 eligible projects awarded undertaken by 2,923 companies.[335] As a result, the most a company could receive for any one project was about $244,000, leaving firms highly disappointed from getting much smaller allotments than initially anticipated ($5 million maximum) and too insignificant to have a real financial impact.[336] While many vaccine development projects (such as anthrax, influenza, hepatitis B, chlamydia, herpes, cholera, rabies, malaria, yellow fever, HPV, measles, etc.) qualified under the QTDP program, the absolute majority of companies

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WF4U] (noting how current R&D paradigms focus on drugs targeting late-stage cancers). *See generally* Rick A. Vreman et al., *Unmet Medical Need: An Introduction to Definitions and Stakeholder Perceptions*, 22 VALUE HEALTH 1275 (2019) (exploring the concept of "unmet medical need").

[331] *See, e.g.*, Patient Protection and Affordable Care Act §§ 48D(d)(3), 9023.

[332] *See* I.R.S. Notice 2010-45, 2010-23 I.R.B. 742 (detailing the program guideline).

[333] STAFF OF JOINT COMM. ON TAX'N., JCX-18-10, TECHNICAL EXPLANATION OF THE REVENUE PROVISIONS OF THE "RECONCILIATION ACT OF 2010," AS AMENDED, IN COMBINATION WITH THE "PATIENT PROTECTION AND AFFORDABLE CARE ACT" 121 (2010); I.R.S. Notice 2010-45, 2010-23 I.R.B. 735–37 (describing the process by which taxpayers can apply to have a therapeutic discovery project certified as eligible for a credit or grant).

[334] According to the Internal Revenue Service, the QTDP program awarded total grants of approximately $970 million and $17 million in total credits. *See generally Qualifying Therapeutic Discovery Project Grants*, IRS, https://www.irs.gov/pub/irs-utl/qtdpgrants.pdf [https://perma.cc/2RH2-93ZD]; *Qualifying Therapeutic Discovery Project Credits*, IRS, https://www.irs.gov/pub/irs-utl/qtdpcredits.pdf [https://perma.cc/77KE-3ZU2]; *Qualifying Therapeutic Discovery Project Credits and Grants*, IRS, http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed/Qualifying-Therapeutic-Discovery-Project-Credits-and-Grants [https://perma.cc/W4HK-RMHP] (Mar. 3, 2020).

[335] Alex Philippidis, *Revival of Tax Credit Program Depends on Job Creation and Scientific Results*, GEN. ENG'G & BIOTECH. NEWS (July 18, 2011), https://www.genengnews.com/insights/revival-of-tax-credit-program-depends-on-job-creation-and-scientific-results/ [https://perma.cc/Z2WE-YZ4B].

[336] Steven Overly, *Biotech Grants Stretched Thin*, WASH. POST, Nov. 8, 2010, at A10. NIH Director Francis S. Collins captured, "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." *Id.*

receiving grants operated in more lucrative medicinal fields such as cancer, chronic diseases, and therapies to repair tissue and organ damage.[337] Finally, the program concluded at the end of 2013, viewed by the government and constituents as a promising, yet resource-intensive, endeavor.[338]

E. *Patent Donations*

The last notable tax scheme for promoting innovation is the deductibility of charitable contributions of intellectual property.[339] In addition to pursuing altruistic, reputational, or other strategic goals, for-profit firms can support research institutions and universities by transferring to them unused intellectual property to develop future applications and streams of income.[340] Patent donations are a form of beneficial transfer of indolent, yet conceivably valuable, intellectual property to nonprofit organizations who are motivated and capable of developing it further.[341] Charitable contributions of intellectual property can also include "copyright[s,] . . . trademark[s], trade name[s], trade secret[s], know-how, software[,]" and other non-tangible property.[342] To be able to obtain a charitable deduction, the transfer must include the taxpayer's entire interest in the intellectual property and follow a written agreement.[343]

In the late 1990s, firms began to widely utilize this benefit realizing the potential for savings via intellectual property donations.[344] Yet, this preference benefitted mostly mainstream and technological discoveries as donations rarely included pharmaceutical intellectual property.[345] Categorically, vaccine-related

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[337] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 48D, 9023, 124 Stat. 877, 887–78 (2010) (establishing the eligibility criteria for the QTDP credit). *See generally Qualifying Therapeutic Discovery Project Grants*, *supra* note 334.

[338] *See* Philippidis, *supra* note 335; *Qualifying Therapeutic Discovery Project Credits and Grants*, *supra* note 334. The Qualifying Therapeutic Discovery Project credit was repealed in 2018. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, 132 Stat. 348, 1209.

[339] I.R.C. § 170(m).

[340] *See, e.g.*, *Boeing Patent Donation to the University of Pennsylvania Could Help Treat Bone Disease and Injuries*, BOEING (Oct. 15, 2001) [hereinafter *Boeing Patent Donation*], https://boeing.mediaroom.com/2001-10-15-Boeing-Patent-Donation-to-the-University-of-Pennsylvania-Could-Help-Treat-Bone-Disease-and-Injuries [https://perma.cc/89XP-TKL3].

[341] *See, e.g.*, *Boeing Donates Patents; Food Processing Could Change*, WSU INSIDER (May 9, 2003) [hereinafter *Boeing Food Processing*], https://news.wsu.edu/2003/05/09/boeing-donates-patents-food-processing-could-change/ [https://perma.cc/G73G-G8SW].

[342] I.R.C. § 170(e)(1)(iii).

[343] I.R.C. § 170(f)(3), (8).

[344] Nicole Ziegler, Oliver Gassmann & Sascha Friesike, *Why Do Firms Give Away Their Patents for Free?*, 37 WORLD PAT. INFO. 19, 20 (2014).

[345] *See, e.g.*, *id.* at 4–5; Xuan-Thao Nguyen & Jeffrey A. Maine, *Giving Intellectual Property*, 39 U.C. DAVIS L. REV. 1721, 1725 (2006).

patents, which have a limited ability to apply outside of transmittable diseases, were predominantly left out of such intellectual property transfers.[346]

The most prominent patent donations have been technology-related transfers by large companies.[347] For example, in 2001 Boeing donated to the University of Pennsylvania intellectual property related to a thermoplastic syntactic foam, a type of material Boeing initially developed to eliminate electromagnetic interference in antenna units mounted in aircraft wings.[348] Research performed by University of Pennsylvania scientists on the heels of this patent donation led to the discovery that this biocompatible material is useful for bone augmentation procedures.[349] 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 nanotechnology.[350] Subsequently, in 2003, Boeing donated the ability to use microwave dehydration technology to Washington State University.[351] The technology was originally developed to dry spacecrafts upon ocean landing, but Washington State University researchers were able to use it in research on additive-free food products.[352]

Procter & Gamble provides a rare illustration of intellectual property donations in the field of pharmaceutical innovation.[353] 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 to cover research and other expenses associated with patent maintenance for a period of three years.[354] 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 research on a synthetic vernix for coating premature infants.[355] Procter & Gamble's director of pharmaceuticals noted that

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[346] Nguyen & Maine, *supra* note 345, at 1725; *see* Rutschman, *Intellectual Property*, *supra* note 13, at 177.

[347] *See, e.g.*, *Boeing Patent Donation*, *supra* note 340; *Boeing Food Processing*, *supra* note 341.

[348] *Boeing Patent Donation supra* note 340.

[349] *Id.*

[350] *Boeing Donates Electrophoresis Patent to Vanderbilt*, VAND. UNIV. (Feb. 3, 2002), https://news.vanderbilt.edu/2003/02/03/boeing-donates-electrophoresis-patent-to-vanderbilt-60112/ [https://perma.cc/8PXM-88ZX].

[351] *Boeing Food Processing*, *supra* note 341.

[352] *Id.*

[353] Leigh Macmillan, *Procter & Gamble Patents to Spark New Drug Discovery,* REPORTER (Nov. 10, 2000), https://reporter.newsarchive.vumc.org/index.html?ID=1269 [https://perma.cc/YX7X-BCM8].

[354] *Id.*

[355] *Cincinnati Children's Hospital Receives Cubosome Patent Donation from Procter & Gamble*, BIOTECH PAT. NEWS (Sept. 2003), http://bi.gale.com.ezp.slu.edu/global/article/GALE|A110537606/894ee9293cf403ed7bf117f87bbd1de6?u=sain44199 (on file with *Ohio State Law Journal*).

the firm's patent donations were derived from creating more technology than it can possibly develop in-house.[356]

The Boeing and Procter & Gamble cases clearly illustrate the lifecycle and progress of innovative discoveries. Firms unable or uninterested in further developing their technologies for additional downstream applications donate them forward to others.[357] The latter successfully make new findings, advance scientific discoveries, and promote knowledge spillovers.

Inappropriately though, certain firms have abused this mechanism by donating valueless patents whilst overinflating their monetary worth to extract high charitable deductions.[358] For example, beginning in 1996 with a donation to Case Western Reserve University, Dow Chemical donated over 10,000 patents and benefited from over $40 million in saved maintenance fees and tax credits.[359] It was not the only one.[360] After almost a decade of widespread exploitation of patent donations, in 2004, Congress felt that assessing the actual revenue generated from such intellectual property—rather than the expected stream of income—would give a more precise estimate of what the charitable deduction is worth.[361] It added a rule that limited the charitable deduction to the donor's adjusted basis in the contributed intellectual property, which usually has negligible value.[362] It was not worth the trouble of even reporting the donation

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[356] Macmillan, *supra* note 353.

[357] *See, e.g.*, *id.*

[358] Teresa Riordan, *Patents; Some Corporations Take Generous Tax Write-Offs for Donated Patents, An Industry Gadfly Says*, N.Y. TIMES (Mar. 17, 2003), https://www.nytimes.com/2003/03/17/business/patents-some-corporations-take-generous-tax-write-offs-for-donated-patents.html [https://perma.cc/VG5L-UK3Q] (highlighting concerns raised over many patent donations being worthless or at least overinflated for tax purposes); Cassell Bryan-Low, *Deductions for Patent Donations Draw Deeper Scrutiny from IRS*, WALL ST. J. (Oct. 7, 2003), https://www.wsj.com/articles/SB106547705230804800 [https://perma.cc/XB7C-UZJX] (describing IRS agents questioning the legitimacy of patent valuations of charitable patent donations).

[359] Ron Layton & Peter Bloch, *Please Donate Patents on the Shelf; Tax Benefits Can Be Focused for Greater Good*, LEGAL TIMES MAG. (Mar. 2004), https://iipi.org/wp-content/uploads/2010/07/IP_Donations.pdf [https://perma.cc/LWA3-NMK5] ("Speaking for Dow Chemical at a 2001 conference, Rick Gross provided some hard numbers. He said Dow had discovered '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.'").

[360] Ziegler, Gassmann & Friesike, *supra* note 344, at 20; *see supra* note 358 and accompanying text.

[361] Nguyen & Maine, *supra* note 345, at 1746–47, 1752.

[362] American Jobs Creation Act of 2004, Pub. L. No. 108-357, § 882, 118 Stat. 1418, 1628–31; Nguyen & Maine, *supra* note 345, at 1746–47. Congress followed with a rule allowing a contributor 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. I.R.C. § 170(m)(7). Tax years 1 and 2 with a deductible percentage of 100%, tax year 3 with a 90%, tax year 4 with an 80%, tax year 5 with a 70%, tax year 6 with a 60%, tax year 7 with a 50%,

anymore. Many scholars opined that this change added much complexity, uncertainty, and controversy.[363] They criticized taking away entirely the economic incentive for patent donations and leaving nonprofit organizations to rely strictly on philanthropy and rare generosity of managers of for-profit organizations.[364] Such change, they asserted, has likely hindered collaborative efforts between the private and public sector in developing innovations.[365]

To summarize this Part, past and current innovation tax schemes have proven to be complex, highly prone to abuse, and equally applicable to *every* form of innovation research done in *all* types of organizations. While such policy can be beneficial to enhancing innovation research generally, it does little to remedy (and may even harm) vaccine innovation facing additional hurdles arising from severe underfunding, anti-vaccination campaigns, limited products with isolated use, and lower return on investment. Even incentives explicitly designed for spurring pharmaceutical research—such as the Orphan Drug Credit and the late QTDP[366]—have been applied to advance mainly research on rare, chronic, or generally noninfectious diseases, thus prioritizing them over vaccine-preventable diseases.[367] Moreover, as discussed next, these incentives were mostly utilized by established and profitable market players with positive income. While there is no single best strategy to encourage scientific research for developing new vaccines, the following will propose a new approach to channel tax revenues into advancing human immunology and vaccine discovery in a more effective manner.

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tax year 8 with a 40%, tax year 9 with a 30%, tax year 10 with a 20%, tax years 11 and 12 with a 10%. *Id.* To be eligible for such future charitable deduction the donor must provide a written notice to the charitable organization. I.R.C. §§ 170(m)(8)(B),170(e)(3)(A)(iii).

[363] *See, e.g.*, Nguyen & Maine, *supra* note 345, at 1724, 1764; *see also* Nicholas C. Tomlinson, *Tax Abuse Halting Progress? An Inside Look at Patent Donations and Their Deductibility*, 35 SW. U. L. REV. 183, 199–202 (2006) (discussing the problems and limitations in accurately valuating patents).

[364] *See, e.g.*, Bo Carlsson, Monica Dumitriu, Jeffrey T. Glass, Craig Allen Nard & Richard Barrett, *Intellectual Property (IP) Management: Organizational Processes and Structures, and The Role of IP Donations*, 33 J. TECH. TRANSFER 549, 557 (2008) (finding that "generating good will . . . tax benefits 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, 305 (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.").

[365] Nguyen & Maine, *supra* note 345, at 1754–55; Ziegler, Gassmann & Friesike, *supra* note 344, at 22 ("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." (citations omitted)).

[366] *See infra* Part IV.C–D.

[367] *Id.*

V. A NOVEL FRAMEWORK FOR PROMOTING VACCINE INNOVATION

The current innovation policy landscape has used traditional IP and non-IP levers homogeneously to spur all types of innovation, including nonpharmaceutical, thus nudging investors away from the idiosyncratic aspects of vaccine development.[368] Here, we offer a straightforward solution tailored for increasing human immunology research and advancing vaccine innovation. Yet, it is worthwhile, at this point, to briefly recap the inefficiencies of developing vaccine discoveries.

In our current day and age, there are numerous pathogens causing diseases for which there are no approved vaccines or therapies such as Ebola, Salmonella, Nipah, Lassa fever, Middle East Respiratory Syndrome, and including coronaviruses related to the one that triggered the recent pandemic.[369] Vaccine development is performed under extreme uncertain conditions and unknowns about market effects, regulatory implications, competitive conditions, and product commercialization and pricing.[370] The recent increase in anti-vaccine and vaccine-questioning movements prefer relying on risk of infection or herd immunization threats to drive down the demand for vaccines.[371]

As a result, current innovation policy landscape represses vaccine research and does not accord to its social value. The total return to society from continuous vaccine discoveries and prevention of a widespread outbreak is much greater than the return on investment for the pharmaceutical firms that do engage in such research.[372] Thus, the level of private spending on vaccine discovery falls short of the optimal amount warranted by the social benefits of advancing human immunology.[373] As noted above, an outbreak may

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[368] *See generally supra* Part IV.

[369] Plotkin, Mahmoud & Farrar, *supra* note 61, at 298; WORLD HEALTH ORG., *supra* note 4, at 22; *see also NIH Launches Clinical Trial of mRNA Nipah Virus Vaccine*, NAT'L INST. ALLERGY & INFECTIOUS DISEASES (July 11, 2022), https://www.niaid.nih.gov/news-events/nih-launches-clinical-trial-mrna-nipah-virus-vaccine [https://perma.cc/67XW-DKE2]; *Scientists Develop Novel Vaccine for Lassa Fever and Rabies*, NAT'L INSTS. HEALTH (Oct. 11, 2018), https://www.nih.gov/news-events/news-releases/scientists-develop-novel-vaccine-lassa-fever-rabies [https://perma.cc/P8WM-6SUM].

[370] *See supra* Part III.A; Plotkin, Mahmoud & Farrar, *supra* note 61, at 297–98.

[371] *See supra* notes 208–10 and accompanying text.

[372] On the uncertainty that is involved in innovation, see generally, Mirit Eyal-Cohen, *Through the Lens of Innovation*, 43 FLA. ST. U. L. REV. 951, 978–81 (2016).

[373] *See generally* Stephen R. Hanney, Steven Wooding, Jon Sussex & Jonathan Grant, *From COVID-19 Research to Vaccine Application: Why Might It Take 17 Months Not 17 Years and What Are the Wider Lessons?*, 18 HEALTH RES. POL'Y SYST. 1 (2020), https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-020-00571-3 [https://perma.cc/5E8K-RH2V] (describing how COVID-19 was an anomaly in vaccine development due to the worldwide human toll that spurred "[r]apid progress . . . through a combination of large-scale funding, work being conducted in parallel (between different teams globally and

temporarily reduce or suspend some of these market inefficiencies, but we should be careful not to assume it solves them.[374] If anything, the recent pandemic provided an extreme illustration of the importance of vaccine innovation to the well-being of society and the economy.[375]

Public health imperatives prescribe robust vaccine development as the most cost-effective tool to defray health and economic costs caused by transmittable pathogens.[376] Society already spends abundant resources on R&D acknowledging its importance to spurring innovation.[377] At present, however, the current innovation policy landscape fails to accord to differences between everyday technology, mainstream drugs, and vaccines. Reported underinvestment in vaccine research reveals existing IP and non-IP levers do not efficiently incentivize and allocate resources to overcome the idiosyncratic features of vaccine research.[378] Today, more than ever, there exists a stark justification to reassess and redirect government intervention in more efficient ways by providing optimal stimuli for vaccine innovation.

Accordingly, we propose here a framework that improves price allocation, investment incentives, and cost distribution of undertaking vaccine development. We do so by suggesting redesigning tax policy more effectively in the vaccine context. As opposed to patents, grants, prizes and other incentives, tax benefits are unique in their capacity to encourage behavior *ex ante* while leaving the choice of projects and progression to private firms with better knowledge and expertise to make such decisions.[379] At the same time, policymakers can employ the tax system to prioritize vaccine research in underfunded areas and adjust it when reaching sufficient levels of vaccine preparedness.[380]

A. *Incentivizing Vaccine R&D*

Today, even as epidemics and pandemics are projected to occur with increased frequency,[381] tax incentives for vaccine development are still perceived by most market players in the pharmaceutical research arena as trivial.[382] Current tax schemes do not provide strong enough leverage to nudge

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through working in overlapping tracks), working at greater (but proportionate) risk to safety than usual, and adopting various new processes").

[374] *See supra* note 57–60 and accompanying text.

[375] On the toll of the current COVID-19 pandemic, see *supra* notes 1–3 and accompanying text.

[376] Rutschman, *supra* note 20, at 730, 751.

[377] Price II, *supra* note 112, at 3–4.

[378] *See* Rutschman, *supra* note 20, at 731.

[379] Hemel & Ouellette, *supra* note 22, at 328.

[380] *See generally infra* Part V.A.1.

[381] Belluz, *supra* note 32.

[382] *See* Hemel & Ouellette, *supra* note 27, at 551–52 ("In the United States, direct funding from the federal government through grants and national laboratories accounts for

companies towards making huge investments in time and money in vaccine discoveries. For example, small and start-up pharmaceutical companies with little or no positive income must carry forward unused tax benefits to a point in time when they become profitable, if ever.[383] Accordingly, such benefits provide good fortune to accounting firms, but do not affect in a meaningful way the decision to engage in vaccine research efforts. It is possible, though, that if structured appropriately, tax mechanisms can offer purposeful *ex ante* stimuli that can complement other IP and non-IP incentives for vaccine innovation.

It is important to begin, then, with a general observation that in order to level, and even increase, motivation to engage in vaccine research, it is necessary to respond to the fact that the market tends to value investment in blockbuster diseases *over* vaccine research.[384] Drug development generally, and vaccine R&D specifically, are extremely costly activities.[385] Yet, vaccine innovation yields less profits compared to ordinary drugs, and thus suffers from underinvestment and amplified market uncertainty.[386] Consequently, applying the same tax incentives to engage in traditional, technological, and pharmaceutical innovations disadvantages vaccine research projects. An innovation policy landscape that treats all types of innovation research efforts in the same manner fails to recognize inherent vaccine research deficiencies. Such equal treatment of investments with unequal returns pushes rational researchers and investors away from vaccine development and towards common and mainstream drugs or stirs them altogether in favor of non-medical technological innovation. The following prioritizes vaccine research and may help level this tendency.

1. *A New Incentive, Allocation, and Distribution Mechanism*

Innovation policy levers function in a distinct manner. In their article, *Innovation Policy Pluralism*, Professors Hemel and Ouellette proposed to conceptualize elements of knowledge-producing systems based on their underling function, namely allocation or incentive.[387] Allocation mechanisms set the terms and price of the right to access knowledge and discoveries.[388] Incentive mechanisms provide market-based rewards to producers of knowledge goods.[389] We propose injecting tax into a new framework of IP and

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nearly *one-quarter of the five hundred billion dollars* spent on research and development (R&D) each year. R&D tax incentives . . . cost the federal government an additional *twenty billion dollars*." (emphasis added) (footnotes omitted)).

[383] Hemel & Ouellette, *supra* note 22, at 337; *see also* Mirit Eyal-Cohen, *The Cost of Inexperience*, 69 ALA. L. REV. 859, 907 (2018).

[384] *See supra* notes 198–208 and accompanying text.

[385] Oyston & Robinson, *supra* note 94, at 891–92.

[386] *See generally* Kremer & Snyder, *supra* note 194.

[387] Hemel & Ouellette, *supra* note 27, at 547.

[388] *Id.*

[389] *Id.*

non-IP mechanisms that combines these functions in the vaccine context. For that reason, we introduce a new tax apparatus, a credit that will incentivize vaccine research by increasing its rate of return and lowering its pre-tax cost of capital. As a condition for claiming this tax benefit, firms will release information on their vaccine discoveries, thus allocating open access to the public (and other researchers) for the knowledge paid for with taxpayers' money. Thereafter, the government can layer such domestic instruments with international IP policies to recover and share such cost with other countries that consume and benefit from such knowledge goods.

Research, clinical trials, and regulatory reviews are cash-intensive and time-consuming, with the prospect of returns often years away.[390] Public scrutiny on vaccine prices often presents even more reduced prospects of a competitive return on investment.[391] Yet, tax mechanisms have the ability of freeing up more internal funding to conduct research.[392] A tax policy that creates excess returns on new investments ultimately may also cause vaccine-producing firms' value to increase. Indeed, studies found positive correlation between the existence of investment credits and increases in firm value.[393] Thus, we anticipate that the new tax credit for vaccine innovation will increase the likelihood pharmaceutical firms will reinvest their own capital, or alternatively attract outside investors, for vaccine development projects.

Tax policy can also be beneficial as an effective distributional apparatus. The dissipation of costs of vaccine R&D can be dispersed through the tax system more equitably on all citizens as future benefactors of such knowledge. There are few mechanisms aimed at preventing individuals who elect not to receive a vaccine from benefitting from herd immunity and disease containment.[394]

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[390] *See supra* notes 93–94 and accompanying text.

[391] *See generally, e.g.*, Yee Chan, Gaurav Datt, Asadul Islam, Birenda Rai & Liang C. Wang, *Public Support in the United States for Global Equity in Vaccine Pricing*, 12 SCI. REP. 8960 (2022).

[392] Hemel & Ouellette, *supra* note 22, at 321–28 (comparing the advantages of R&D tax credits); Alessandro Modica & Thomas Neubig, *Taxation of Knowledge-Based Capital: Non-R&D Investments, Average Effective Tax Rates, Internal vs. External KBC Development and Tax Limitations* 7–11 (OECD Tax'n, Working Paper No. 24, 2016), https://www.oecd-ilibrary.org/docserver/5jm2f6sfz244-en.pdf [https://perma.cc/4LFV-HRSA] (observing the effect of tax incentives on firm's capital accounts). *But 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, 423 (2016) (discussing the difficulty of quantifying value of research tax incentives—either spurring innovation or wasted).

[393] *See generally* Andrew B. Lyon, *The Effect of the Investment Tax Credit on the Value of the Firm*, 38 J. PUB. ECON. 227 (1989) (finding a positive relationship between firm value and enactment of investment tax credit).

[394] A notable exception is the case of vaccination mandates associated with a benefit, such as school attendance or admittance to a certain type of venue, such as a restaurant or concert hall. *See, e.g.*, Devon Greyson, Chris Vriesema-Magnuson & Julie A. Bettinger, *Impact of School Vaccination Mandates on Pediatric Vaccination Coverage: A Systematic*

Nevertheless, tax expenditures can compel citizens to internalize costs of social goods. Tax policy geared toward vaccine innovation can reassure, more optimally, that all constituents, regardless of their vaccine ideology, share the cost of vaccine development. It presents a creative equitable remedy to tough political, moral, and legal challenges around free exercise issues.[395] Tax will function as a distribution mechanism and reassure that the public and the government partner together to fund vaccine innovation through tax dollars. Such mechanism can also be adjusted to desired levels of vaccine preparedness. As health conditions and budget constraints vary, the government can adjust cross-subsidization of vaccine discovery along with other IP and non-IP policies.

Past lessons from the late QTDP program mentioned above attest to willingness of small firms to delve into vaccine innovation if only capital is accessible.[396] Yet, the high demand, onerous application process, and large pool of approved projects rendered the QTDP program ineffective.[397] We offer a simpler and more administrable model to induce meaningful and continues vaccine research. The new tax policy we envision will not require an arduous application process. There will not be a limited pool of available research awards. The tax benefit for vaccine innovation will reward investments in a predetermined list of emerging transmittable diseases.[398] Government officials will not be required to take on high level picking and choosing, thus eliminating the possibility of favoring research that will render them news headlines.[399]All companies involved in qualified vaccine research will be eligible to receive a benefit based on actual investments reported in their tax returns.

The timing for recognizing the benefits of the new policy lever is also vital.[400] Tax preferences deliver a reduction in tax liability within shorter timeframes as opposed to awards given to selective few firms via grants or prizes at the end of a successfully proven application process. Under the new policy, firms conducting vaccine research will receive a tax benefit at the end of

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Review, 7 CMAJ OPEN E524, E524 (2019), https://www.cmajopen.ca/content/cmajo/7/3/E524.full.pdf [https://perma.cc/KMK9-TB9K].

[395] *See, e.g.*, Wendy E. Parmet, *Rediscovering* Jacobson *in the Era of Covid-19*, 100 B.U. L. REV. ONLINE 117, 121 (2020) (discussing religious opposition to vaccination); Ariel Porat & Omri Yadlin, *A Welfarist Perspective on Lies*, 91 IND. L.J. 617, 620 (2016) (claiming that, in light of herd immunity, doctors are strictly prohibited by law to lie to their patients to convince them to get vaccinated).

[396] *See supra* notes 327–33 and accompanying text.

[397] *See supra* notes 334–38 and accompanying text.

[398] *See infra* Part V.A.2.

[399] Hemel & Ouellette, *supra* note 27, at 576–77.

[400] The phrase "recognition" in tax context denotes the determination of gains and losses for tax liability purposes. I.R.C. §1001(a)-(c); *see* JOEL S. NEWMAN, DOROTHY A. BROWN & BRIDGET J. CRAWFORD, FEDERAL INCOME TAXATION: CASES, PROBLEMS, AND MATERIALS 31 (7th ed. 2019) (distinguishing between tax realization and recognition).

each year and cut the long-delayed awards, that may (or may not) await them, at the end of a long research, experimentation, and development process.

Lastly, the proposed tax policy aims to achieve cross-subsidization and distribution of the cost of research for vaccine innovation on all its beneficiaries. Searching for 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.[401] Claimants under the new tax policy will be required to publish information on their scientific inquiries and preliminary results (while maintaining IP knowledge similar to the case of grants and prizes). This will speed knowledge spillover and avoid duplicating research efforts.[402] Prioritizing vaccine innovation via *ex ante* tax policy underlines the notion that vaccine research on set transmittable diseases is valuable. Nevertheless, while the government controls the rules, the size of these market-set rewards is determined by market forces.[403]

Scientific knowledge on failed therapeutic agents is as important. Maintaining open access to the knowledge will avoid deadweight loss and fewer participant firms who are willing to risk being involved in development of vaccine innovation. It will increase the number of market players studying pathogen structures and virus mechanisms, thus the likelihood of reaching human immunology breakthroughs. It will no longer render valueless investments in vaccine discoveries that came in second or third in place, or even failed.[404] Innovation prizes reward only selective researchers working in a hasty manner focused on deadlines.[405] Yet, combined with a new approach that favors knowledge, whether successful or not, mitigates some of the risk of failure.[406] Our inclusive 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.[407]

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[401] *See, e.g.*, Eisenberg, *supra* note 96, at 374–75 (discussing clinical trial considerations needed for FDA approval).

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

[403] *See* Hemel & Ouellette, *supra* note 27, at 598.

[404] *See* Burstein & Murray, *supra* note 133, at 402; Hemel & Ouellette, *supra* note 27, at 560.

[405] *See* Burstein & Murray, *supra* note 133, at 402; Eyal-Cohen, *supra* note 372, at 981–83 (discussing the beneficial effects of entrepreneurial failure and their significance to the entrepreneurship process).

[406] *See* Hemel & Ouellette, *supra* note 27, at 560.

[407] *See* 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); *cf.* ISRAEL M. KIRZNER, COMPETITION AND ENTREPRENEURSHIP 51 (1973) (arguing that entrepreneurial failure is important in facilitating the innovation process).

Tax policy can also play a role in cultivating more competitive dynamics in the vaccine marketplace.[408] We envision our policy applying to firms engaged in vaccine discovery regardless of their size, scope, or financial viability. As stated above, the vaccine market contains high fixed, sunk costs and idiosyncratic inefficiencies that lower the incentives for firms of all types, large or small, to engage in developing vaccine innovations.[409] Yet, emerging, smaller-scale life science companies often struggle *more* to secure outside financing and rely heavier on internal sources because they are perceived as more volatile and riskier for investors.[410] Accordingly, it is possible to apply the new tax policy in a gradual manner with reduced tiers correlated to scope and scale. As firms become more experienced in the vaccine market, their level of tax benefits can be reduced to allow newer life science companies opportunities to enter and compete in the market.

In addition, the new tax policy can incorporate the feature of refundability. Refundable tax preferences are typically most effective in situations where the government is not properly equipped to evaluate projects compared to other non-IP levers such as grants, prizes, or vouchers.[411] We propose that the new tax policy not only be tiered but also offer refunds to firms with limited scale and scope. As levels of firm's market experience and maturity increase, the tax benefit should phase out as well as its refundable feature. Our goal in introducing refundability is to instill greater equity in the market for vaccine discovery. Refundable tax incentives are not contingent on where companies are situated in the tax brackets.[412] They play an instrumental role for capital-constrains firms.[413] They avoid divergence in the built-in value of tax benefits to firms with different applicable rates (or no positive tax liability at all), such as startup companies. Accordingly, we suggest the latter receiving greater refundable tax benefits while established pharmaceutical firms receiving

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[408] The number of prominent players has slightly increased in the years leading to the COVID-19 pandemic but remains limited. Presently, some of the most prominent vaccine manufacturers are Abbott, AstraZeneca, Johnson & Johnson, GlaxoSmithKline, Merck & Co. Inc., Moderna, Pfizer, and Sanofi. *See* Sumant Ugalmugle & Rupali Swain, *Vaccines Market Size By Age Group (Pediatric, Adult), By Disease (Cancer, Hepatitis, Pneumococcal Disease, DTP, Dengue, Influenza, Human Papilloma Virus, Meningococcal Disease, Polio, Rotavirus), By Technology (Conjugate, Live, Inactivated, Recombinant, Toxoid), Industry Analysis Report, Regional Outlook, Application Potential, Price Trends, Competitive Market Share & Forecast, 2020—2026*, GLOB. MKT. INSIGHTS (Oct. 2020), https:/www.gminsights.com/industry-analysis/vaccines-market [https://web.archive.org/web/20210126062154/https:/www.gminsights.com/industry-analysis/vaccines-market].

[409] *See supra* Part III.E.

[410] *See generally* Eyal-Cohen, *supra* note 383 (describing the ways new firms suffers from a higher regulatory burden thus present higher risk to investors).

[411] *See* Hemel & Ouellette, *supra* note 27, at 557.

[412] *Cf.* Jacob Nussim & Anat Sorek, *Theorizing Tax Incentives for Innovation*, 36 VA. TAX REV. 25, 78–79 (2017) ("Tax benefits due to deductions are contingent on the taxpayer's annual tax brackets.").

[413] *See id.* at 73–74, 78.

reduced non-refundable tax benefits. Next, to avoid a similar fate to that of the QTDP program[414] and maintain focus on vaccine innovation (rather than too broad category of diseases), we narrow qualified research to a specifically designated list of vaccine-preventable diseases with communicable record.

2. *Targeting Specific Emerging Infectious Diseases*

The recent pandemic proved there is immense economic and social value to government investment in the future of vaccine research. Researchers predict that we will have to face increasingly more outbreaks of infectious diseases for which there are currently no approved vaccines.[415] Figure 1 below illustrates several pathogens for which preparedness level is severely lacking.[416] Thus, policymakers seeking to improve immunological readiness should prioritize underfunded, rather than simply orphaned, research. In setting such priorities the government may be at 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 for their development, and their respective social benefits.

Accordingly, we suggest appointing an advisory committee representing domestic health and science organizations such as the FDA, CDC, HHS, or NIH in collaboration with international agencies such as the World Health Organization to designate a list of underfunded qualified vaccine research based on periodic evidence and monitoring of occurrences, investments, and subsidies available around the world. To be clear, the scientific advisory committee we envision should not be engaged in deciding *who* gets the preferential tax treatment but *what* underfunded transmittable diseases are eligible to be on the list. In doing so, the committee should leave the scientific decisions of vaccine development per se to private researchers. Tax agency examination should be limited to the reported research input based on existing standards of eligible expenses. The output of the research process, whether effective new therapeutic breakthrough or not, will be appraised by the public and the market.

The underlying index of transmittable diseases we envision will be more easily administrable because it has limited coverage. It is different than current innovation incentives aiming at heterogenous types of technology. Viewing vaccine preparedness as our goal, the tax measures we propose should be explicitly restricted to research on predesignated vaccine-preventable infectious diseases—diseases for which there is long-felt critical underinvestment, despite

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414 *See supra* note 338 and accompanying text.

415 *See* Plotkin, Mahmoud & Farrar, *supra* note 61, at 298 (listing vaccine-preventable diseases for which there is not vaccine); Katherine F. Smith et al., *Global Rise in Human Infectious Disease Outbreaks*, 11 J. ROYAL SOC'Y INTERFACE 1, 1 (2014), https://royalsocietypublishing.org/doi/epdf/10.1098/rsif.2014.0950 [https://perma.cc/38JY-ZMNL] (noting the increase in outbreaks of infectious diseases in recent history).

416 WORLD HEALTH ORG., *supra* note 4, at 22.

the potential public health toll associated with their occurrence.[417] By means of tailoring to this particular set of emerging transmittable diseases, the framework developed here prioritizes vaccine-specific research over mainstream and orphaned illnesses while leveling the playing field with universal technological innovations.

The configuration of preselected diseases eligible for the new tax policy can be easily modeled after existing directories that track vaccine-preventable diseases for which there are no commercially available vaccines. Examples of such indices can be found in the vaccinology literature[418] or those offered periodically by the World Health Organization:[419]

Figure 1: *2016 WHO Emerging Disease Index*

Diseases to Be Urgently Addressed Under the R&D Blueprint	Crimean-Congo Hemorrhagic Fever Virus
	Filovirus Diseases (i.e., EVD & Marburg)
	Highly Pathogenic Emerging Coronaviruses Relevant to Humans (MERS Co-V & SARS)
	Lassa Fever Virus
	Nipah Virus
	Rift Valley Fever Virus
	Novel Agent: A New Severe Infectious Disease
Serious Diseases Necessitating Further Action as Soon as Possible	Chikunguya Virus
	Severe Fever with Thrombocytopenia Syndrome
	Congenital Abnormalities and Other Neurological Complications Associated with Zika Virus

Adapted from World Health Organization R&D Blueprint (with data relative to May 2016).

[417] *See id.* at 22.
[418] *See, e.g.*, Plotkin, Mahmoud & Farrar, *supra* note 61, at 298.
[419] WORLD HEALTH ORG., *supra* note 4, at 22.

The list could be matched with similar 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 above[420] was initially based on an index of voucher-eligible diseases created by Congress.[421] The list was originally limited to 16 diseases, including malaria, cholera and tuberculosis, and was later expanded to include other rare pediatric diseases.[422] 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."[423] The FDA has used this authority to significantly expand the directory of diseases and solicit public recommendations on possible additions to it.[424] Congress itself has intervened in this area, passing legislation that specifically added Ebola and Zika to the list during the 2014–2015 and 2015–2016 outbreaks, respectively.[425] In a similar manner, public health-oriented agencies—such as the FDA, CDC, HHS, and NIH—are the most well-positioned to serve an advisory role and administer a limited directory of transmittable diseases, whose immunological study will merit the tax policy instruments we propose.

Next, we turn to the combining tax and non-tax instruments as part of the innovation policy landscape. Recall that in *Innovation Policy Pluralism*, Hemel & Ouellette prescribed undertaking innovation policy reform by viewing combinations of IP and non-IP mechanisms in an organized and purposeful method, namely their allocation/incentive function.[426] Incentive mechanisms aim to nudge market players to undertake innovation efforts by promising them monetary rewards for their products, while allocation mechanisms set the level of access to knowledge goods.[427] Hemel and Ouellette suggested arranging innovation levers through "mixing," "matching," and "layering."[428] An

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[420] *See supra* notes 163–69 and accompanying text.

[421] Rutschman, *supra* note 164, at 74.

[422] *Id.* at 78–79.

[423] *Id.* at 79 (alteration in original).

[424] CTR. FOR BIOLOGICS EVALUATION & RSCH. AND CTR. FOR DRUG EVALUATION & RSCH., FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUM. SERVS., TROPICAL DISEASE PRIORITY REVIEW VOUCHERS GUIDANCE FOR INDUSTRY 4 (Oct. 2016), https://www.fda.gov/media/72569/download [https://perma.cc/LAZ4-HQ8J]; *Tropical Disease Priority Review Voucher Program*, FDA, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program [https://perma.cc/ES4W-3XXL] (July 15, 2020) (documenting the current, expansive list of diseases covered by the voucher program and inviting public recommendation for additions to the list). *See generally* Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act, 85 Fed. Reg. 42,860 (July 15, 2020).

[425] Rutschman, *supra* note 164, at 87; *see* Adding Ebola to the FDA Priority Review Voucher Program Act, Pub. L. No. 113-233, 128 Stat. 2127 (2014); 21 U.S.C. § 301.

[426] *See supra* notes 387–89 and accompanying text.

[427] *See supra* notes 388–89 and accompanying text.

[428] Hemel & Ouellette, *supra* note 27, at 559.

innovation strategy of "mixing" denotes combining IP and non-IP on the same side of the incentive/allocation function.[429] The "matching" approach involves pairing IP incentives instruments with non-IP allocation measures, and vice versa.[430] "Layering" regards the use of different innovation policies at domestic and international levels.[431] The following implements our proposed framework based on these principles.

B. *Mixing, Matching, and Layering Vaccine Innovation Policies*

1. *Grants, Prizes, and Vouchers for Basic Vaccine Research*

The recent pandemic has illustrated that the role of nonprofit research institutions in maintaining vaccine preparedness could be much greater.[432] 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.[433] Similar collaborations occurred between industry and nonprofit research institutions.[434] For example, large pharmaceutical company Merck partnered with the International Aids Vaccine Initiative ("IAVI"), a nonprofit scientific research organization,[435] to use Merck-owned vaccine technology developed in response to the 2014–2016 Ebola outbreak in research related to a COVID-19 vaccine candidate.[436] Ideally, this kind of therapeutic research—which on rare occasions can rely on relatively simpler and more well-understood forms of technology than many other types of research—should be further incentivized during pre-outbreak. Non-IP measures such as grants, prizes, and vouchers are especially suitable as strategic

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[429] *Id.* at 573–88.

[430] *Id.* at 563–73.

[431] *Id.* at 588–93.

[432] *See, e.g.*, Tonia Thomas & Rachel Colin-Jones, *Universities Were Key to Fast COVID Vaccine Development*, UNIV. WORLD NEWS (Jan. 16, 2021), https://www.universityworldnews.com/post.php?story=20210115084622247 [https://perma.cc/7C4W-SUKJ]; Christopher Garrison, *How the 'Oxford' Covid-19 Vaccine Became the 'AstraZeneca' Covid-19 Vaccine*, MEDS. L. & POL'Y, https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf [https://perma.cc/2J78-5J9L].

[433] Burke, *supra* note 68.

[434] *Press Releases: GreenLight (ENVI) and IAVI Begin Work on Omicron Variant-Adapted COVID-19 Vaccine Candidate*, IAVI (Dec. 3, 2021), https://www.iavi.org/news-resources/press-releases/2021/greenlight-envi-and-iavi-begin-work-on-omicron-variant-adapted-covid-19-vaccine-candidate [https://perma.cc/RM5S-QVLX].

[435] 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 [https://perma.cc/FU5H-5NHL]; *About*, IAVI, https://www.iavi.org/about [https://perma.cc/ 49WY-X6AQ].

[436] Meredith, *supra note* 435.

tools to encourage nonprofit collaborations in research and experimentation to increase vaccine preparedness.[437]

This strategy can be matched with other policy mechanisms to encourage scientific partnerships. Indeed, for-profit pharmaceutical firms sometimes find it more efficient to outsource portions of basic research to nonprofit entities rather than engage in all intricate facets of discovery.[438] Once initial scientific progress is made, firms can proceed and commercialize it. Absent catalytic public health crises, however, industry-nonprofit collaborations are rarer in the vaccine space. This is likely because vaccine markets have traditionally been of interest only to a restricted number of commercial players.[439] Outside the context of pandemics there are currently only ten institutions operating on a long-term basis as Vaccine and Treatment Evaluation Units.[440]

Accordingly, the government should further pre-outbreak vaccine innovation by adopting IP and non-IP policies that encourage such collaborations in vaccine research. Tax policy can accommodate a step in that direction. It can incentivize greater involvement of the nonprofit sector in pre-clinical vaccine research by including outsourced basic research in its gambit. Basic research performed by universities and research institutions will, in our eye, qualify as well as activities eligible for the refundable credit. "Matching" these non-IP tax incentives with IP allocation policies can maintain desired public access to vaccine knowledge. The government can "layer" such policy with trade-related agreements regarding IP protection.[441] This will allow firms the flexibility to choose the most effective path to procure scientific knowledge. Whether undertaken inhouse or subcontracted with outside nonprofit organizations, qualified vaccine research on the list should be encouraged without differentiation. By incentivizing all types of players in the vaccine research ecosystem to partner together, the new framework will enhance vaccine innovation and public preparedness prior to outbreak-induced vaccine races.

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[437] 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. Ana Santos Rutschman, *Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine*, 127 YALE L.J. F. 651, 654–55 (2018).

[438] CARA ALTIMUS, KIRSTIE KELLER & LATESE BRIGGS, MILKEN INSTITUTE, NONPROFITS: A GROWING FORCE IN DRUG DEVELOPMENT 18–19 (May 2019), https://milkeninstitute.org/sites/default/files/reports-pdf/NPDD-Final_0.pdf [https://perma.cc/T78L-HLLL].

[439] *See* OFF. OF TECH. ASSESSMENT, A REVIEW OF SELECTED FEDERAL VACCINE AND IMMUNIZATION POLICIES 3 (1979) (describing the historical evolution of the supply side of the U.S. vaccine market).

[440] *See Network of VTEU Sites*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, https://www.niaid.nih.gov/research/vteu-network-sites [https://perma.cc/3D9Q-7ETJ] (Apr. 17, 2020). Although VTEUs receive public funding, they are involved in clinical trials for vaccine candidates resulting from public-private collaborations. *Id.*

[441] *See* Hemel & Ouellette, *supra* note 27, at 589.

2. *IP Donations and IP Pricing of Vaccine Technology*

Another step in reframing vaccine policy involves patent donations. So far, this mechanism has been overlooked as a strategic tool in vaccine innovation policy. Patent donations are both tax incentives and allocation mechanisms.[442] A study done shortly before the 2004 change involving interviews within industry members, academics, and professionals, concluded that most corporate donors and university recipients think patent donations have nonquantifiable benefits such as developing university-industry collaborations, increasing inventor morale, and providing more research opportunities for faculty.[443] 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."[444]

The key non-tax impetuses of patent donations are reducing costs through preserving research efforts, improving 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.[445] 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. While these patents sit on the shelf, IP policies limit access to that knowledge. In those cases, patent donations can be an effective way to avoid having potentially valuable discoveries sitting idle or abandoned when they do not fit with the firm's existing priorities. The deductibility of patent donations of vaccine innovations, thus, provides significant premium and public policy tool. Such tax preference can be "matched" with IP allocation mechanism to assign the right for payment to the transferee organization or "mixed" with other non-IP incentive policies. For example, patent donations can be paired with providing extended period of patent protection to the transferee organization conditioned upon continuous development of the protected knowledge.

Early example of patent donations of vaccine technology, albeit rare, have occurred in the case of a malaria vaccine candidate donated to the World Health Organization in the 1990s.[446] Yet, with the post-2004 formula that restricts the value of the IP contribution to the cost basis, the value of such donations became

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[442] Carlsson, Dumitriu, Glass, Nard & Barrett, *supra* note 364, at 557.

[443] Layton & Bloch, *supra* note 359.

[444] *Id.*

[445] *Id.*

[446] *Scientists with Vision: Dr. Manuel Elkin Patarroyo*, WORLD INTELL. PROP. ORG. MAG. (Sept. 2005), https://www.wipo.int/wipo_magazine/en/2005/05/article_0002.html [https://perma.cc/JPJ7-R79Z]; *Renowned Pathobiologist Discusses Vaccinology, Malaria at CVM*, TEXAS A&M UNIV. SCHOOL OF VET. MED. & BIOMEDICAL SCI. (May 1, 2017), https://vetmed.tamu.edu/news/internal-news/renowned-pathobiologist-discusses-vaccinology-malaria-at-cvm/ [https://perma.cc/MQ68-A6UC].

trivial or zero.[447] By eliminating the financial benefit of charitable patent donations, the current legal system fails to incentivize socially desirable vaccine-related IP donations.[448] Accordingly, promoting vaccine innovation should involve a change in patent donations regime. Structured property, patent donations can become a catalyzer for vaccine innovation and can be "mixed" with other non-IP mechanisms discussed above.[449] We, therefore, propose that in cases of donated vaccine intellectual property we revert to the pre-2004 rule that relied on the fair market value of the IP matched with modified allocation of access to the patented knowledge. This can be further "layered" with international IP policies to provide cost sharing among other countries that consume this knowledge goods. We predict that this tax preference not only would foster collaboration and help improve public health but will provide even greater knowledge spillover and societal benefits in other medical areas.

Indeed, valuations are extremely subjective, and appraisals of intellectual property are highly susceptible to manipulation, especially in vaccine research where the value of new therapeutics and developments is very hard to assess.[450] Yet, scholars have proposed a variety of effective solutions to prevent abuse and overvaluation concerns, such as structured reporting and clearer standards for valuation.[451] Avoiding gamesmanship, ensuring administrability, and lowering compliance costs are important goals of every policy reform. As the following demonstrates, the proposed new vaccine policy framework fulfills those objectives.

3. *Administrating the New Vaccine Innovation Landscape*

We recognize that the creation of innovation policies and preferences can attract—and has engaged—players seeking to explore loopholes in the system. In contrast with more transversal embodiments of incentives regimes such as the voucher program,[452] our proposed framework is tailored to a very narrow

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[447] Nguyen & Maine, *supra* note 345, at 1746–47.

[448] *Id.* at 1754–55 (criticizing the 2004 amendment and calling for adopting of a Fair Market Value deduction for Patent donations).

[449] Carlsson, Dumitriu, Glass, Nard & Barrett, *supra* note 364, at 557 (generating good will, profiting from tax deductions and other financial benefits, and philanthropy were motives of the firms to donate their patents).

[450] *See* William A. Drennan, *Charitable Donations of Intellectual Property: The Case for Retaining the Fair Market Value Tax Deduction*, 2004 UTAH L. REV. 1045, 1108–11.

[451] *See, e.g.*, Tomlinson, *supra* note 363, at 190, 206 (explaining a study by Arthur Anderson in 1992 demonstrating the profitability of patent donations—catalyzed the practice by corporations). Others suggested qualified appraisal requirements, penalties on appraisers for valuation errors, heightened information requirements, and lengthening the statute of limitations. *See* Drennan, *supra* note 450, at 1084 (proposing ways to lessen abuse in patent donations).

[452] For instance, 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

list of predetermined underfunded infectious diseases and a specific set of biopharmaceutical technologies. Albeit crucial from a public health perspective, vaccines target specific viruses (or their components),[453] and thus involve relatively straightforward forms of technological discoveries with a predominantly preventative function.[454] A given vaccine is not likely to be deployed to target a large swath of conditions—emerging COVID-19 vaccines target the structure of this pathogen alone, for instance.[455] For those reasons, we believe that the vaccine arena generally, and our proposal specifically, are less prone to gamesmanship.[456]

A possible form of deadweight loss that may arise from government policies relates to compliance costs[457] and inefficient administrability.[458] Generally speaking, subject-matter agencies possess higher specialization in technological and scientific matters than tax authorities.[459] For those reasons, in the choice of optimal innovation-inducing strategies, cash transfers may be viewed as superior to tax preferences.[460] Yet, as far as organizational administrability, our proposal directly relates to, complements activities within, and may benefit

States, and which had been in use for the previous 10 years. *See* Tatum Anderson, *Novartis Under Fire for Accepting New Reward for Old Drug*, 373 LANCET 1414, 1414 (2009).

[453] mRNA, for example, is a new technology that takes advantage of the process that cells use to make proteins in order to trigger an immune response and build immunity to the virus. *Understanding mRNA COVID-19 Vaccines*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html [https://perma.cc/Z9BU-AF75] (Sept. 16, 2022).

[454] Rutschman, *supra* note 437, at 654 (noting that the leading Zika vaccine candidate developed during the 2015–2016 outbreak was adapted from a pre-existing vaccine).

[455] We again note that our proposal expressly excludes any emerging forms of vaccine technology, such as the mRNA vaccine currently being developed 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 February 2021, 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 COVID-19 Treatment and Vaccine Tracker*, *supra* note 153.

[456] *See* Rutschman, *supra* note 20, at 742.

[457] *See, e.g.*, Rochelle Cooper Dreyfuss, Response, *Tailoring Incentives: A Comment on Hemel and Ouellette's Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 131, 137–38 (2014) (outlining compliance and enforcement costs of innovation incentive schemes).

[458] *See generally, e.g.*, Nussim & Sorek, *supra* note 41x2 (developing an organizational theory of implementation costs based on tax expenditures).

[459] *Id.* at 30.

[460] *Id.* at 57–65. *But see* Shaun P. Mahaffy, Note, *The Case for Tax: A Comparative Approach to Innovation Policy*, 123 YALE L.J 812, 832–36 (2013) (discussing the advantages of tax credits to lower administrative costs); Xuan-Thao Nguyen & Jeffrey A. Maine, *The History of Intellectual Property Taxation: Promoting Innovation and Other Intellectual Property Goals?*, 64 SMU L. REV. 795, 798, 851–57 (2011) (comparing the benefits of utilizing tax versus IP as incentives for innovation).

from, tax expertise.[461] Our proposal focuses on R&D expenditures currently observed and enforced by tax authorities without the need for scientific or technological expertise. Moreover, adherence to a predetermined list of diseases leaves scientific discretion to the committee of public health experts rather than tax agents.

Lastly, scholars have raised concerns for political capture[462] by claiming tax preferences are susceptible for abuse by special interest groups because they likely offer political rent-extracting and rent-seeking opportunities.[463] This is especially so in the context of cross-party unison on topics such as innovation incentives.[464] Nonetheless, our proposed framework prescribes matching and mixing several IP and non-IP policies with marginal discretion to one government agency. The same is true for the public health committee, whose discretion is curbed to devising the list of predesignated underfunded diseases. Altogether, each agency's limited function greatly restricts opportunities for political capture and lowers expected administrative costs.

VI. CONCLUSION

Lack of robust research in vaccine R&D exposes both health systems and markets to significant social costs. The recent pandemic has provided a noteworthy illustration of this phenomenon, with its enormous toll on human life, health systems, and the economy.[465] At the same time, it has provided us

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[461] Nussim & Sorek, *supra* note 412, at 77 ("Innovation-inducing programs may be contingent, inter alia, on income or expenses, which are strongly related to [IRS] activities.").

[462] *See, e.g.*, Jennifer L. 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 ASS'N 69, 69–70 (2015).

[463] *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, 340 (2006) (describing temporary tax provisions as a 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, 66–69 (1990) (claiming a key motive of certain tax legislation is rent extracting).

[464] *See* Charles J. Delmotte, *The Case Against Tax Subsidies in Innovation Policy*, 48 FLA. ST. U. L. REV. 285, 332 (2021) ("[T]ax 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 86, at 14–15 (claiming concentrated investors' interests affect the legislative process towards overprotection of patents); Eisenberg, *supra* note 96, at 366 (pointing out that drug companies may be reticent to innovate primarily in reliance on nonpatent incentives if they are perceived as more likely to be revised downward).

[465] *See, e.g.*, *From Equality to Global Poverty: The Covid-19 Effects on Societies and Economies*, WELLCOME (June 29, 2021), https://wellcome.org/news/equality-global-poverty-how-covid-19-affecting-societies-and-economies [https://perma.cc/3ZFX-4NUC].

with a rare opportunity to reexamine the role of traditional IP and non-IP strategies in the stifling of investment motivations in socially beneficial innovations.[466] Tax law has so far been neglected as an innovation policy lever in the vaccine context. Moreover, current tax schemes apply largely in homogenous ways to different types of innovations.[467] This flawed design de facto pushes firms away from vaccine, and toward technological, research with higher commercialization value and repeated clienteles. This Article identified ways in which tax policy can be redesigned to produce superior *ex ante* incentives and distributional outcomes while playing a more salient role in stimulating development of pathogen technologies. Thereafter, we suggested lawmakers and policymakers to "match," "mix," and "layer" IP policies alongside the proposed tax instruments and other non-IP strategies to bolster vaccine innovation more effectively.

An innovation policy landscape that combines the tax instruments proposed above can avoid divergence in the built-in value of policy preferences to firms with different financial viabilities. It can maintain flexibility and independence of market players by leaving major decisions to private parties—the freedom to choose the nature of and priority given to each study, the distribution of resources to each experiment, and the desired level of reward for it, to name a few. It holds promise to encourage younger market players to enter, compete, and collaborate in vaccine innovation that carries high social value. It can provide a more just and equitable manner to distribute the social costs of vaccines across all citizens (and countries) as potential beneficiaries of herd immunity. Lastly, by prioritizing vaccine R&D while adhering to our prescription for a limited directory of underfunded transmittable diseases, our proposed framework works in a blind manner, as opposed to cash-based direct incentives that may be more costly and susceptible to political economy.

From a boarder normative aspect, this Article provides opportunities to increase pluralism of innovation policies. The tasks of spurring research and allocating its cost are best served through combination of various policy levers. Experimenting with the framework developed here can serve as a model and help rethink ways to encompass different variations of IP and non-IP measures while aiming to narrow each combination's complexity, abuse opportunities, and rent seeking. After the dust settles on the current pandemic, policymakers should fine-tune the vaccine innovation policy landscape. The framework outlined here provides a starting point to better prepare for the next outbreak.

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[466] *See generally* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989 (1997) (providing an overview of the relationship between patents and inventive improvements). *See* Hemel & Ouellette, *supra* note 22, at 327.

[467] *See supra* Part V.A.