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HEALTH LAW—A HARD PILL TO SWALLOW: AN EXAMINATION OF THE U.S. DRUG DEVELOPMENT PROCESS AND STATE AND FEDERAL GOVERNMENT MEASURES TO EXPAND PATIENT ACCESS TO INVESTIGATIONAL DRUGS

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HEALTH LAW—A HARD PILL TO SWALLOW: AN EXAMINATION OF THE U.S. DRUG DEVELOPMENT PROCESS AND STATE AND ! FEDERAL GOVERNMENT MEASURES TO EXPAND PATIENT ACCESS ! TO INVESTIGATIONAL DRUGS !

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The drug development process—regulated by the U.S. Food and Drug Administration (FDA)—is complex, lengthy, and costly. For years, reformers have sought more liberal access to potential drug treatments that have not yet reached the final stages of the process. "Right to Try" laws and the FDA's expanded access program are among some of the government measures designed to allow terminally ill patients to obtain investigational drugs before they receive FDA approval. This Article explores the strengths and shortcomings of some of the measures undertaken by state and federal governments, while highlighting the policy struggle between providing individuals early access to potentially life-saving drugs and maintaining the necessary government oversight to ensure consumer safety.

INTRODUCTION

Today, as the world faces the unprecedented global health crisis related to the novel coronavirus—COVID-19—pandemic, many are asking the critical question of whether there is an effective treatment for those who have been infected by the virus. Thus far, none have been identified. President Donald Trump has held a major role in the effort to explore potential treatment options, repeatedly advocating for the unintended use of various drugs whose effectiveness on the coronavirus

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has not been proven.[1] The President's fervent insistence that patients have the right to seek out unconventional and unapproved treatments during this health crisis underscores a much larger discussion surrounding the nation's complex drug approval process and the concern that it may actually impede access to life-saving drugs.

The U.S. Food and Drug Administration (FDA), the oldest consumer protection agency in the United States, is predominantly responsible for overseeing the nation's drug and medical device markets.[2] The Food, Drug, and Cosmetic Act (FDCA), through which Congress delegated its enforcement power to the FDA, requires all drugs to be approved for safety and efficacy by the FDA prior to their release into the consumer market.[3] A pharmaceutical drug's journey from its preclinical to market-ready stage is long and arduous. It is often estimated that the average length for the drug development process is upwards of ten years; the number popularly expressed is twelve years.[4] Drug manufacturers can spend up to five billion dollars to bring a new treatment to market.[5] Patients suffering from terminal illnesses, or who are simply desperate for a treatment, often do not have the luxury of waiting for such an extensive

1. *See, e.g.*, *Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing*, WHITE HOUSE (Apr. 15, 2020) https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-26/ [https://perma.cc/9PDK-CZ5S]. President Trump, on numerous occasions during press briefings regarding the coronavirus, touted drugs including chloroquine, hydroxychloroquine, and remdesivir as promising treatment solutions against COVID-19. *Id.*

2. *The History of FDA's Fight for Consumer Protection and Public Health*, FDA (June 29, 2018) https://www.fda.gov/about-fda/history-fdas-fight-consumer-protection-and-public-health [https://perma.cc/BK4H-XWWU].

3. *See generally* 21 U.S.C. § 301–399i (2018).

4. Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 170, 171 (2016), https://basictranslational.onlinejacc.org/content/btr/1/3/170.full.pdf [https://perma.cc/MVA8-HPFC]; Richard C. Mohs & Nigel H. Greig, *Drug Discovery and Development: Role of Basic Biological Research*, 3 ALZHEIMER'S & DEMENTIA: TRANSLATIONAL RES. & CLINICAL INTERVENTIONS 651, 651 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5725284/pdf/main.pdf [https://perma.cc/Q8L9-BCUN]; BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES, PHRMA 1, http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf [https://perma.cc/8ELA-JHHP]; *The Drug Development and Approval Process,* FDAREVIEW.ORG, https://www.fdareview.org/issues/the-drug-development-and-approval-process/ [https://perma.cc/2U39-DDAG].

5. MARK FLATTEN, DEAD ON ARRIVAL: FEDERAL "COMPASSIONATE USE" LEAVES LITTLE HOPE FOR DYING PATIENTS, GOLDWATER INST. 4 (Feb. 24, 2016), https://goldwaterinstitute.org/wp-content/uploads/2016/02/Dead-On-Arrival-Report.pdf [https://perma.cc/CH9L-RY5W].

period of time to receive medication that could potentially save their lives. Patients and advocates continue to fight for the right to access investigational drugs before they are on the market; this effort is colloquially referred to as the "Right to Try" (RTT) movement.[6]

This Article begins by providing an overview of the FDA's lengthy drug development and approval process. Next, it explores various governmental measures aimed at creating emergency use exceptions to either abbreviate or circumvent such process—including the FDA's expanded access program, state RTT laws, and the federal RTT Act—and evaluates their effectiveness in improving patient access to drugs in emergency situations that would not otherwise have been available. Finally, this Article briefly examines the implications of these measures in light of the COVID-19 health crisis.

I. ' TRIALS AND TRIBULATIONS: THE STEPS OF DRUG DEVELOPMENT

The successful production of a new pharmaceutical drug requires an enormous amount of time and expense on the part of the manufacturer, primarily due to the extensive statutory and regulatory schemes governing the drug's manufacturing and testing procedures.[7] The FDA is intimately involved throughout the life of the drug, from its inception to its eventual arrival on the market, and beyond. An overview of the standard process is outlined below.

The drug development and approval process can be broken down into five basic steps: (1) discovery and development, (2) preclinical research, (3) clinical research, (4) FDA review, and (5) post-market safety monitoring.[8] During the discovery and development phase, researchers identify promising compounds for development and conduct preliminary experiments to gather information on various basic properties, including potential benefits, best dosage, and delivery method.[9] Prior to testing on humans, researchers must determine whether a drug is toxic, or has the

6. *See* Tamara J. Patterson, Note, *The Cost of Hope at the End of Life: An Analysis of Right-To-Try Statutes*, 105 KY L.J. 685, 686 (2017).

7. This Article focuses on the development process for a new drug through a new drug application; it does not address the development of generic drugs, for which a different, abbreviated process is utilized, nor does it address the development of biologics through a biologics license application. *See* 21 U.S.C. § 355(j) (2018); *see generally* 21 C.F.R. §§ 320–320.63, 600–680 (2020).

8. $*See Drug Development and Approval Process, supra* note 4.

9. *Step 1: Discovery and Development*, FDA, https://www.fda.gov/patients/drug-development-process/step-1-discovery-and-development [https://perma.cc/47VZ-XKZS].

potential to cause serious harm.[10] This is done in the next phase, preclinical research, wherein the sponsor[11] screens the drug for toxicity in animals.[12] Following preclinical testing, researchers analyze the findings and decide whether to test the drug in humans.[13] When the sponsor decides to test the drug's therapeutic potential on humans, it must file an Investigational New Drug (IND) application containing information in three areas: animal pharmacology and toxicology studies, manufacturing information, and clinical protocols and investigator information for proposed clinical studies.[14] After submitting an IND to the FDA, the sponsor must wait thirty days before it may begin clinical trials.[15] During this time, the FDA reviews the IND "for safety to assure that research subjects will not be subjected to unreasonable risk."[16] If the FDA does not object to the IND within the thirty days, the IND becomes effective and the sponsor may begin testing on humans through clinical trials.[17]

Perhaps the most critical stage of the development process is the clinical research stage, which is further broken down into three phases. In Phase I, approximately twenty to eighty healthy individuals are treated with the drug, predominantly to establish its safety and profile; this phase typically takes about one year.[18] In Phase II, the drug's efficacy is assessed on one hundred to three hundred patient volunteers with the

10. *Step 2: Preclinical Research*, FDA, https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research [https://perma.cc/9MSL-VG59].

11. A sponsor of a drug is "a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator." 21 C.F.R. § 511.3.

12. *IND Applications for Clinical Investigations: Pharmacology and Toxicology (PT) Information,* FDA, https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-applications-clinical-investigations-pharmacology-and-toxicology-pt-information [https://perma.cc/3GMG-WTRZ].

13. *Step 2: Preclinical Research*, *supra* note 10.

14. *See Investigational New Drug (IND) Application*, FDA, https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application [https://perma.cc/W4KP-53HW]; *see also FDA Drug Approval Process*, DRUGS.COM, https://www.drugs.com/fda-approval-process.html [https://perma.cc/68EV-G9JP].

15. *Investigational New Drug (IND) Application*, *supra* note 14.

16. *Id.*

17. *See IND Application Procedures: Overview*, FDA, https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-procedures-overview [https://perma.cc/6RR2-5X6U].

18. *Step 3: Clinical Research*, FDA, https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [https://perma.cc/24KR-ZBCF].

specific condition or disease the drug is aimed to treat (the target population); this phase typically lasts approximately two years.[19] At the end of this phase, the manufacturer will meet with the FDA to discuss, among other things, any concerns the FDA may have and the protocols for Phase III if the FDA deems the drug is ready to proceed.[20] Phase III is the most extensive part of the drug development process. Several thousand patients in healthcare facilities such as clinics and hospitals are monitored for the drug's efficacy and additional side effects.[21] On average, this phase lasts about three years.[22]

Once Phase III is complete, the manufacturer must file a new drug application (NDA).[23] The application, which entails thousands of pages of material—including all animal and human data, side effects, dosing, and directions for use, among other data—must comply with the requirements set forth in 21 U.S.C. § 355(b).[24] The FDA must review the application within 180 days of submission and either approve the application or notify the applicant of an opportunity for a hearing for further determination.[25] Once approved, the drug may be marketed with FDA regulated labeling, and the drug becomes available for physicians to prescribe.[26]

The process does not end there, however. The FDCA provides the FDA with the authority to require manufacturers to conduct post-market safety studies and trials to continue monitoring possible risks associated with the drugs.[27] The FDA is required to publish an annual notice in the *Federal Register*, containing information on the performance of post-market studies and clinical trials that the FDA requires, or has requested, of manufacturers.[28] Safety monitoring continues for the life of the drug through tracking reports of adverse events, which are unfavorable and unintended signs, symptoms, or diseases associated with the use of the

19. *Id*.

20. *Drug Development and Approval Process*, *supra* note 4.

21. *FDA Drug Approval Process*, *supra* note 14.

22. *Id.*

23. 21 U.S.C. § 355(a) (2018).

24. *Id.* at § 355(b).

25. *Id.* at § 355(c)(1).

26. *Drug Development and Approval Process*, *supra* note 4; *FDA Drug Approval Process*, *supra* note 14.

27. *See* Food and Drug Administration Amendment Acts of 2007, Pub. L. No. 110-85, § 901 et seq, 121 Stat. 823.

28. 21 U.S.C. § 356b (a), (c) (2018).

drug, whether or not related to drug itself.[29] "If adverse events appear to be systematic and serious, the FDA may withdraw a product from the market."[30]

Broken down in this manner, it is not difficult to understand why the process typically takes nearly a decade and costs billions of dollars to bring a drug to market. The FDA recognizes the need for measures allowing for deviation from this standard procedure in emergency situations where it would not be feasible or beneficial to adhere to the process strictly.

II. ' A NEED FOR SPEED: THE FDA'S FACILITATION OF ACCESS TO LIFE-SAVING DRUGS

The FDA has taken steps to ensure that critically ill patients are able to receive drugs that may not otherwise be available to them. It has done so, first, by encouraging the production of such drugs, and second, by enacting measures allowing patients to gain access to those drugs quickly and efficiently.

A. *Special Designations and Accelerated Review*

The FDA has enacted measures to encourage the development of certain drugs, particularly those that "may represent the first available treatment for an illness, or ones that have a significant benefit over existing drugs."[31] These are drugs that manufacturers are often reluctant to pursue under usual marketing conditions due, in large part, to financial risk. The FDA created special drug designations—fast track,[32]

29. *CDER Conversation: Tracking and Acting on Safety Data Throughout a Drug's Lifecycle*, FDA, https://www.fda.gov/drugs/news-events-human-drugs/cder-conversation-tracking-and-acting-safety-data-throughout-drugs-lifecycle [https://perma.cc/S8CF-MN94].

30. *Drug Development and Approval Process*, *supra* note 4.

31. *Development & Approval Process: Drugs*, FDA, https://www.fda.gov/drugs/development-approval-process-drugs[https://perma.cc/R2QW-WD29].

32. Fast track is a process designed to expedite the review of drugs that treat serious conditions and fill an unmet medical need. This designation must be requested by the sponsor and may be done so at any time during the development process. If the designation is received, the drug and sponsor may be eligible for benefits including: "[m]ore frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval," "[m]ore frequent written communication from FDA about such things as the design of the proposed clinical trials" and "[e]ligibility for accelerated approval and priority review, if relevant criteria are met." *Fast Track*, FDA, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track [https://perma.cc/XU23-23L2].

breakthrough therapy,[33] and priority review[34]—meant to alleviate some of the burden on the part of the manufacturer and help incentivize production of treatments by providing additional resources and expediting the overall process.

Additionally, the FDA instituted accelerated approval, which provides faster approval of drugs for serious conditions that fill an unmet medical need by relying on the use of surrogate endpoints during clinical trials.[35] This can considerably shorten the time required prior to receiving FDA approval.

B. ' *Expanded Access*

The FDA's special designations and accelerated review are predominantly directed toward facilitating a more efficient review process on the manufacturing end. The FDA's "expanded access," or

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33. The breakthrough designation is similar to that of fast track, but is specifically "designed 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(s)." *Breakthrough Therapy*, FDA, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy [https://perma.cc/L7PM-9NVM].

34. Priority review provides that the FDA's goal is to take action on the application within six months, rather than ten months under a standard review process. "A priority review designation will direct overall attention and resources to the evaluation of applications for 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." *Priority Review*, FDA, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review [https://perma.cc/T79X-F8V6].

35. Clinical trials typically use endpoints that definitively demonstrate a clinical benefit to a patient; accelerated approval, however, utilizes earlier markers that predict clinical benefit without yet proving it.

> Drug companies are still required to conduct studies to confirm the anticipated clinical benefit. These studies are known as phase 4 confirmatory trials. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, [the] FDA has regulatory procedures in place that could lead to removing the drug from the market.

Accelerated Approval Program, FDA, https://www.fda.gov/drugs/information-healthcare-professionals-drugs/accelerated-approval-program [https://perma.cc/8BNG-CN4G].

"compassionate use"[36] program, codified in the FDCA,[37] facilitates access on the patient end, allowing terminal patients to access medications that are still being tested in clinical trials and, therefore, would not otherwise be available to them.[38]

1. What is Expanded Access?

The expanded access program allows the use of an unapproved drug outside of a clinical trial by individuals with serious or life-threatening conditions who do not meet the enrollment criteria for clinical trials. The FDA's internal regulation allows expanded access submissions as either a new IND or a protocol amendment to an existing IND.[39] It provides for three categories of expanded access: (1) individual patients,[40] (2) intermediate-size patient populations,[41] and (3) widespread use.[42] The primary difference between the three categories is the number of patients participating. Each of these categories contains a set of criteria that must

36. This Article uses the terms "expanded access" and "compassionate use" interchangeably.

37. 21 U.S.C. § 360bbb (2018). Under the FDCA, a patient can seek expanded access for investigational products for the diagnosis, monitoring, or treatment of a serious disease or condition if the following conditions are met:

> (1) [T]he licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the person from the investigational drug or investigational device is not greater than the probable risk from the disease or condition; (2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1); (3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and (4) the sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the [FDA requirements], describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

Id. *See also* *Expanded Access (Compassionate Use)*, FDA, https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm [https://perma.cc/8BJ6-9L8R].

38. *See* Jonathan P. Jarow et al., *Overview of FDA's Expanded Access Program for Investigational Drugs*, 51 THERAPEUTIC INNOVATION & REG. SCI. 177 (2017).

39. *See* 21 C.F.R. §§ 312.300–312.320 (2020).

40. 21 C.F.R. § 312.310 (2020).

41. 21 C.F.R. § 312.315 (2020).

42. *See* 21 C.F.R. § 312.320 (2020); *see also Expanded Access (Compassionate Use)*, *supra* note 37.

be met in order for a patient to receive approval.[43] The most common request is for individual use by a single patient, which includes use sought for emergency situations where treatment may be provided even before a formal request has been submitted to the FDA.[44]

Though meant to expedite and simplify the process to drug access, the expanded access program comes with its own hurdles. Before an individual patient can gain expanded access, many steps need to be undertaken. Among them, a licensed physician must confirm the patient's qualification for the program, gain industry cooperation, facilitate the process, and manage the treatment.[45] Overall, the regulation attempts to balance the competing interests of providing access to treatments that may ultimately prove successful (and for which normal approval would have come too late) with protecting patients from using drugs that may be harmful and actually worsen their conditions.[46]

2. Challenges of Expanded Access

While federal regulations have provided a path for patients to gain access to investigational drugs, this path is laden with various obstacles, making it nearly impossible to access. Even after patients satisfy the requirements as outlined by the regulations to become eligible for expanded access, they are faced with hidden hurdles that further frustrate their journey.

Ultimately, whether patients are actually able to receive the investigational drugs rests on the manufacturer. The FDA cannot require

43. *See* 21 C.F.R. §§ 312.300–312.320 (2020); *see also Expanded Access (Compassionate Use)*, *supra* note 37.

44. Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 NEW ENG. J. MED. 279, 279 (2015). "Treatment is initially requested and authorized by telephone or other rapid means of electronic communication, and may start immediately upon FDA authorization. The written submission (i.e., the individual patient expanded access IND) must be submitted within 15 business days of the telephone authorization." *Expanded Access Categories for Drugs (Including Biologics)*, FDA, https://www.fda.gov/news-events/expanded-access/expanded-access-categories-drugs-including-biologics [https://perma.cc/SK7S-R4QL].

45. *Expanded Access: Information for Physicians*, FDA, https://www.fda.gov/news-events/expanded-access/expanded-access-information-physicians [https://perma.cc/Z6UV-RL7H].

46. Darrow et al., *supra* note 44, at 279–80.

a manufacturer to provide a drug.[47] Therefore, manufacturers must volunteer to provide the product, and there are many reasons for them to refuse to do so. Primarily, there is a huge financial risk in providing the drugs to patients before they are ready for the market. Although the FDA allows companies to charge the direct costs of the drug to patients or their insurance companies, there is fear that it may cause adverse publicity, because these costs will often be less than the price of the finalized drug on the market.[48] Additionally, it is unlikely that most insurance companies would be willing to cover the costs of these drugs, leaving patients unable to afford them on their own.[49] Therefore, the FDA reports that most manufacturers do not actually charge for their expanded access products.[50] Whereas some large corporations may be able to make up these losses through other revenue streams, smaller manufacturers may be relying solely on the profits that these investigational products will eventually produce when brought to market. Similarly, larger companies may have the resources to supply excess drugs for expanded access patients, while smaller companies may not have the resources to produce the drugs in excess of what is needed for clinical trials.[51]

Another obstacle is the administrative burden placed on the pharmaceutical company as the sponsor. The FDA has estimated that it requires approximately 120 hours of human labor for a company to prepare a protocol for an intermediate-size patient population.[52] Even for

47. *Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's Work to Mitigate Shortages of Intravenous Drugs, Shorten Supply Disruptions and Better Predict Vulnerabilities* (May 31, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-work-mitigate-shortages-intravenous-drugs-shorten [https://perma.cc/V6FB-2BU2].

48. Darrow et al., *supra* note 44, at 281.

49. *Id.*

50. *Id.*

51. *Id.*

52. An intermediate-size population ranges from tens to hundreds of patients. *Id.* at 280. The FDA attempted to address these concerns by making changes to the application process. In its testimony to the Senate, the FDA's then-Commissioner explained:

> Last year, FDA implemented significant changes to streamline the process for requesting expanded access for individual patients and promote greater transparency. We took a comprehensive and thorough look at the information requested by the Agency—and slashed the number of required fields and attachments to streamline this process. It now takes about 45 minutes to complete a single patient application form and requires just one attachment (compared with

large companies, it is a significant sacrifice, considering the alternative ways the resources could be spent (i.e., designing and implementing clinical trials). Small pharmaceutical companies will rarely be able to provide drugs through expanded access, as it is simply unlikely that they will have the physical capacity to dedicate the necessary resources.

For both small and large companies alike, all adverse events experienced by patients through expanded access must be reported to the FDA. Once the FDA receives notice, it may choose to suspend clinical trials on the drug.[53] Adverse events could also affect the overall chance of approval, lead to additional label warnings, or create negative publicity.[54] Though suspension due to adverse events is a logical concern, a review of almost 11,000 expanded access requests demonstrated that only two drug programs were suspended due to adverse events observed in patients receiving expanded access, and these suspensions were only temporary.[55]

Physician participation is another major obstacle in the successful implementation of the expanded access program. In order for an individual to qualify for compassionate use, a sponsor must submit an IND application on the patient's behalf.[56] Physicians typically serve as this sponsor.[57] Before taking on this responsibility, physicians would need to be sure that they are able to handle the burden that lies ahead. In addition to completing the expanded access application, the physician will need to obtain review and approval by an Institutional Review Board ("IRB").[58] "The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights, safety and welfare of humans participating as subjects in the research."[59] The FDA

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up to eight attachments previously required). The new form is accompanied by step-by-step instructions on how to complete it.

Examining Patient Access to Investigational Drugs: Hearing on H.R. 1020 and S. 204 Before the Subcomm. on Health, *H. Comm. on Energy and Commerce*, 115th Cong. (statement of Scott Gottlieb, Commissioner, FDA) https://www.fda.gov/news-events/congressional-testimony/examining-patient-access-investigational-drugs-10032017 [hereinafter Gottlieb].

53. FLATTEN, *supra* note 5.

54. Darrow et al., *supra* note 44, at 281.

55. Jarow et al., *supra* note 38, at 178.

56. 21 C.F.R. § 312.305(b) (2020).

57. *See* FLATTEN, *supra* note 5, at 9.

58. *See generally* 21 C.F.R. § 56 (2020).

59. *IDE Institutional Review Boards (IRB)*, FDA, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046745.htm [https://perma.cc/WFS6-B8SX].

has acknowledged potential downsides of the process, namely, that the difficulty in convening a full review board may "impede prompt decision-making and vital treatment."[60] Should the application be approved, the doctor must be willing to oversee the patient's treatment and work with industry participants in managing the use of the investigational drug.[61] This responsibility includes discussing risks and benefits with the patient and obtaining all required informed consent.[62] Not only do the doctors have to follow FDA guidelines, but they also must abide by the dispensing and monitoring requirements imposed by the manufacturing company, which typically mirror those of the ongoing clinical trials to minimize unpredictable incidents and reactions.[63]

Once an expanded access application is successfully submitted to the FDA, the agency has thirty days to make a determination.[64] According to the FDA, "[e]mergency requests for individual patients are usually granted immediately over the phone and non-emergency requests are generally processed within a few days."[65] Additionally, the FDA reports that it approves ninety-nine percent of the applications that it receives for expanded access.[66] Critics argue that these statistics are meaningless, or at least misleading, because they only account for those applications that were formally submitted to the FDA.[67] What these numbers do not show are the number of requestors and potential requestors who never even make it near that final stage.[68] For example, there are instances wherein patients may submit requests directly to manufacturers, without reporting to the FDA; any denials stemming from those cases are not accounted for by the FDA.[69] Ultimately, though the FDA regulation was enacted in good faith, it falls short in practical application.

60. Gottlieb, *supra* note 52.

61. *Expanded Access: Information for Physicians*, *supra* note 45.

62. Darrow et al., *supra* note 44, at 282.

63. FLATTEN, *supra* note 5, at 9.

64. 21 C.F.R. § 312.305(d)(1) (2020).

65. Gottlieb, *supra* note 52.

66. Caitlyn Martin, *Questioning the "Right" in State Right to Try Laws: Assessing the Legality and Effectiveness of These Laws*, 77 OHIO L.J. 159, 171 (2016).

67. *See* FLATTEN, *supra* note 5, at 5.

68. *See* Martin, *supra* note 66, at 171; *see also* FLATTEN, *supra* note 5, at 5.

69. Ellen A. Black, *State "Right to Try" Acts: A Good Start, But a Federal Act is Necessary*, 45 SW. L. REV. 719, 727 (2016).

III. IF AT FIRST YOU DON'T SUCCEED: RIGHT TO TRY LAWS

The shortcomings of the expanded access program led to patient activism aimed at acquiring greater patient access to investigational drugs outside of the program. The Abigail Alliance for Better Access to Developmental Drugs (Alliance) is largely credited with catalyzing the movement.[70] The group sued the FDA, arguing that the terminally ill have a fundamental right to seek experimental treatment.[71] Though the ensuing legal battles are outside the scope of this Article, the Alliance created the foundation for the RTT movement that has continued to grow in the years since.

A. ' *State Right to Try Laws*

In an attempt to fill the gaps in the FDA's compassionate use program, a majority of states have enacted legislation allowing manufacturers to provide experimental drugs to terminally ill patients without FDA approval.[72] These state laws are colloquially known as RTT laws and are created in response to what the states perceive as overly-strict FDA standards that may prevent patients from receiving potentially life-saving treatments. Colorado started the movement in 2014.[73] Currently, there are forty-one states that have enacted RTT laws and a few others that have legislation in the works.[74] The states that have enacted RTT laws include: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina,

70. Valarie Blake, *The Terminally Ill, Access to Investigational Drugs, and FDA Rules*, 15 AM. MED. ASS'N J. ETHICS 687, 687–89 (2013), https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-05/hlaw1-1308.pdf.

71. *See generally* Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695 (2007); Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470 (2006); Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 469 F.3d 129 (2006).

72. *What is Right to Try?*, RIGHTTOTRY, http://righttotry.org/about-right-to-try/ [https://perma.cc/U292-ABGL].

73. Martin, *supra* note 66, at 176 n.110.

74. *Right to Try in Your State,* RIGHTTOTRY, http://righttotry.org/in-your-state/ [https://perma.cc/2ZSR-FD2P].

South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.[75]

This movement was primarily spearheaded by the think tank Goldwater Institute.[76] The group's initiative is to "allow terminal patients access to investigational drugs that have completed basic safety testing, thereby dramatically reducing paperwork, wait times and bureaucracy, and most importantly, potentially saving lives."[77] The Goldwater Institute has provided template legislation that some states have utilized.[78]

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75. ALA. CODE §§ 22-5D-1–22-5D-10 (2020); ALASKA STAT. § 08.64.367 (2020), ARIZ. REV. STAT. ANN. §§ 36-1311-36-1314 (2020); ARK. CODE ANN. §§ 20-15-2101–20-15-2111 (2020); CAL. CODE HEALTH & SAFETY CODE § 111548 (West 2020); COLO. REV. STAT. §§ 25-45-101–25-45-108 (2020); CONN. GEN. STAT. § 20-14q (2020); FLA. STAT. § 499.0295 (2020); GA. CODE ANN. §§ 31-52-1–31-52-10 (2020); IDAHO CODE §§ 39-9401 –39-9409 (2020); 410 ILL. COMP. STAT. 649/10(5) (2020); IND. CODE §§ 16-42-26-1–16-42-26-5 (2020); IOWA CODE §§ 144E.1–144E.9 (2020); KY. REV. STAT. ANN. § 217.5401-5408 (West 2020); LA. STAT. ANN. §§ 40:1169.1–40:1169.6 (2019); ME. STAT. tit. 22, §§ 2671–2677 (2020); MD. CODE ANN., HEALTH-GEN § 21-2b-01–21-B-06 (West 2019); MICH. COMP. LAWS §§ 333.26451–333.26457 (2020); MINN. STAT. § 151.375 (2020); MISS. CODE ANN. § 41-131-1 (2019); MO. ANN. STAT. § 191.480 (West 2020); MONT. CODE ANN. §§ 50-12-101–50-12-110 (2019); NEB. REV. STAT. §§ 71-9601–71-9611 (2020); NEV. REV. STAT. § 454.690 (2019); N.H. REV. STAT. ANN. § 126-Z:1–126-Z:5 (2020); N.C. GEN. STAT. §§ 90-325–90-325.7 (2020); N.D. CENT. CODE §§ 23-48-01 23-48-05 (2019); OHIO REV. CODE ANN. § 4729.89 (2020); OKLA. STAT. tit. 63, §§ 3091.1–3091.7 (2020); OR. REV. STAT § 127.819 (West 2020); 35 PA. CONS. STAT. AND CONS. STAT. ANN. §§ 10232.1–10232.7 (2020); S.C. CODE ANN. §§ 44-137-10 44-137-70 (2020); S.D. CODIFIED LAWS §§ 34-51-1–34-51-10 (2020); TENN. CODE ANN. §§ 63-6-301–63-6-310 (2020); TEX. HEALTH & SAFETY CODE ANN. §§ 489.001–489.151 (West 2019); UTAH CODE ANN. §§ 58-85-101–58-85-105 (West 2020); VA. CODE ANN. §§ 54.1-3442.154.1-3442.4 (2020); WASH. REV. CODE §§ 69.77.010–69.77.090 (2018); W. VA. CODE §§ 16-51-1–16-51-8 (2020); WIS. STAT. § 450.137 (2019); WYO. STAT. ANN. §§ 35-7-1801–35-7-1806 (2020).

76. Sy Mukherjee, *Trump Called for a 'Right to Try' Law During His State of the Union: Here's What That Means*, FORTUNE (Feb. 1, 2018, 2:30 PM), http://fortune.com/2018/02/01/trump-state-of-the-union-right-to-try/ [https://perma.cc/B9F8-VTPH].

77. Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of their Treatment,* 266 GOLDWATER INST. 1, 1 (Feb. 11, 2014), https://goldwaterinstitute.org/wp-content/uploads/cms_page_media/2015/1/28/Right%20To%20Try.pdf [https://perma.cc/P5AX-3CQL].

78. Martin, *supra* note 66, at 175. Some key provisions in the template include:

> To gain access to treatment, an individual must be an Eligible Patient, defined as someone with an advanced Illness who has considered all other FDA-approved treatment options, received recommendation from her physician, given informed consent, and secured documentation from her physician that she meets the criteria of an Eligible Patient.

Id. Additionally, "[d]octors, hospitals, and manufacturers that do not follow the FDA approval process are protected from disciplinary actions taken by a licensing board or disciplinary subcommittee." *Id.* at 176.

Though specific requirements vary by state, a majority of the provisions are similar to those outlined in expanded access.[79] There are, however, some major differences between the FDA expanded access and state RTT laws. For example, most states do not require approval by an IRB.[80] While this removes a significant barrier that would otherwise exist in the expanded access program, it does so at the expense of the patient, who is no longer protected by the oversight and expertise of the review board. States likely expected that the circumvention of the FDA and the removal of the stricter requirements present in the expanded access program would automatically increase the likelihood that terminally ill patients receive access to investigational drugs. This assumption, however, is misguided.

As with expanded access, the party ultimately responsible for the success of the RTT laws is the drug manufacturer. Removing the FDA from the process does not make it more likely that these companies will cooperate. In fact, they would be less likely to participate. It is generally agreed upon by experts that drug companies are unlikely to make their products available under state laws alone.[81] They do not want to risk going against the FDA, the agency that has the authority to control their operations and the ability to bring their drugs to market. As with compassionate use, manufacturers run the risk of jeopardizing approval for market entry should they choose to supply investigational drugs that result in adverse conditions. Assisting the small group of patients who request products under RTT laws may occur at the expense of the drug's ultimate approval for use by the general population.[82] It is highly unlikely that many companies will sacrifice the time and resources necessary to provide investigational drugs.

Ultimately, there are both strong supporters and opponents of the RTT laws. Regardless, the mere existence of RTT laws in a majority of states suggests the need for amendments to the expanded access program.

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79. Only patients who have exhausted all other treatment options can receive investigational drugs under RTT laws; the patient's physician must determine that the drug is likely the patient's best chance at survival. *See* FLATTEN, *supra* note 5, at 24. Michigan is an example of a state with such provisions. *See* MICH. COMP. LAWS ANN. § 333.26452(1) (West 2015).

80. FLATTEN, *supra* note 5, at 24; Carolyn Riley Chapman, et al., *Oversight of Right-to-Try and Expanded Access Requests for Off-Trial Access to Investigational Drugs*, 42 ETHICS & HUMAN RES. 2, 5 (2020).

81. FLATTEN, *supra* note 5, at 24.

82. *See supra* Part II.B.2 (regarding the risks a manufacturer faces, should there be adverse effects).

Advocates for patients' rights also pushed for the enactment of a federal RTT act that would bridge the gap between the state acts and the agency program.[83] Indeed, the movement gained traction at the federal level, and the platform was taken up by the Trump administration.

B. *Federal Right to Try Act*

During Donald Trump's first State of the Union address, the President urged Congress to pass a RTT bill for terminally ill patients.[84] He was quoted saying: "We also believe that patients with terminal conditions should have access to experimental treatments that could potentially save their lives."[85] Trump essentially implied that terminally ill patients must go to other countries in order to seek treatment when he said, "People who are terminally ill should not have to go from country to country to seek a cure—I want to give them a chance right here at home. It is time for the Congress to give these wonderful Americans the right to try."[86]

Vice President Michael Pence has similarly been a supporter of the RTT movement and has met with advocates to promote the cause.[87] In 2015, as governor, he enacted Indiana's RTT law.[88] During his first month as Vice President, he held a White House meeting with patients and families and vowed to help "get this done" on the federal level.[89] With the strong support of the administration, it was only a matter of time before the RTT advocacy resulted in actionable measures by the federal legislature.

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83. *See* Martin, *supra* note 66, at 185, 193.

84. Donald J. Trump, President of the United States, State of the Union Address (Jan. 30, 2018), https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-state-union-address/ [https://perma.cc/7GNB-QYWS].

85. *Id.*; Mukherjee, *supra* note 76.

86. Mukherjee, *supra* note 76.

87. Thomas M. Burton, *Trump Supports 'Right to Try' Law Expanding Access to Experimental Drugs for Terminally Ill*, WALL ST. J. (Jan. 31, 2018), https://www.wsj.com/articles/trump-supports-right-to-try-law-expanding-access-to-experimental-drugs-for-terminally-ill-1517420125 [https://perma.cc/V3MX-RZ4G].

88. IND. CODE ANN. § 16-42-26-4 (West 2020); 2015 Ind. Legis. Serv. P.L. 2-2015 (H.E.A. 1065), http://iga.in.gov/legislative/2015/bills/house/1065#document-53b37ee0 [https://perma.cc/H2MX-U64A].

89. Elise Viebeck, *House Approves 'Right-to-Try' Bill Giving Seriously Ill Patients Access to Experimental Drugs*, WASH. POST (Mar. 21, 2018), https://www.washingtonpost.com/powerpost/house-approves-right-to-try-bill-giving-seriously-ill-patients-access-to-experimental-drugs/2018/03/21/b87c2a1c-2d2c-11e8-b0b0-f706877db618_story.html?utm_term=.5083d7158464 [https://perma.cc/X5B4-S2KP].

In August 2017, the Senate unanimously passed the Wendler, Mongiello, McLinn, and Bellina Right to Try Act.[90] The bill was presented to the House of Representatives for vote on May 22, 2018, and was passed in identical form. On May 30, 2018, President Trump officially signed into law Public Act 115-176, the federal Right to Try Act.[91] The Act amended Chapter V of the FDCA by inserting Section 561B—"Investigational Drugs for Use by Eligible Patients"—which provides, in pertinent part:

> Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 502(f), 503(b)(4), 505(a), and 505(i) of this Act, section 351(a) of the Public Health Service Act, and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.[92]

By definition, to be eligible for investigational drug access, a patient must (1) have a life-threatening illness, (2) have exhausted all treatment options and be unable to participate in a clinical trial of the requested drug, and (3) provide to the treating physician written informed consent.[93] Therefore, the eligibility requirements are quite similar to those present in the expanded access program. The most significant distinction, and the one that causes concern among critics, is the exclusion of the FDA in the process.

C. *Concerns Surrounding the RTT Act*

When the RTT Act was first introduced in the Senate, it was a cause of concern for the drug industry, public health advocates, and the FDA, all of whom were worried that it could undermine patient safety and drug

90. Right to Try Act, S. 204, 115th Cong. (2017).

91. Right to Try Act, Pub. L. No. 115-176, 132 Stat. 1372 (2018).

92. *Id.*

93. *Id.*

development processes.[94] A key provision of this bill was that manufacturers and physicians would not be required to obtain FDA approval prior to treating patients, though they would still be required to report any adverse effects that occurred.[95] The FDA's then-Commissioner, Scott Gottlieb, urged the Senate to amend the bill's language to maintain the FDA's oversight power over treatments.[96]

Many of the concerns expressed by critics regarding the state RTT laws are prevalent in the federal law. Critics worry that the RTT laws will threaten FDA standards "by allowing wider use of untested drugs in an unnecessarily broad population."[97] It has been reported that approximately ten to eleven percent of compassionate use proposals submitted to the FDA require modifications to their dosages, informed consent procedures, and safety monitoring.[98] RTT laws could lead to less safe and less effective use of experimental drugs. Public health advocates argue that the majority of terminally ill patients' needs are already satisfied through the compassionate use program and that the creation of

94. Letter from Am. Cancer Society Cancer Action Network et al., to Paul Ryan, Speaker & Nancy Pelosi, Minority Leader (Feb. 6, 2018), https://www.fightcancer.org/sites/default/files/National%20Documents/February%20Right%20to%20Try%20Coalition%20Letter%20-%20Final.pdf [https://perma.cc/K924-S4GB]. In a letter sent to the House of Representatives, a group of forty advocacy groups expressed their concern with the proposed House and Senate bills. They wrote, in relevant part:

> Our organizations support patient access to unapproved therapies. However, the Right to Try bills currently under consideration in the House do not effectuate policy changes that would afford our patients greater access to promising investigational therapies.
>
> . . . We do not believe S.204 or H.R.878 would successfully increase access to promising investigational therapies for those in need. Both of these bills remove the Food and Drug Administration (FDA) from the initial approval process for accessing an investigational therapy outside of a clinical trial. Removing FDA from this process is not likely to facilitate increased access to investigational therapies.

Id.

95. Right to Try Act, Pub. L. No. 115-176, 132 Stat. 1372 (2018).

96. Carlos Ballesteros, *Critics Warn Trump's Koch-Backed 'Right to Try' Bill is Dangerous for Patients*, NEWSWEEK (Jan. 31, 2018, 3:36 PM), http://www.newsweek.com/koch-brothers-conservative-groups-behind-trumps-right-try-bill-796185 [https://perma.cc/NM5Q-SZF9].

97. Burton, *supra* note 87.

98. Mukherjee, *supra* note 76; Burton, *supra* note 87.

RTT laws could ultimately cause more harm than good.[99] Additionally, critics worry about the lack of recourse for patients who experience adverse effects, as the RTT laws limited their ability to sue for malpractice or negligence.[100] Some have gone as far as to say that RTT laws "immunize physicians administering unapproved medications and the companies behind the drugs and treatment."[101] The federal law contains one such "no liability" provision.[102]

Similarly, the impediments to the success of the expanded access program have not been adequately addressed, if at all, by the federal law. Although the RTT Act grants a patient the right to seek access to an experimental drug, as is the case with compassionate use, it does not require the manufacturer to provide the drug. Many of the reservations that manufacturers may have under the expanded access program remain in the forefront under the federal law. For instance, the concern that providing the drug to patients outside of clinical trials could lead to negative clinical outcomes and disrupt the approval process is not entirely alleviated by the new legislation. Although the law prevents this data from being used unless it is deemed "'critical to determining safety,' bad outcomes might give the FDA pause and delay the approval of drugs that might otherwise be available sooner."[103] For these reasons, manufacturers are still likely to withhold the drug.

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99. Stephen Barlas, *"Right to Try" Legislation Moving Through Congress: But Drug Companies and Some Patient Groups Want Changes*, 42 PHARMACY & THERAPEUTICS 739, 739, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5720486/ [https://perma.cc/WGP4-UP74].

100. Ballesteros, *supra* note 96.

101. *Id*.

102. The Act provides, in relevant part:

> With respect to any alleged act or omission with respect to an eligible investigational drug provided to an eligible patient pursuant to section 561B of the Federal Food, Drug, and Cosmetic Act and in compliance with such section, no liability in a cause of action shall lie against—(A) a sponsor or manufacturer; or (B) a prescriber, dispenser, or other individual entity (other than a sponsor or manufacturer), unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.

Pub. L. No. 115-176 § 561B(b)(1). It also protects the parties from liability for a determination *not* to provide access to an IND. *Id.* at § 561B(b)(2).

103. Morten Wendelbo & Timothy Callaghan, *What is "Right to Try" and Will it Help Terminally Ill Patients?*, CBS NEWS (May 30, 2018, 2:35 PM), https://www.cbsnews.com/news/right-to-try-bill-trump-signing-will-it-help-terminally-ill-patients-today-2018-05-30/ [https://perma.cc/RR3F-UFKZ].

IV. DRUG ACCESS DURING THE CORONAVIRUS PANDEMIC[104]

In early March of 2020, President Trump began promoting hydroxychloroquine and chloroquine as potential cures for the coronavirus.[105] These drugs, however, are only FDA-approved to treat malaria, lupus, and rheumatoid arthritis,[106] thus renewing the discussion surrounding access of nonapproved drugs in emergency situations. So far, it seems RTT will play but a small role, if any, in the discussion as the nation continues its fight against COVID-19.

On March 17, 2020, the Goldwater Institute released a statement urging policymakers to expand RTT even further amid the new coronavirus outbreak.[107] In its statement, the group wrote:

> For patients who have either become infected, are at high risk, or simply wish to inoculate themselves from the COVID-19 virus, patients, under their physician's care, should be allowed to access treatments and vaccines prior to government approval, if and when they are made available by manufacturers.[108]

There seems to be little need for this RTT expansion, however, as the FDA has acted swiftly in allowing for the exploration of hydroxychloroquine and chloroquine as treatment options for the coronavirus, despite there being a severe lack of empirical data.[109] On March 28, 2020, the FDA issued an emergency use authorization (EUA) for both drugs, allowing them to be "donated to the Strategic National Stockpile to be distributed and prescribed by doctors to hospitalized teen

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104 Due to the constantly evolving nature of the coronavirus pandemic response, the reader should note that the following discussion reflects the state of affairs as of May 2020.

105. Philip Bump, *The Rise and Fall of Trump's Obsession with Hydroxychloroquine*, WASH. POST (Apr. 24, 2020, 2:17 PM), https://www.washingtonpost.com/politics/2020/04/24/rise-fall-trumps-obsession-with-hydroxychloroquine/ [https://perma.cc/RR3F-UFKZ].

106. FDA, FREQUENTLY ASKED QUESTIONS ON THE EMERGENCY USE AUTHORIZATION (EUA) FOR CHLOROQUINE PHOSPHATE AND HYDROXYCHLOROQUINE SULFATE FOR CERTAIN HOSPITALIZED COVID-19 PATIENTS, 1 (2020) [hereinafter FREQUENTLY ASKED QUESTIONS], https://www.fda.gov/media/136784/download [https://perma.cc/NPK2-WZR7].

107. GOLDWATER INST., *Now is the Time to Expand Right to Try*, IN DEFENSE OF LIBERTY (Mar. 17, 2020), https://indefenseofliberty.blog/2020/03/17/now-is-the-time-to-expand-right-to-try/ [https://perma.cc/TF8Y-HBA4].

108. *Id.*

109. William Feuter, *WHO Says There's "No Empirical Evidence" Trump-Touted Hydroxychloroquine Helps Treat or Prevent Coronavirus,* CNBC, https://www.cnbc.com/2020/05/27/who-says-no-empirical-evidence-trump-touted-hydroxychloroquine-helps-treat-or-prevent-coronavirus.html [https://perma.cc/39N6-G99J].

and adult patients with COVID-19, as appropriate, when a clinical trial is not available or feasible."[110] Additionally, the FDA is expected to authorize a similar EUA for the experimental antiviral drug remdesivir.[111]

In certain types of emergencies, the FDA may issue an EUA to facilitate access to medical countermeasures (drugs, biologics, vaccines, and devices) that can be used to diagnose, treat, or prevent a serious disease or condition in a public health emergency.[112] Before authorizing such use, the FDA "decides whether the use of the product is likely to [be] more helpful than harmful for the emergency use; i.e., the FDA determines that the known and potential benefits of the medical products for their intended uses outweigh their known and potential risks."[113]

The FDA's ability to collect data on the experimental treatments for COVID-19 brings to the forefront the key pitfall of the federal RTT law. Under RTT, clinical data would not be formally reported unless adverse events took place.[114] Scientists had already been skeptical of the use of hydroxychloroquine and chloroquine when reports first suggested that they may be effective in treating the coronavirus, "noting the lack of data on the drugs' efficacy for coronavirus care and worries that it would siphon medication away from patients who need it for other conditions, calling instead for the FDA to pursue its usual clinical trials."[115] Even with the FDA's explicit involvement by issuing the EUA, the skepticism remains. "[O]utside of a clinical trial, it can be hard to assess the drug's value, especially when it is being given to a variety of patients, of different ages and medical conditions, and at different points in their disease," a

110. *Emergency Use Authorization*, FDA, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization [https://perma.cc/RA8B-GTAF].

111. Maggie Fox, et al., *FDA Will Reportedly Authorize Use of Remdesivir for Covid-19 After Trial Shows "Positive Effect" on Recovery Time*, CNN (April 30, 2020, 5:03 AM), https://www.cnn.com/2020/04/29/health/gilead-sciences-remdesivir-covid-19-treatment/index.html [https://perma.cc/3HKA-SZDW].

112. *See* 21 U.S.C. § 360bbb–3(a)(1) (2018); *see also Emergency Use Authorization*, *supra* note 109; *HHS Accepts Donations of Medicine to Strategic National Stockpile as Possible Treatments for COVID-19 Patients*, HHS.GOV (Mar. 29, 2020), https://www.hhs.gov/about/news/2020/03/29/hhs-accepts-donations-of-medicine-to-strategic-national-stockpile-as-possible-treatments-for-covid-19-patients.html [https://perma.cc/6GWL-US3G].

113. *See* FREQUENTLY ASKED QUESTIONS, *supra* note 106.

114. *See* Pub. L. No. 115-176 § 561B(d)(1).

115. Dan Diamond, *FDA Issues Emergency Authorization of Anti-Malaria Drug for Coronavirus Care*, POLITICO (Mar. 29, 2020), https://www.politico.com/news/2020/03/29/fda-emergency-authorization-anti-malaria-drug-155095 [https://perma.cc/X8KX-PFQB].

health expert has explained.[116] The FDA's involvement is critical, however, as it is "expected to facilitate more access to the drugs by allowing more donations, and a second EUA is under consideration that would allow more manufacturers to produce it."[117] This, presumably, would allow for important results of the drugs to amass while clinical trials are underway.[118] Ultimately, it remains to be seen whether RTT laws will find a place alongside the EUA in the government's efforts to find an effective treatment for COVID-19.

CONCLUSION

Amidst the complex statutory and regulatory landscapes on drug development, approval, and access, it is likely that there will be an ensuing policy struggle between allowing individuals liberal access and providing necessary governmental oversight and restrictions. There is perhaps no setting more apt for this debate to unfold than during a global health emergency. As health officials work tirelessly to combat this pandemic, governments are faced with the high-stakes challenge of balancing speed of access with safety. The discussions on expanded access, RTT, and the general policy debates regarding drug access will surely continue, if not be reinvigorated, when the pandemic subsides.

116. Katie Thomas, *Trump Calls this Drug a 'Game Changer.' Doctors Aren't So Sure.*, N.Y. TIMES (Apr. 17, 2020), https://www.nytimes.com/2020/04/17/health/trump-hydroxychloroquine-coronavirus.html [https://perma.cc/RMJ4-VB3V].

117. Diamond, *supra* note 115.

118. *See* U.S. Nat'l Library of Med., *Search of: COVID-19*, CLINICALTRIALS.GOV, https://clinicaltrials.gov/ct2/results?cond=COVID-19 (last visited May 20, 2020) [https://perma.cc/P5AX-3CQL].