RECONSIDERING DISCRETION IN EXPEDITED VACCINE APPROVAL IN LIGHT OF THE NOVEL CORONAVIRUS

*Daniel Joshua Ganz**

As the world continues to combat the COVID-19 pandemic and the economies of many US cities and states remain largely closed, there is growing evidence that the 2020 general election has put pressure on policymakers to rush the development and testing of a vaccine. The legal rules on expedited development and review of vaccines provide substantial discretion to the Secretary of Health and Human Services, and this discretion is at risk of being abused in an election year. I provide three proposals for reducing the risks of abuses of discretion in the vaccine approval process. Congress would be prudent to implement in some form one or more of these proposals to ensure the integrity of US vaccine development and testing in this and other election years.

I. INTRODUCTION

As the novel coronavirus continues to spread and wreak havoc throughout the world, the international community has become focused on developing a vaccine for the virus. The United States has committed more than one billion dollars to the development of a coronavirus vaccine,[1] and other countries are also working tirelessly towards a vaccine.[2]

As the economies of many US cities and states remain largely closed and the 2020 election draws near, there is a real threat that it will pressure policymakers to rush the development and testing of a vaccine. The legal framework surrounding vaccine testing and approval, which gives significant discretion to the Secretary of Health and Human Services to expedite the development of a

* Daniel Ganz is a concurrent degree student at the University of California, Irvine. He is pursuing a JD (expected May 2021) and a PhD in Economics (expected June 2022).

1. Antonio Regalado, *Here's What We Have to Do to Show a Coronavirus Vaccine Works*, MIT TECH. REV. (May 26, 2020), https://www.technologyreview.com/2020/05/26/1002191/how-show-a-coronavirus-vaccine-prevents-covid-19/ [https://perma.cc/94UZ-3NLQ].

2. Claire Felter, *What Is the World Doing to Create a COVID-19 Vaccine?*, COUNCIL ON FOREIGN RELATIONS (Aug. 26, 2020), https://www.cfr.org/backgrounder/what-world-doing-create-covid-19-vaccine [https://perma.cc/XCB5-AXC2].

vaccine, may result in an imprudent rush towards vaccine development and approval. These concerns are especially salient in the United States' current political climate, where the short-term political calculations of policymakers may outweigh the guidance of sound science.

In this Article I argue that the legal framework on expediting drug approval provides significant discretion to the Secretary of Health and Human Services, and that this discretion is at risk of being abused in an election year. I provide some proposals to reduce the amount of discretion given to the Secretary on expediting drug approval. I also propose protections for individuals who wish to obtain vaccinations only after the vaccine has been thoroughly tested according to the guidance of sound science.

The remainder of this Article is organized as follows. Part II provides a summary of the legal framework on the approval of pharmaceutical drugs, including expedited development and testing of these drugs. Part III summarizes the situation regarding the novel coronavirus, the search for a vaccine, and the special problems that arise when significant discretion is given to government officials to expedite the development of a vaccine. Part IV provides proposals for reform to reduce the risk of an unsound rush towards a vaccine. Part V concludes.

II. LEGAL BACKGROUND

This Part provides an overview of the legal framework governing approval of pharmaceutical drugs and clinical trials. Section A discusses the history of the FDA's authority to regulate the approval process for pharmaceutical drugs. Section B summarizes the legal framework and timeline for the ordinary review process. Section C provides an overview of expedited review and how the different components of expedited review can affect the timeline for drug approval.

A. History of the FDA's Regulatory Authority

The United States Food and Drug Administration (FDA) is the federal agency responsible for protecting the public from unsafe and mislabeled food.[3] Congress granted the FDA the authority to regulate the drug production process through a line of twentieth century statutes, starting in 1906 with the Pure Food and Drug Act of 1906.[4] The passage of this law was prompted by the publication of Upton Sinclair's *The Jungle*, which revealed highly unsanitary conditions in

3. Caitlyn Martin, *Questioning the "Right" in State Right to Try Laws: Assessing the Legality and Effectiveness of These Laws*, 77 OHIO ST. L.J. 159, 165 (2016).

4. Christine Coughlin et al., *Regenerative Medicine and the Right to Try*, 18 WAKE FOREST J. BUS. & INTELL. PROP. L. 590, 596 (2018).

US meat production.[5] The Pure Food and Drug Act made it unlawful to sell misbranded or adulterated food and drugs in interstate commerce,[6] and although this law predates the establishment of the FDA, it created the administrative background for what would become the FDA.[7]

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA), which enabled the FDA to regulate cosmetics and medical devices, in addition to drugs and food.[8] Congress passed the FDCA in response to the sulfanilamide disaster of 1937, in which over one hundred Americans were killed after receiving an early antibiotic that contained diethylene glycol, a poisonous chemical regularly used in antifreeze.[9] The FDCA also mandated that all new drugs undergo pre-market approval, where the manufacturer must prove to the FDA that a drug was safe before it could be sold.[10]

Finally, in 1962 Congress passed the Kefauver-Harris Amendments, which require drug manufacturers to demonstrate the safety of their drugs before they become available for public consumption.[11] The amendments resulted in the development of a "more complex, lengthy, and regulated clinical trial process."[12] This clinical trial process, and the expedited reviews that the process allows for, are discussed in Sections B and C below.

B. Ordinary Clinical Trial Process

There are typically several stages of drug development and review, including animal testing, review of an Investigational New Drug (IND) Application, clinical trials, and review of a New Drug Application (NDA), with several review meetings throughout these stages.[13] The clinical trials are ordinarily divided into three phases.[14] Phase 1 studies are usually conducted in healthy volunteers, with sample sizes typically ranging from twenty to eighty subjects.[15] The objective of

5. *The Pure Food and Drug Act*, U.S. CAPITOL VISITOR CTR., https://www.visitthecapitol.gov/exhibitions/congress-and-progressive-era/pure-food-and-drug-act [https://perma.cc/7FGL-VXRK] (last visited Oct. 1, 2020).

6. *Id.*

7. Coughlin et al., *supra* note 4.

8. Jodie M. Gross & Judi Abbott Curry, *The Federal Preemption Debate in Pharmaceutical Labeling Product Liability Actions*, 43 TORT TRIAL & INS. PRAC. L.J. 35, 43 (2007).

9. Coughlin et al., *supra* note 4, at 596; Sheryl Lawrence, *What Would You Do with a Fluorescent Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 ECOLOGY L. QUARTERLY 201, 215 (2007).

10 *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-ii-1938-food-drug-cosmetic-act [https://perma.cc/DWE7-BLWY] (last updated Nov. 27, 2018).

11. Coughlin et al., *supra* note 4, at 596–97.

12. *Id.* at 597.

13. *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2017), https://www.fda.gov/drugs/drug-information-consumers/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective [https://perma.cc/9GMA-YH74].

14. *See id.*

15. *Id.*

the Phase 1 study is to determine what side effects are most commonly associated with the drug, and often how the drug is metabolized and excreted.[16]

Phase 2 studies only begin if the Phase 1 studies do not reveal unacceptable toxicity.[17] The sample sizes in Phase 2 studies typically range from a few dozen to roughly 300 subjects, and the objective here is to determine the drug's effectiveness.[18] The drug is tested on people with a certain disease or condition to determine if it is effective in treating that disease or condition, often in reference to a control group receiving an inactive placebo.[19]

The FDA and the drug sponsor typically have a review meeting after the Phase 2 studies to come to an agreement on how the large-scale Phase 3 studies should be conducted.[20] In the Phase 3 studies, the drug is tested among a larger population usually ranging in size from several hundred to 3,000 subjects.[21] Several different populations are studied, different dosages of the drug are administered, and the drug is used in combination with other drugs to see how it may interact with those other drugs.[22] After the clinical studies, the drug sponsor submits a New Drug Application, which is then reviewed by the FDA before the FDA approves the new drug for marketing in the US.[23]

C. Expedited Reviews

A drug manufacturer can obtain expedited FDA approval of investigational drugs that can treat a serious and previously untreatable medical condition under the FDA's Accelerated Approval programs.[24] The FDA has developed four distinct approaches to making drugs available as quickly as possible when those drugs are the first available treatment for a medical condition or if the drug has advantages over existing treatments.[25] These four approaches are known as Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review.[26]

The FDA's Fast Track program is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need.[27] To determine how serious a condition is, the FDA typically looks to whether the drug "will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will

16. *Id.*
17. *Id.*
18. *Id.*
19. *Id.*
20. *Id.*
21. *Id.*
22. *Id.*
23. *Id.*
24. Coughlin et al., *supra* note 4, at 604.
25. *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review*, U.S. FOOD & DRUG ADMIN. (Feb. 23, 2018), https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review [https://perma.cc/2N52-M5ER].
26. *Id.*
27. *Fast Track*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track [https://perma.cc/BPD7-HC4X].

progress from a less severe condition to a more serious one."[28] Any drug developed to treat or prevent a condition with no current therapy qualifies as one that is directed at an unmet need.[29] Vaccine candidates may be eligible for Fast Track designation, as was the HPV vaccine Gardasil.[30] A drug that receives Fast Track designation is potentially eligible for more frequent meetings with and written communication from the FDA to discuss the drug's development plan and clinical trials, and a drug that has received Fast Track designation may also be eligible for Accelerated Approval and Priority Review.[31]

Breakthrough Therapy designation is a process to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint or endpoints.[32] Vaccines candidates may also be eligible for Breakthrough Therapy designation, as was the meningococcal group B vaccine Bexsero in 2014.[33] A drug that receives Breakthrough Therapy designation is eligible for all Fast Track designation features, in addition to intensive guidance on an efficient development and organizational commitment involving senior managers.[34]

Accelerated Approval regulations allow drugs for serious conditions that fill an unmet medical need to be approved based on a surrogate endpoint, which enables the FDA to approve these drugs more quickly.[35] A surrogate endpoint is a marker that is thought to predict clinical benefit, but is not itself a measure of clinical benefit.[36] For example, instead of having to learn whether a cancer treatment drug actually extends survival for cancer patients, the FDA may approve a drug based on evidence that the drug shrinks tumors because tumor shrinkage is likely to predict a real clinical benefit.[37] As with Fast Track and Breakthrough Therapy designations, vaccine candidates may be eligible for Accelerated Approval, as was the Canadian influenza vaccine FluLaval in 2006.[38]

Finally, a Priority Review designation means that the FDA will attempt to take action on an application within six months, compared to a standard review

28. *Id.*

29. *Id.*

30. Katherine S. Homan, *Do the Ends Justify the Means? Compelling the Use of HPV Vaccination on Men*, 27 J. CONTEMP. HEALTH L. & POL'Y 183, 190 (2010).

31. *Fast Track*, *supra* note 22.

32. *Breakthrough Therapy*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy [https://perma.cc/XT23-2BES]. A clinically significant endpoint is generally one that measures an effect on irreversible morbidity or mortality (IMM) or on symptoms that represent serious consequences of the disease. *Id.*

33. Jonathan J. Darrow & Aaron S. Kesselheim, *A New Wave of Vaccines for Non-Communicable Diseases: What Are the Regulatory Challenges?*, 70 FOOD & DRUG L.J. 243, 246–47 (2015).

34. *Breakthrough Therapy*, *supra* note 29.

35. *Accelerated Approval*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval [https://perma.cc/5MAB-6CF6].

36. *Id.*

37. *Id.*

38. *FDA Approves Another Vaccine for Upcoming Flu Season Letter No. 2285*, FOOD DRUG COSM. L. REP. 8254261 (C.C.H.), 2006 WL 8254261 (Oct.16, 2006).

period of ten months.[39] Drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications may obtain Priority Review designation.[40] Significant improvement may be demonstrated by evidence of increased effectiveness in treatment, prevention, or diagnosis; the elimination or substantial reduction of a treatment-limiting drug reaction; evidence of safety and effectiveness in a new subpopulation; and other advantages.[41] The vaccine Gardasil, in addition to receiving Fast Track designation, was approved in six months after receiving the Priority Review designation.[42]

Under the Federal Food, Drug, and Cosmetic Act, it is the Secretary of Health and Human Services that has the power to grant the Fast Track and Breakthrough Therapy designations and to approve a drug for Accelerated Approval.[43] Moreover, the Secretary of Health and Human Services is ordinarily (if not always) responsible for granting Priority Review designations.[44] Given the substantial amount of time that can be saved if a drug participates in one or more of these programs, the Secretary of Health and Human Services has substantial discretionary power to guide the development of vaccines and other drugs in a way that can influence the overall safety of the drugs.

III. THE PROBLEM

In this Part I discuss recent developments that illustrate why discretionary aspects of pharmaceutical drug review are problematic when political pressure is likely to be high. Section A provides background on the novel coronavirus, and Section B explains the steps the US and other countries are taking to find a vaccine. Section C explains how, given the legal framework for expediting drug approval that vests significant discretion in the Secretary of Health and Human Services, there is an unacceptable risk that political expediency will outweigh the guidance of sound science in the decision to accelerate vaccine development and testing.

39. *Priority Review*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review [https://perma.cc/7Z2Y-CMFF].

40. *Id.*

41. *Id.*

42. Darrow & Kesselheim, *supra* note 30.

43. 21 U.S.C. § 356.

44. *Id.* § 360n(b)(1) (giving the Secretary of Health and Human Services the authority to award priority review status to tropical disease products); *id.* § 360n-1(a) (same for qualified infectious disease products); *id.* § 360ff(b)(1) (same for rare pediatric disease products); *id.* § 360bbb-4a(b) (same for material threat medical countermeasures).

A. The Novel Coronavirus

Coronaviruses are a family of viruses that can cause the common cold, severe acute respiratory syndrome, Middle East respiratory syndrome, and other illnesses.[45] In 2019, a new coronavirus now known as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was identified as the cause of a disease outbreak that began in China and quickly spread across the world.[46] SARS-CoV-2 causes a disease called coronavirus disease 2019 (COVID-19).[47] The World Health Organization (WHO) declared COVID-19 a pandemic in March 2020.[48]

As the virus spread across the world, countries implemented measures to slow the spread of the virus, including national quarantines, school closures, bans on large events and gatherings, and closures of non-essential businesses.[49] The United States has been hit especially hard by the coronavirus, with the highest number of total cases, serious/critical cases, and total deaths of all countries in the world.[50] Among the ninety countries with a population of at least 10 million people, the US has the fourth-highest number of total cases per capita (Peru, Chile, and Brazil exceed the US in this metric as of September 30), as well as the eighth-highest number of total deaths per capita (Peru, Belgium, Spain, Bolivia, Brazil, Chile, and Ecuador exceed the US in this metric as of September 30),[51] though notably many countries likely have underreported total cases and total deaths.[52]

In addition to the health impact of the pandemic, the coronavirus has ravaged economies around the world as well. As the coronavirus spread throughout the world, governments discouraged and then prohibited people from going to work, which led to a sudden contraction of the labor supply in these countries.[53] This labor supply shock then led to a loss of consumer confidence, which contributed to further contractions in economies around the world.[54] In the United States, 22 million Americans filed for unemployment benefits over the span of only four weeks.[55] The overwhelming majority of countries have instituted travel

45. *Coronavirus Disease 2019 (COVID-19)*, MAYO CLINIC (Sept. 11, 2020), https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963 [https://perma.cc/8C5V-32PP].

46. *Id.*

47. *Id.*

48. *Id.*

49. Juliana Kaplan et al., *Our Ongoing List of How Countries Are Reopening, and Which Ones Remain Under Lockdown*, BUS. INSIDER (Aug. 25, 2020, 1:30 PM), https://www.businessinsider.com/countries-on-lockdown-coronavirus-italy-2020-3 [https://perma.cc/ZSD2-Y6C8].

50. *COVID-19 Coronavirus Pandemic*, WORLDOMETERS, https://www.worldometers.info/coronavirus/ [https://perma.cc/6D7T-2LV7] (last updated Oct. 5, 2020, 16:17)

51. *Id.*

52. *China, Russia, Brazil and the Underreporting of Covid-19 Cases*, INT'L OBSERVATORY HUM. RTS. (May 13, 2020), https://observatoryihr.org/news/china-russia-brazil-and-the-underreporting-of-covid-19-cases/ [https://perma.cc/PX8T-QGYG].

53. *COVID-19's Historic Economic Impact, in the U.S. and Abroad*, HUB (Apr. 16, 2020), https://hub.jhu.edu/2020/04/16/coronavirus-impact-on-european-american-economies/ [https://perma.cc/RWA6-PG2J].

54. *Id.*

55. *Id.*

restrictions to help combat the spread of the virus,[56] which has further depressed economic activity. And most US states have issued lockdown orders for their residents, and public officials across the country have urged people around the United States to stay in their homes as much as possible to slow the spread of the virus.[57] As Americans struggle to make ends meet after months of significantly depressed economic activity, many have called for ending coronavirus lockdowns so that Americans can go back to work, even at the risk of public health.[58]

B. The Accelerated Search for a Vaccine

The health impact of the virus combined with the economic toll that the pandemic has taken have motivated the United States government to work quickly towards finding a vaccine. The United States announced in May that it would provide up to $1.2 billion to support a vaccine from Oxford University and AstraZeneca.[59] President Trump has called the search for a virus "Operation Warp Speed,"[60] and National Defense Production Act policy coordinator Peter Navarro has said that the US is moving in "Trump time" to find a vaccine.[61]

Other countries have also worked tirelessly towards finding a vaccine, albeit sometimes using a different approach. In July, the United States, the United Kingdom, and Canada reported that Russian hackers have attempted to steal coronavirus vaccine data.[62] The National Security Agency said that a hacking group implicated in hackings of Democratic Party servers in 2016 was trying to steal intelligence on vaccines from universities, companies, and other organizations.[63] American intelligence officials said that the Russians were trying to steal research so that they could develop their own vaccine more quickly, and they

56. *Travel Restrictions by Country*, KAYAK, https://www.kayak.com/travel-restrictions [https://perma.cc/2LCQ-W4NB] (last updated Sept. 19, 2020, 2:58 AM).

57. Jiachuan Wu et al., *Stay-at-Home Orders Across the Country*, NBC NEWS (Apr. 29, 2020), https://www.nbcnews.com/health/health-news/here-are-stay-home-orders-across-country-n1168736 [https://perma.cc/44CF-FCHT].

58. Kirk Siegler, *Some Protesters Call for Ending Coronavirus Lockdowns, Despite Public Health Warnings*, NPR (Apr. 19, 2020, 8:00 AM), https://www.npr.org/2020/04/19/838073222/some-protesters-call-for-ending-coronavirus-lockdowns-despite-public-health-warn [https://perma.cc/H2U6-T8Y2].

59. Regalado, *supra* note 1; *Trump Administration's Operation Warp Speed Accelerates AstraZeneca COVID-19 Vaccine to Be Available Beginning in October*, HHS.GOV (May 21, 2020), https://www.hhs.gov/about/news/2020/05/21/trump-administration-accelerates-astrazeneca-covid-19-vaccine-to-be-available-beginning-in-october.html [https://perma.cc/SWS6-XF4Q].

60. Regalado, *supra* note 1.

61. Ben Werschkul, *'Trump Time': Peter Navarro Says the Manufacturing of a Coronavirus Vaccine Will Be Swift*, YAHOO! FIN. (June 11, 2020), https://finance.yahoo.com/news/trump-time-peter-navarro-says-coronavirus-vaccine-manufacture-will-be-swift-191354925.html [https://perma.cc/J6F6-D4X6].

62. Julian E. Barnes, *Russia Is Trying to Steal Virus Vaccine Data, Western Nations Say*, N.Y. TIMES (Aug. 11, 2020), https://www.nytimes.com/2020/07/16/us/politics/vaccine-hacking-russia.html [https://perma.cc/KDN2-AD64]; Zachary Cohen et al., *UK, US and Canada Allege Russian Cyberattacks on Covid-19 Research Centers*, CNN POL. (July 17, 2020, 7:04 AM), https://www.cnn.com/2020/07/16/politics/russia-cyberattack-covid-vaccine-research/index.html [https://perma.cc/C8K8-KPWN]; Chris Fox & Leo Kelion, *Coronavirus: Russian Spies Target Covid-19 Vaccine Research*, BBC NEWS (July 16, 2020), https://www.bbc.com/news/technology-53429506 [https://perma.cc/R39Q-5YKK].

63. Barnes, *supra* note 59.

apparently were not attempting to sabotage the efforts of other countries to find a vaccine.[64] A month later, Russian President Vladimir Putin announced the approval of a coronavirus vaccine.[65]

Health experts are understandably skeptical about a vaccine that was allegedly researched, developed, and tested eight months after the virus that the vaccine targets was first identified.[66] Experts have said that it is impossible to know if a vaccine works or whether it causes any harmful effects on the user if the vaccine has not gone through a large phase 3 clinical trial.[67] Even Russia's Association of Clinical Trials Organizations said that fast-tracking the approval of a vaccine "will just expose consumers of the vaccine to unnecessary danger."[68]

Ordinarily, health officials in all countries would likely advise governments to restrict the importation of a vaccine that has been developed and tested in less than a year, especially one that is being touted by a government that has almost certainly misstated its own number of coronavirus-related cases and deaths.[69] But according to Russia, twenty countries had already pre-ordered one billion doses of its vaccine by the time Russia announced that the vaccine had been approved.[70] Shortly after the vaccine's approval was announced, the Brazilian state of Paraná signed a deal to test and produce the vaccine, with testing including Phase 3 clinical trials.[71]

Some are also worried that the approval of a Russian vaccine could put pressure on the United States to approve a vaccine that has not been fully tested.[72] Paul Offit, chief of the Division of Infectious Diseases at Children's Hospital Philadelphia, said that he is worried "that our administration would interpret this as anything other than what it is, which is that Russia, if anything, is

64. *Id.*

65. Zahra Ullah & Zamira Rahim, *Putin Says Russia Has Approved 'World First' Covid-19 Vaccine. But Questions Over Its Safety Remain*, CNN (Aug. 12, 2020 1:27 AM), https://www.cnn.com/2020/08/11/europe/russia-coronavirus-vaccine-putin-intl/index.html [https://perma.cc/D92R-WEBC].

66. *Russia Approves and Touts a Coronavirus Vaccine, But Critics Are Skeptical*, L.A. TIMES (Aug. 11, 2020, 6:56 AM), https://www.latimes.com/world-nation/story/2020-08-11/russia-touts-coronavirus-vaccine-critics-skeptical [https://perma.cc/M26K-TAXA]; Berkeley Lovelace Jr., *Scientists Worry Whether Russia's 'Sputnik V' Coronavirus Vaccine Is Safe and Effective*, CNBC (Aug. 11, 2020, 2:45 PM), https://www.cnbc.com/2020/08/11/scientists-worry-whether-russias-sputnik-v-coronavirus-vaccine-is-safe-and-effective.html [https://perma.cc/6CDS-PKZ5].

67. Lovelace Jr., *supra* note 63.

68. *Russia Approves and Touts a Coronavirus Vaccine, But Critics Are Skeptical*, *supra* note 66.

69. Joshua Yaffa, *Why Is Russia's Coronavirus Case Count So Low?*, NEW YORKER (Mar. 25, 2020), https://www.newyorker.com/news/dispatch/why-is-russias-coronavirus-case-count-so-low [https://perma.cc/RH8K-KRWK].

70. Chitranjan Kumar, *Russia Says 20 Countries Have Pre-Ordered a Billion Doses of its COVID-19 Vaccine*, BUS. TODAY (Aug. 11, 2020, 23:34), https://www.businesstoday.in/current/economy-politics/russia-develops-world-first-coronavirus-vaccine-20-countries-pre-ordered-billion-doses/story/412694.html [https://perma.cc/95QK-WU53].

71. *Brazil State Signs to Test, Make Russian Vaccine*, ASIA TIMES (Aug. 13, 2020), https://asiatimes.com/2020/08/brazil-state-signs-to-test-make-russian-vaccine/ [https://perma.cc/3V2T-FTB2].

72. *Scientists Worry Whether Russia's 'Sputnik V' Coronavirus Vaccine is Safe and Effective*, *supra* note 63.

behind where we are in the United States on this vaccine."[73] Offit said that he worries that Russia's vaccine approval could pressure the US to deploy a vaccine before one is ready, saying that "[i]t could be a major mistake. It could cause a lot of harm."[74]

There is some indication that these developments have not put significant pressure on the United States to rush toward an untested vaccine. A recent article in the Journal of American Medical Association co-authored by Stephen Hahn, the United States Commissioner of Food and Drugs, noted that candidate COVID-19 vaccines "will be reviewed according to the established legal and regulatory standards for medical products."[75] The article argued that "[w]hile Operation Warp Speed is an important initiative . . . there is a line separating the government's efforts to focus resources and funding to scale vaccine development from FDA's review processes, which are rooted in federal statute and established FDA regulations.[76]

Nevertheless, recent comments and actions by the Trump Administration have raised concerns that political pressures are leading the Administration to rush too quickly toward vaccine approval. Shortly after Moncef Slaoui, the head of Operation Warp Speed, said that there is a "very, very low chance" that the late-stage clinical trials of various coronavirus vaccines would be completed by the end of October, the President repeated his earlier assertion that a vaccine could be ready before November.[77] And after Dr. Robert Redfield, the director of the Centers for Disease Control and Prevention (CDC), told Senate lawmakers that vaccinations beginning in November or December will only be in limited quantities, the President said that Dr. Redfield was mistaken and that mass distribution could begin as early as October.[78]

The President's tendency to contradict top health officials on the vaccine timeline and his clear intent to obtain an approved vaccine before Election Day suggests that political pressures are in large part driving the Administration's push for a vaccine. These mixed messages from the Administration may explain

73. Suzanne Smalley, *Russia Is Moving Too Fast with COVID-19 Vaccine, U.S. Experts Warn*, AOL (Aug. 12, 2020 1:51 PM), https://www.aol.com/article/news/2020/08/12/russia-is-moving-too-fast-with-covid-19-vaccine-us-experts-warn/24589203/ [https://perma.cc/VS96-CXK2].

74. *Scientists Worry Whether Russia's 'Sputnik V' Coronavirus Vaccine is Safe and Effective*, *supra* note 63.

75. Anand Shah et al., *Viewpoint: Unwavering Regulatory Safeguards for COVID-19 Vaccines*, JAMA (Aug. 7, 2020), https://jamanetwork.com/journals/jama/article-abstract/2769421 [https://perma.cc/GU3S-EY8F].

76. *Id.*

77. Sarah Owermohle, *Trump Contradicts Health Officials, Says 'Probably' a Covid-19 Vaccine in October*, POLITICO (Sept. 4, 2020, 6:28 PM), https://www.politico.com/news/2020/09/04/trump-coronavirus-vaccine-october-409248 [https://perma.cc/RM6G-SXHT].

78. Berkeley Lovelace Jr. & Noah Higgins-Dunn, *Trump Says U.S. Could Start Distributing a Coronavirus Vaccine in October, Contradicting CDC's Timeline*, CNBC (Sept. 16, 2020, 5:33 PM), https://www.cnbc.com/2020/09/16/trump-says-he-thinks-us-could-start-distributing-a-coronavirus-vaccine-in-october.html [https://perma.cc/J64P-QZ2N].

why only 39% of Americans reported in September that they would take a government-approved coronavirus vaccine.[79] Democratic Vice Presidential candidate Kamala Harris has even warned that she would not trust the President alone on the safety of a coronavirus vaccine.[80] And as the situation surrounding the search for a coronavirus vaccine continues to evolve, it is more than likely that additional fissures between health experts and top Administration officials will become apparent.

As discussed in Part II, federal law provides substantial discretion to the Secretary of Health and Human Services to significantly accelerate the development and review of drugs to fill unmet medical needs, including vaccination. It is this legal framework that will drive whether or not the US government rushes coronavirus vaccine testing, as well as whether or not the US decides to import the Russian vaccine.

C. The Problem of Discretion in Expediting Vaccine Testing

The COVID-19 pandemic combined with the looming US presidential election reveals risks in a legal framework for expediting vaccine approval that grants significant discretion to the Secretary of Health and Human Services. Ordinarily, Congress grants health officials substantial latitude to expedite the review of vaccines and other drugs because we trust health officials to make decisions in a way that is largely insulated from political pressures. In explaining how regulatory agencies have been granted more discretionary authority since before the New Deal era, Cass Sunstein wrote that this extension of authority is based on the expectation that these agencies are "politically insulated, self-starting, and technically sophisticated."[81]

But things have changed since the New Deal era, and scholars have begun to reconsider the extent to which administrative agencies are insulated from political pressures. Paul Stephan has questioned whether independent agencies truly operate independently of political pressures, noting that the behavior of independent agencies shifts as administrations change.[82] Even if the agencies are independent from the President, in many cases Congress sets the budget of the agency and can call hearings on the agency's operations.[83]

79. Robin Foster & E.J. Mundell, *Most Americans Don't Trust Trump's Vaccine Comments: Poll*, U.S. NEWS & WORLD REP. (Sept. 15, 2020, at 9:00 AM), https://www.usnews.com/news/health-news/articles/2020-09-15/most-americans-dont-trust-trumps-vaccine-comments-poll.

80. Caroline Kelly, *'I Will Not Take His Word for It': Kamala Harris Says She Would Not Trust Trump Alone on a Coronavirus Vaccine*, CNN (Sept. 5, 2020, 3:17 PM), https://www.cnn.com/2020/09/05/politics/kamala-harris-not-trust-trump-vaccine-cnntv/index.html [https://perma.cc/YB6U-6CVY].

81. Cass R. Sunstein, *Constitutionalism After the New Deal*, 101 HARV. L. REV. 421, 440 (1987); *see also* Jeffrey Rudd, *The Evolution of the Legal Process School's "Institutional Competence" Theme: Unintended Consequences for Environmental Law*, 33 ECOLOGY L. QUARTERLY 1045, 1052 (2006).

82. Paul Stephan, *Are Independent Agencies Really Independent?*, THE REGUL. REV. (Dec. 14, 2016), https://www.theregreview.org/2016/12/14/stephan-independent-agencies-really-independent/ [https://perma.cc/CEH6-P2XQ].

83. *Id.*

The situation is even worse for non-independent agencies. Jennifer Nou has noted that in normal bureaucratic governance, the President must delegate tasks to his agents and assure their fidelity, which can result in efforts to politicize the bureaucracy through the appointments process and through removal of subordinates.[84] And with a President with a fondness for loyalty tests for his political appointees[85] and who removed his FBI director in a way that raised serious concerns that the President was trying to interfere in an investigation into election interference,[86] there is substantial concern that the current President will use the mechanisms at his disposal to exert influence over federal agencies.

Further compounding matters is the fact that it is the Secretary of Health and Human Services—a political appointee who serves at the pleasure of the President[87]—and not a more independent group that has discretion over the expedited reviews. And finally, with the fact that the search for a vaccine is occurring in the midst of an election season in which the incumbent President is running for reelection, there is ample reason to be worried that the decision to expedite review of the coronavirus vaccine will be influenced by political considerations.

Top health officials may have their own personal ambitions, but in ordinary times the personal ambitions of the officials are usually best served by making the right public health decisions for the country. But in the current health crisis, the decision to expedite development of a coronavirus vaccine can no longer be considered politically insulated. Part IV outlines three proposals for reigning in the discretion currently granted to the Secretary of Health and Human Services in deciding whether to expedite development of vaccines and other drugs.

IV. PROPOSED SOLUTIONS

In this Part I provide three proposals for reforming the process for expediting development of vaccines and other drugs to ensure that this discretion is not abused for political purposes. Section A proposes transferring discretion for expediting drug development from the Secretary of Health and Human Services to an independent board within or outside the Department of Health and Human Services. Section B proposes removing the discretionary power to expedite drug development entirely and allowing only Congress to expedite drug development. Finally, Section C proposes reforming rules on mandatory vaccinations so that if a vaccine was developed under expedited development, public agencies can only

84. Jennifer Nou, *Agency Self-Insulation Under Presidential Review*, 126 HARV. L. REV. 1755, 1765 (2013).

85. Dan Diamond et al., *Trump Team Launches a Sweeping Loyalty Test to Shore Up Its Defenses*, POLITICO (July 16, 2020 1:30 PM), https://www.politico.com/news/2020/07/15/trump-appointees-loyalty-interviews-364616 [https://perma.cc/P3KN-KU9S].

86. Michael D. Shear & Matt Apuzzo, *F.B.I. Director James Comey Is Fired by Trump*, N.Y. TIMES (May 9, 2017), https://www.nytimes.com/2017/05/09/us/politics/james-comey-fired-fbi.html [https://perma.cc/5LKF-X7JM].

87. *Serving at the Pleasure of the President*, NJSBF (Nov. 27, 2017), https://njsbf.org/2017/11/27/serving-pleasure-president/ [https://perma.cc/UPC2-TV4B].

mandate vaccination using that vaccine if the vaccine was approved through an independent board.

A. Transfer Expedited Approval Power from the Secretary to an Independent Board

One option for addressing the problems of discretion in expedited drug development is to transfer the power to expedite approval from the Secretary of Health and Human Services to an independent board. As a cabinet official, the Secretary of Health and Human Services can be fired by the President for any reason,[88] and therefore the Secretary's independent judgment in making expedited review decisions cannot be guaranteed.

An independent board would be able to exercise discretion in making expedited review decisions in a way that is at least somewhat more insulated from political pressures. The structure of the board will have a large impact on the independence of the board and its ability to make judgments that are insulated from political pressures.

For ideas on how the independent board may be structured, we can look to how similar independent agencies are structured. The Federal Trade Commission (FTC), for example, is headed by five Commissioners nominated by the President and confirmed by the Senate, with no more than three Commissioners members of the same political party.[89] Each Commissioner serves a term of seven years, and the President chooses one Commissioner to act as the Chairperson.[90] Under the Federal Trade Commission Act, the President can remove a Commissioner only for inefficiency, neglect of duty, or malfeasance in office,[91] and the Supreme Court has upheld this restriction as a valid restriction on the power of the executive.[92] The Securities and Exchange Commission (SEC)[93] and the Federal Communications Commission (FCC)[94] are structured in a similar manner.

By structuring the independent board in a way that the members serve a fixed term and cannot be removed by the President except with good cause, the board will be appropriately insulated from short-term political pressures. Restricting membership of the board to individuals with a medical or scientific background will also help ensure that any decisions to expedite the development of vaccines and other drugs are made based on the guidance of sound science and not political considerations.

88. *Id.*

89. *Commissioners*, FED. TRADE COMM'N, https://www.ftc.gov/about-ftc/commissioners [https://perma.cc/WM25-P9D5] (last visited Sept. 20, 2020).

90. *Id.*

91. Federal Trade Commission Act, § 1, 15 U.S.C. § 41.

92. Humphrey's Executor v. United States, 295 U.S. 602, 631–32 (1935).

93. *Current SEC Commissioners*, U.S. SEC. & EXCH. COMM'N (Sept. 17, 2013), https://www.sec.gov/Article/about-commissioners.html [https://perma.cc/7S4L-2L4M].

94. *The Federal Communications Commission (FCC)*, NAT'L TELECOMMS. & INFO. ADMIN., https://www.ntia.doc.gov/book-page/federal-communications-commission-fcc [https://perma.cc/K2B4-WU65] (last visited Aug. 13, 2020).

While this independent board could be a truly independent agency (like the FTC, the SEC, and the FCC), this is probably unnecessary as long as the board is structured as described above so that the members are insulated from political pressures. Thus, the board can either be housed within the Department of Health and Human Services, or it can be a truly independent agency without any parent organization. By giving the discretion to expedite drug development to an independent board, Americans can be more certain that decisions on expediting drug development are being made based on sound science.

B. Require Legislative Action to Expedite Development of Any Drug

Another option would be to remove the discretion to expedite drug development from the executive branch entirely, and to instead rest that power with Congress. In such a proposal, Congress would repeal 21 U.S.C. section 356, subsections (a), (b), and (c) (granting the Secretary of Health and Human Services authority to grant Breakthrough Therapy and Fast Track designations and to allow accelerated approval of a drug), as well as any statutes granting the Secretary authority to grant Priority Review designations.[95]

In the future, if there is any need for expedited review and approval of a new drug, Congress can pass a single act granting the drug in question whatever designations are appropriate. Rather than giving any discretion to regulators, Congress would simply create ad hoc exceptions as the needs for particular drugs arise. In this approach, the people deciding whether to grant expedited development and review would be directly accountable to the people. Thus, at first glance it might seem that this approach may result in more, not less, political pressure on expedited review decisions.

However, in the current approach the one person directly responsible for expedited review decisions (the Secretary) is directly accountable to one person (the President), who is in turn directly accountable to the people. So, a single person facing significant political pressures (the President) may wield significant influence over the Secretary's decision. In the proposed approach, there are hundreds of legislators voting on whether or not to allow for accelerated review, so accountability is diffused across hundreds of people. And in the Senate, two thirds or more of the decision-makers are not running for reelection for at least two years at any given time, so in at least one chamber of Congress political pressures will likely be more muted than under the current approach.

On the other hand, under this approach it is legislators and not medical or health experts making decisions about expedited review. To the extent that technical expertise in health and medicine is highly relevant to making an informed expedited review decision, an independent board composed of medical and health experts making these decisions would be preferable. The legislators may be able to obtain the requisite expertise by having health and medical experts

95. *See* statutes cited *supra* note 41.

testify before Congress, but this would likely slow down Congress and be counterproductive to the objectives of expedited review.

There is also some risk that creating exceptions for drugs on an ad hoc basis would lead to legal challenges alleging that the creation of an exception for some drugs but not others violates the Equal Protection Clause of the Fourteenth Amendment.[96] Classifications that neither involve fundamental rights nor proceed along suspect lines are subject to rational basis review, which merely requires that there is a rational relationship between the disparity of treatment and some legitimate governmental purpose.[97]

Since the classifications that Congress would be drawing are based on the urgency of the need for each drug and not on a suspect or quasi-suspect classification like race or gender, the classification likely would only need to survive rational basis review to survive an Equal Protection challenge.[98] Because the distinctions are designed to protect public health by ensuring that drugs with a significant need can be available to the public quickly while other drugs are fully tested for safety, these classifications likely would survive an Equal Protection challenge.[99]

Some may argue that these classifications involve fundamental rights, such as the right to obtain the medicine of one's choice, and therefore these classifications must satisfy a higher level of scrutiny to survive an Equal Protection challenge. But courts have generally indicated that one does not have a fundamental right to obtain the medicine of one's choosing, free of the lawful exercise of government police powers.[100] And the problem of Equal Protection challenges is not a problem that is unique to a proposal requiring legislative action to expedite drug development, since classifications made by administrative agencies also must satisfy equal protection analysis.[101]

Overall, creating an independent board to evaluate expedited review requests would likely be more manageable than removing the discretion from agencies entirely. Given the challenges involved in requiring Congress to pass ad hoc expedited review decisions every time one is necessary, the better of the two proposals is to grant discretion to an independent board to evaluate expedited review requests. However, removing the discretion from the executive branch entirely and resting the discretion with Congress would nevertheless be an improvement over the status quo.

96. U.S. Const., amend. XIV, § 1.

97. Armour v. City of Indianapolis, 566 U.S. 673, 680 (2012).

98. *Id.*

99. *Cf. id.*

100. *See, e.g.*, Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980) ("Constitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the exercise of government police power."); Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980) ("It is apparent in the context with which we are here concerned that . . . [a patient's] selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health."); Garlic v. U.S. Food and Drug Admin., 783 F. Supp. 4, 5 (D.C.D.C. 1992).

101. Ball v. Massanari, 254 F.3d 817, 823 (9th Cir. 2001) (noting that equal protection analysis extends to administrative actions); Ellis v. Apfel, 147 F.3d 139, 144–45 (2d Cir. 1998) (applying equal protection analysis to an administrative classification); Rehbock v. Dixon, 458 F. Supp. 1056, 1062 (N.D. Ill. 1978).

C. Require Approval from an Independent Board Before a Vaccine Is Mandated by a Public Agency When the Vaccine Went Through Expedited Development

A third option would be to keep the authority to grant expedited review with the Secretary of Health and Human Services, but require an independent board to approve a vaccine before the vaccine can be mandated by a public agency. In this way, drugs (including vaccines) would become available to the general public on an expedited timeline if the Secretary so decides, as is currently the case. However, public agencies will not be able to mandate vaccinations using a vaccine that was approved on an expedited timeline unless an independent board confirms that the drug was reviewed legitimately and according to sound science during the expedited review.

Courts generally uphold mandatory vaccinations as a condition for public school enrollment.[102] The California Court of Appeal has said that it is "well established that laws mandating vaccination of school-aged children promote a compelling governmental interest of ensuring health and safety by preventing the spread of contagious diseases."[103] All fifty states require specified vaccines for students, with exemptions for children who, for medical reasons, are unable to safely take the vaccine.[104] Forty-five states and the District of Columbia also grant religious exemptions for those who have religious objections to immunizations.[105] Fifteen states allow philosophical exemptions for those who object to immunizations because of personal, moral, or other beliefs.[106]

However, if a vaccine is approved under expedited review procedures and an individual is unsure about the safety of the vaccine, it is unclear if the individual can decline a mandatory vaccination using that vaccine without facing a loss of rights or privileges. It seems likely that an objection based on the perceived safety of the vaccine would qualify the individual for a philosophical exemption in the fifteen states that recognize such exemptions.[107] But in the remaining thirty-five states and the District of Columbia, such an individual would likely be out of luck.

If an independent board is required to approve a vaccine for mandatory vaccinations by public agencies when the vaccine was approved by the FDA under expedited review, individuals who fear rushed testing and approval could decline the vaccine until the independent board has certified that the vaccine was tested according to sound science. Individuals who do not have concerns about

102. *See, e.g.*, Phillips v. City of New York, 775 F.3d 538, 543–44 (2d Cir. 2015); Love v. State Dept. of Education, 29 Cal. App. 5th 980, 996 (2018).

103. *Love*, 29 Cal. App. 5th at 990.

104. *States with Religious and Philosophical Exemptions from School Immunization Requirements*, NCSL (June 26, 2020), https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx [https://perma.cc/F4KC-67J5].

105. *Id.*

106. *Id.*

107. *Id.*

the vaccine's safety will still be able to receive the vaccine even before the independent board has approved the review procedures, and businesses could still require their workers to obtain the vaccination before returning to work. Thus, this proposal would represent a balancing between the rights of individuals concerned about undue political pressure affecting vaccine approval, and the public health interests in approving urgently needed vaccines in a timely fashion.

The novel coronavirus is in fact providing precedent for a similar such proposal at the state level. California announced in late September that it will conduct its own review of potential COVID-19 vaccines, suggesting that the state does not trust the federal government's vaccine development and review process.[108] Dr. Mark Ghaly, California Health and Human Services Secretary, said that a review board of leading scientists at academic institutions will assess the safety and effectiveness of any vaccine candidate.[109] As Vanderbilt University's Dr. William Schaffner explained, the states—not the federal government—have the authority to distribute a vaccine, and these states can independently evaluate vaccine data and reject vaccines that they believe are unsafe.[110]

Ordinarily, in determining whether to distribute a vaccine, states follow the decision of the Advisory Committee on Immunization Practices (ACIP), an independent committee that assesses data on FDA-approved vaccines and makes recommendations to the CDC.[111] However, this committee does not have the authority to decide whether public agencies can mandate vaccinations with a vaccine that the committee believes has not been adequately reviewed. Establishing an independent board with legal authority to determine if a vaccine can be mandated by public agencies would help ensure that individuals are not forced to take a vaccine that has undergone a rushed approval process.

Finally, under this proposal, if the independent board cannot certify that the vaccine's expedited development met sound drug development practices, the federal government could still persuade the public to seek immunization with the vaccine by providing incentives for individuals to get vaccinated and by otherwise demonstrating the vaccine's safety. This third proposal therefore represents a careful balancing between the federal government's need for flexibility in expediting the development of vital vaccines, and the interest in ensuring that individuals are confident in the safety and effectiveness of the vaccine before being required to take one. As such, this third proposal, or a close adaptation of it, is likely the best option for guaranteeing the safe development of vital vaccines, insulated from temporary political considerations.

108. Lisa M. Krieger, *California Plans to Independently Vet COVID-19 Vaccine Data*, MERCURY NEWS (Sept. 25, 2020, 5:09 PM), https://www.mercurynews.com/2020/09/25/california-plans-to-independently-vet-covid-19-vaccine-data/.

109. *Id.*

110. *Id.*

111. *Id.*

V. CONCLUSION

Congress can grant substantial discretion to administrative agencies to implement and enforce the laws that Congress passes.[112] Ordinarily, there is no significant fear that the agencies will abuse this discretion as a result of political pressures. However, during a public health crisis taking place during an election year, a substantial grant of discretion to a single individual who serves at the pleasure of the President presents a serious risk that political influences may outweigh sound science in making expedited development decisions.

This Article has considered three options for reducing the risk that political considerations will overshadow sound science in the decision to expedite the development of vaccines. There are also other options for reducing this risk that were not considered in this Article, including simple congressional oversight of the Secretary of Health and Human Services' exercise of discretion. It should be clear, however, that the status quo is not desirable. Congress should take action quickly to ensure that decisions about expediting drug development and review are truly insulated from political considerations.

112. Gundy v. United States, 139 S. Ct. 2116, 2123 (2019); United States v. Wass, 954 F.3d 184, 188 (4th Cir. 2020).