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The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines

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The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines

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Medicines and vaccines are complex products, and it is often extraordinarily difficult to know whether they help or hurt. The Food and Drug Administration (FDA) holds an enormous reservoir of data that sheds light on that precise question, yet currently releases only a trickle to researchers, doctors, and patients. Recent examples show that data secrecy can be deadly, and existing laws such as the Freedom of Information Act (FOIA) cannot solve the problem. We present here a wealth of new evidence about the urgency of the problem and argue that the FDA must "reboot" its rules to proactively disclose all safety and efficacy data for drugs and vaccines with minimal redactions, deploying data use agreements to ensure the most sensitive data is handled appropriately. In line with the literature that has been critical of simplistic calls for "transparency," we urge a more contextual form of "data publicity." We also show that clinical trial data publicity can be achieved without legislative reform, while respecting privacy, protecting any legitimate trade secrets, and maintaining or improving incentives to innovate. The FDA must adapt to protect and expand structural accountability and to protect the public and its trust. The model we offer here could guide similar action at other regulatory agencies as well, enabling better oversight of information-intensive industries and helping safeguard the agencies themselves.

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INTRODUCTION

Few issues are more important to the American public than the quality and safety of our medicines. About half of all Americans take one or more prescription drugs,[1] and medicines represent a startling 2% of total U.S. gross

Collaboration for Research Integrity and Transparency (CRIT); this Article builds on CRIT's work and would not have been possible without them. All errors are our own.

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1. Shelly Hagan, *Nearly One in Two Americans Takes Prescription Drugs: Survey*, BLOOMBERG (May 8, 2019), https://www.bloomberg.com/news/articles/2019-05-08/nearly-one-in-two-americans-takes-prescription-drugs-survey [https://perma.cc/L54F-GH7S].

domestic product (GDP) each year.[2] Life as we know it relies on vaccines that prevent dangerous diseases. But there is a structural problem at the heart of our system for the development and assessment of therapeutics and vaccines:[3] a problem of secrecy in the age of big data.

The problem of data secrecy is especially visible in the shadow of the COVID-19 pandemic. As we complete this in the summer of 2020, governments around the world are taking unprecedented measures to promote the development of a COVID-19 vaccine. Billions of dollars of public money are being invested, with dozens of potential vaccines in development.[4] But researchers have raised an outcry, pointing out that they have no access to some of the most basic and important information about the design and outcomes of the most promising COVID-19 vaccine trials.[5] Access to this information could enable scientists to understand key clinical trial decisions in time to influence them, to evaluate the quality of the evidence as it emerges, and to protect against mistakes and misconduct, such as changes in trial endpoints that produce spurious results. Researchers could also make novel uses of the data collected, advancing our understanding of COVID-19 at a critical time.[6] Under pressure, several companies (as of this writing) have begun to release some such data voluntarily.[7] This is a positive step and a proof of concept. But there are important gaps in what has been provided[8] and no systems in place to be sure that they will be remedied, despite the extraordinary stakes.

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2. *See National Health Expenditures 2017 Highlights*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf [https://perma.cc/9A95-FAR9].

3. This article generally uses the terms "drug" or "medicine" to cover both therapeutics and vaccines because the relevant legal and scientific issues are similar. We clarify the few places where there are relevant differences in regulatory structure.

4. *See COVID-19 R&D Tracker*, POL'Y CURES RSCH. https://www.policycuresresearch.org/covid-19-r-d-tracker [https://perma.cc/GLR8-HWLK] (providing an overview of the global pipeline of potential new vaccines, therapeutics, and diagnostics currently under investigation for COVID-19).

5. *See* Katie Thomas, *Vaccine Makers Keep Safety Details Quiet, Alarming Scientists*, N.Y. TIMES (Sept. 16, 2020), https://www.nytimes.com/2020/09/13/science/coronavirus-vaccine-trials.html [https://perma.cc/JL4J-WUY6].

6. For example, pooling data from vaccine studies might help us understand background immune responses. *See* Peter Doshi, *Covid-19: Do Many People Have Pre-Existing Immunity?*, BRIT. MED. J. (Sept. 17, 2020), https://doi.org/10.1136/bmj.m3563 [https://perma.cc/XU6X-S867]. On subgroup analysis, see Sally Hollis et al., *Best Practice for Analysis of Shared Clinical Trial Data*, BMC MED. RSCH. METHODOLOGY, July 2016 (Supp. 1), at 15, 18 (2016).

7. *See, e.g.*, Denise Grady & Katie Thomas, *Moderna and Pfizer Reveal Secret Blueprints for Coronavirus Vaccine Trials*, N.Y. TIMES (Sept. 17, 2020), https://www.nytimes.com/2020/09/17/health/covid-moderna-vaccine.html [https://perma.cc/A6YE-VJ8L]; Denise Grady, Katherine J. Wu & Sharon LaFraniere, *AstraZeneca, Under Fire for Vaccine Safety, Releases Trial Blueprints*, N.Y. TIMES (Sept. 19, 2020), https://www.nytimes.com/2020/09/19/health/astrazeneca-vaccine-safety-blueprints.html [https://perma.cc/Y3GM-WR49].

8. *See* Ed Silverman, *Public Health Experts Push Vaccine Makers, HHS to Release Covid-19 Trial Protocols*, STAT NEWS (Oct. 20, 2020), https://www.statnews.com/pharmalot/2020/10/20/covid19-coronavirus-pandemic-vaccine-hhs-pfizer-

The inability to access data related to COVID-19 vaccine development sheds light on the problems caused by systemic data secrecy in clinical trials. Therapeutics and vaccines are complex products. We cannot know whether they hurt or help without rigorous clinical trials, whose conduct and interpretation are highly complicated. Today these trials, particularly at later stages, are typically conducted by companies with strong financial interests in the outcomes.[9] This is a key justification for our drug regulatory system: independent experts are needed to protect the public by examining and validating data about the effects of medicines.[10] But our drug regulatory bodies are under-resourced, and recent examples show that outside expert analysis can reveal concealed risks of medicines.

The rise and fall of the painkiller rofecoxib (Vioxx) offers a stark example of the harms of data secrecy. The drug was promoted as being safer than aspirin and became a blockbuster. It earned $2 billion each year for Merck before it was abruptly removed from the market because it caused heart attacks, strokes, and heart failures.[11] The evidence only became known to outside experts through litigation.[12] Later independent research showed that signals of these risks were present in data held by the FDA nearly *3.5 years* before the drug was withdrawn from the market.[13] That evidence did not reach doctors or patients because the data was not made available to the scientific community.[14] An FDA official later estimated that tens of thousands of people died as a result.[15]

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moderna-astrazeneca/ [https://perma.cc/VBE8-63P9] (describing an expert letter to Department of Health and Human Services (HHS) Secretary Alex Azar that identifies gaps in voluntary corporate disclosures and urges the FDA and the National Institutes of Health (NIH) to publicize more information about COVID-19 vaccine studies).

9. *See* Kenneth A. Getz, *Sizing Up the Clinical Research Market*, APPLIED CLINICAL TRIALS (Mar. 1, 2010), http://www.appliedclinicaltrialsonline.com/print/213683?page=full [https://perma.cc/BGE5-KMZB] (estimating that industry funds approximately 90% of the clinical trials conducted for investigational drugs and devices).

10. *See* Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production, Past and Future*, 102 MINN. L. REV. 2357, 2373–74 (2018).

11. Joseph S. Ross, David Madigan, Kevin P. Hill, David S. Egilman, Yongfei Wang & Harlan M. Krumholz, *Pooled Analysis of Rofecoxib Placebo-Controlled Clinical Trial Data: Lessons for Postmarket Pharmaceutical Safety Surveillance*, 169 ARCHIVES INTERNAL MED. 1976, 1976–77 (2009).

12. *See* Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 309 (2007).

13. Ross et al., *supra* note 11, at 1979; *see also* YALE COLLABORATION FOR RSCH. INTEGRITY & TRANSPARENCY, WHAT'S IN YOUR MEDICINE CABINET? 35 (3d ed. 2018), https://law.yale.edu/sites/default/files/area/center/crit/document/crit_policy_paper_february_2018_3rd_edition.pdf [https://perma.cc/94RQ-6YE7].

14. Ross et al., *supra* note 11, at 1983.

15. *See* David J Graham, David Campen, Rita Hui, Michele Spence, Craig Cheetham, Gerald Levy, Stanford Shoor & Wayne A Ray, *Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with Cyclo-Oxygenase 2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs: Nested Case-Control Study*, 365 LANCET 475, 480 (2005); *see also* Carolyn Abraham, *Vioxx Took Deadly Toll: Study*, GLOBE & MAIL (Jan. 25, 2005), https://www.theglobeandmail.com/life/vioxx-took-deadly-toll-study/article1113848/

Data secrecy also causes harm by undermining our health care system. Secrecy prevents us from making the best allocation of scarce resources and obscures avenues for systematic reforms at the FDA and in the pharmaceutical industry. Data secrecy may also undermine trust. The American public, for example, expressed widespread hesitancy about any COVID-19 vaccine that was to be rushed to market before the November 2020 U.S. election.[16] Sharing safety and efficacy data on drugs and vaccines—including COVID-19 vaccines—would help to secure public trust in the FDA review process and in the products that emerge from it and would help to protect the scientific integrity of the FDA review process from political pressure.[17]

There is, accordingly, an emerging consensus that independent researchers need better access to clinical trial data to keep both the industry and regulators honest and accountable.[18] Yet existing tools for an independent assessment of clinical trial data are inadequate. What remains missing is an effective legal and regulatory framework for the release of this data within the United States. For several years, working closely with medical researchers and a legal team, we have worked to maximize the potential of existing strategies for clinical trial data disclosure. This Article sets out a key lesson of that work: existing tools are inadequate for the task. If researchers are to have systematic access to the clinical trial data needed to help spot unsafe and ineffective medicines, the FDA will have to make clinical trial data available proactively.

We show that the agency can, consistent with existing law, make clinical trial data available proactively. We describe how the FDA can do so while navigating the two main challenges of data sharing: protecting the privacy of individuals who participate in trials and addressing claims that company data

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[https://perma.cc/8QZ4-5APP] ("[A]nywhere from 39,000 to 61,000 deaths in the United States could be linked to Vioxx.").

16. *See generally* Alec Tyson, Courtney Johnson & Cary Funk, *U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine*, PEW RSCH. CTR. (Sept. 17, 2020), https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/ [https://perma.cc/CB2X-WKGU] (showing that as of September 2020, 49% of Americans polled would definitely not or probably not take a COVID-19 vaccine if one had been available at that time).

17. *See* Jeff Cronin & Richard Adcock, *Nation's Leading Vaccine Authorities Urge Thorough Review of Safety and Efficacy of COVID-19 Vaccines*, CTR. FOR SCI. PUB. INT. (Aug. 5, 2020), https://www.cspinet.org/news/nation%E2%80%99s-leading-vaccine-authorities-urge-thorough-review-safety-and-efficacy-covid-19-vaccines [https://perma.cc/MM2K-A2A7]; G. Caleb Alexander, Aaron S. Kesselheim & Thomas J. Moore, *Searching for an Effective Covid-19 Treatment: Promise and Peril*, STAT NEWS (Apr. 10, 2020), https://www.statnews.com/2020/04/10/searching-for-an-effective-covid-19-treatment-promise-and-peril/ [https://perma.cc/52VJ-P692]; Christopher J. Morten, Amy Kapczynski, Harlan M. Krumholz & Joseph S. Ross, *To Help Develop the Safest, Most Effective Coronavirus Tests, Treatments, and Vaccines, Ensure Public Access to Clinical Research Data*, HEALTH AFFS. BLOG (Mar. 26, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200326.869114/full/ [https://perma.cc/F6AH-7YLP].

18. *See* INST. OF MED. OF THE NAT'L ACADS., SHARING CLINICAL TRIAL DATA: MAXIMIZING BENEFITS, MINIMIZING RISK 1 (2015).

should remain confidential. Drawing on examples of successful data sharing in other countries and at other agencies, we also show that the process can be done effectively and manageably. Our central contribution is a wealth of new evidence about the significance of the problem and an updated argument for proactive disclosure that can be achieved without legislative reform.[19] We reveal the flaws in arguments that comprehensive proactive disclosure is prohibited under U.S.

19. The most important earlier analysis of the problem dates to the late 1970s, when Robert Halperin argued for a similar outcome based on different legal authority, and with less evidence of the problem. *See* Robert M. Halperin, *FDA Disclosure of Safety and Effectiveness Data: A Legal and Policy Analysis*, 1979 DUKE L.J. 286 (1979). Two intervening Supreme Court cases undermined Halperin's legal argument for disclosure. *See* Chrysler Corp. v. Brown, 441 U.S. 281, 312 (1979) (holding that the federal "housekeeping statute," 5 U.S.C. § 301, cannot authorize regulations that limit the scope of the federal Trade Secrets Act, 18 U.S.C. § 1905 *et seq*.); Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1008–09 (1984) (presenting new takings concerns that Halperin did not address). We describe how disclosure can be achieved under existing law nonetheless. Other analyses that have called for more disclosure of clinical trial data do not address the many legal and practical barriers or counterarguments that we address here. *See* William R. Pendergast, *The Responsibility of the FDA to Protect Trade Secrets and Confidential Data*, 27 FOOD DRUG COSM. L.J. 366 (1972); Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837 (1980); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007); Christine D. Galbraith, *Dying to Know: A Demand for Genuine Public Access to Clinical Trial Results Data*, 78 MISS. L.J. 705 (2009); Mustafa Ünlü, Note, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, 16 MICH. TELECOMM. & TECH. L. REV. 511 (2010); Rebecca S. Eisenberg, *Data Secrecy in the Age of Regulatory Exclusivity*, *in* THE LAW AND THEORY OF TRADE SECRECY 467 (Rochelle C. Dreyfuss & Katherine. J. Strandburg, eds., 2011); Peter Doshi & Tom Jefferson, *Disclose Data Publicly, Without Restriction*, 45 J.L. MED. & ETHICS 42 (2017); Joshua M. Sharfstein et al., *Blueprint for Transparency at the U.S. Food and Drug Administration: Recommendations to Advance the Development of Safe and Effective Medical Products*, J.L. MED. & ETHICS 7 (2017). *See also* Rachel E. Sachs & Thomas J. Hwang, *Increasing the Transparency of FDA Review to Enhance the Innovation Process*, *in* TRANSPARENCY IN HEALTH AND HEALTH CARE IN THE UNITED STATES: LAW AND ETHICS 185, 191 (Holly Fernandez Lynch et al. eds., 2019) (addressing the importance of transparency for a smaller subset of drug-related information, including summaries of complete response letters issued by the FDA, placements of clinical holds, and meetings between the FDA and clinical trial sponsors).

federal statutes[20] or, if permitted, will require expensive compensation to the industry for intellectual property violations.[21]

This Article is centrally aimed at solving an important public health problem, but it also contributes to two broader literatures. The first is the literature on transparency and the implications of freedom of information laws. Transparency as an ideal has been rightly criticized recently as having taken on a formalistic, decontextualized quality. As an ideal, transparency does not appropriately recognize that "freedom" at times requires more than unfettered, standardless exchange[22] and does not appreciate how freedom of information laws can be weaponized to undermine public interests.[23] We show here that the implications of data sharing turn on and should be sensitive to a broader political-economic context. Data sharing can serve public interests because of a wider ecology that provides researchers with the necessary resources to analyze the data and includes publications and norms (of the "open science" tradition in academic medicine, for example) that help generate and validate important new insights and challenge false claims. Data itself does not produce these insights, and a context that enables trustworthy analysis is essential if data sharing is to work well.

To this end, we argue that data use agreements will be an important component of data disclosures in our "big data" age. They provide a means to navigate issues of privacy and commercial interest—issues that can otherwise shut down data sharing, rightly or wrongly—and a mechanism to develop and

20. *See* Jeffrey K. Francer & Natalie A. Turner, *Responsible Clinical Trial Data Sharing: Promoting Medical Advancement, Patient Privacy, and Incentives to Invest in Research*, 8 J. HEALTH & LIFE SCI. L. 63, 92 (2014) ("Federal law consistently has protected the confidentiality of companies' non-public clinical trial information provided to FDA as part of the new drug approval process, including study reports, protocols, and raw safety and effectiveness data."); Amy Westergren, Note, *The Data Liberation Movement: Regulation of Clinical Sharing in the European Union and the United States*, 38 HOUS. J. INT'L L. 887, 909 (2016); David S. Levine, *The Impact of Trade Secrecy on Public Transparency*, *in* THE LAW AND THEORY OF TRADE SECRECY 406, 431–32 (Rochelle C. Dreyfuss & Katherine J. Strandburg, eds., 2011) ("[Both] FOIA and the Trade Secrets Act (TSA) . . . act in tandem to prohibit the government from releasing any information that meets a FOIA trade secret definition."). *See also* Eisenberg, *Data Secrecy*, *supra* note 19, at 488–89 (suggesting statutory reform to permit proactive disclosure while not explicitly arguing that proactive disclosure is prohibited under current statute); Galbraith, *supra* note 19, at 776 ("[G]enuine statutory reform to make the clinical trials process more transparent must occur so that proper protection is provided for all patients requiring medical care.").

21. *See* Erika Lietzan, *A New Framework for Assessing Clinical Data Transparency Initiatives*, 18 MARQ. INTELL. PROP. L. REV. 33, 39 (2014); Anna B. Laakmann, *A Property Theory of Medical Innovation*, 56 JURIMETRICS 117, 156 (2016).

22. *See* David E Pozen, *Transparency's Ideological Drift*, 128 YALE L.J. 100 (2018); Philip Mirowski, *The Future(s) of Open Science*, 48 SOC. STUD. SCI. 171 (2018); Mary D. Fan, *Private Data, Public Safety: A Bounded Access Model of Disclosure*, 94 N.C. L. REV. 161, 197 (2015).

23. *See* Pozen, *Transparency's Ideological Drift*, *supra* note 22; Margaret B. Kwoka, *FOIA, Inc.*, 65 DUKE L.J. 1361, 1388 (2016).

impose other publicly minded conditions.[24] The role of these agreements here illustrates the importance of contract as a tool to facilitate information exchange and innovation.[25] Decontextualized demands for "openness" have gained traction in recent decades[26] and might suggest that in every instance we need unfettered data exchange that treats all parties equally, including companies. We argue instead that the FDA should prioritize health researchers over industry actors and that it should use data use agreements to ensure those researchers protect legitimate public interests. These contracts are possible only with proactive disclosure and are inconsistent with reactive FOIA requests.

We join other scholars in suggesting that the future of freedom of information, if it is to achieve its aims, lies in the development of robust proactive disclosure systems. In part to mark these distinctions, we call what we seek here not data transparency, but data "publicity." The term as we use it, which draws upon early progressive traditions, marks the need for attention to context, power, and resources if data sharing is to serve the public.[27]

We also seek to contribute to the broader literature on the future of the regulatory state and the conditions of democracy broadly understood. Today, we live in an extraordinarily information-intensive age. Decades of dramatic advances in technologies for information processing have transformed the core of the modern economy and enabled the emergence of massively complex new industries and firms. This means that not only pharmaceuticals but also products like cars, insurance, airplanes, and phones are far more informationally intensive today than they were twenty years ago. Informationally intensive products and systems are complex, opaque, and dynamic.[28] Systems that are improperly or fraudulently designed—think here about Volkswagen's deceptive "defeat

24. *See* Fan, *supra* note 22, at 198 (proposing "[e]xpert-[o]riented [b]ounded [a]ccess" to government agency-held data under data protection plans to permit meaningful use of that data while insulating agencies from legal risk).

25. *See* Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017).

26. *See* Amy Kapczynski, *The Law of Informational Capitalism*, 129 YALE L.J. 1460 (2020) (reviewing SHOSHANA ZUBOFF, THE AGE OF SURVEILLANCE CAPITALISM (2019); JULIE E. COHEN, BETWEEN TRUTH AND POWER: THE LEGAL CONSTRUCTIONS OF INFORMATIONAL CAPITALISM (2019)).

27. *See* Pozen, *Transparency's Ideological Drift*, *supra* note 22, at 148 ("The progressives in the early 1900s spoke of 'publicity,' rhetorically tethering their efforts to the notion of a public and its needs and demands."); Matthew Herder, *Denaturalizing Transparency in Drug Regulation*, 8 MCGILL J.L. & HEALTH S57, S61 (2015) (explaining the progressive tradition of "publicity" in Canadian consumer protection law and policy in the late nineteenth and early twentieth centuries).

28. *See* JULIE E. COHEN, BETWEEN TRUTH AND POWER: THE LEGAL CONSTRUCTIONS OF INFORMATIONAL CAPITALISM 172 (2019) ("Industrial-era regimes of economic regulation presumed well-defined industries, ascertainable markets and choices, and relatively discrete harms amenable to clear description and targeted response. The shift to an informational political economy has disrupted those presumptions . . . .").

device" to evade emissions testing,[29] or Boeing's defective automated flight software for the 737 Max[30]—generate serious social and individual harms. Regulators face growing challenges in this environment, and we need structures to allow the public to hold both regulators and the industry accountable. Yet the same barriers that appear in this context—issues of privacy, corporate claims to trade secrecy and confidentiality, and difficulties with reactive data release models (FOIA especially)—will reappear throughout the administrative state. Our Article thus can help inform a wide variety of regulators who face related issues, whether in the area of consumer products, environmental protection, or artificial intelligence. Data publicity will have plausible benefits elsewhere, and regulators can learn from how it can be achieved at the FDA. But they must also learn from the fertile conditions in the pharmaceutical and medical context that allow clinical trial data publicity to inform the public. It is not open data alone, but data publicity in a context where resources and expertise exist to enable intelligible uses of such data, that furthers democratic accountability.[31]

We begin in Part I by describing the need for proactive disclosure of safety and efficacy data[32] and why existing legal avenues, such as FOIA, fail to create adequate data publicity. In Part II, we show that, contrary to the conventional wisdom and the (usual) view of the FDA itself, federal law does not prohibit the FDA from disclosing such data, even from the moment of drug or vaccine approval. Consistent proactive disclosure, however, will require revisions to the FDA's current regulations, corrections to its interpretations of certain statutes, and, for the most sensitive data, data use agreements. We also show that the move should not hurt and may improve innovation, nor should it require compensation under the Takings Clause. If the agency does not act, Congress can and should, as we describe in Part III.

29. Margot Sanger-Katz & John Schwartz, *How Many Deaths Did Volkswagen's Deception Cause in the U.S.?*, N.Y. TIMES (Sept. 28, 2015), https://www.nytimes.com/2015/09/29/upshot/how-many-deaths-did-volkswagens-deception-cause-in-us.html [https://perma.cc/NFF9-GCLM].

30. Niraj Chokshi, *U.S. Watchdog's Report Faults Boeing's Disclosures on 737 Max Software*, N.Y. TIMES (July 1, 2020), https://www.nytimes.com/2020/07/01/business/boeing-faa-737-max.html [https://perma.cc/UVZ9-WFRC].

31. For a discussion of the relationship between democracy and expertise, see, for example, ROBERT C. POST, DEMOCRACY, EXPERTISE, ACADEMIC FREEDOM & A FIRST AMENDMENT JURISPRUDENCE FOR THE MODERN STATE 27–35 (2012).

32. We use the term "efficacy" broadly to cover any and all evidence that drugs work as intended and provide some therapeutic benefit for some intended use. "Efficacy" thus covers both evidence of therapeutic benefit under controlled laboratory conditions and under less-than-ideal real-world conditions. Some medical literature uses "efficacy" more narrowly to refer only to evidence generated under controlled laboratory conditions, and the term "effectiveness" to refer to real-world evidence. *See, e.g.*, E. Ernst & M. H. Pittler, Letter to the Editor, *Efficacy or Effectiveness?*, 260 J. INTERNAL MED. 488 (2006).

I.
THE NEED FOR PROACTIVE PUBLICITY OF SAFETY AND EFFICACY DATA

A. Protecting Health with Data Publicity

In the United States today, a company may not sell a new drug or vaccine until it first submits studies to the FDA that show the product is safe and efficacious.[33] Though not widely recognized, the FDA's primary function in this context is to generate and validate information.[34] The FDA requires companies to produce not only positive but also negative information about their products, to share data with regulators who can validate the data,[35] and to create labeling and guidance that summarize this information for patients and practitioners.[36]

The clinical studies or clinical trials that drug companies submit to the FDA typically cost many millions of dollars to conduct, take years to complete, and occur in a variety of stages.[37] Laboratory, animal, and other pre-clinical tests are performed[38] even before clinical trials. If these yield promising results, researchers begin studies in humans, conventionally in three phases: phase 1 trials, typically small and used to evaluate toxicity and dosage; phase 2 trials, larger and used to gather more safety information and to begin to explore efficacy; and phase 3 trials, still larger and used to determine whether the drug has benefits that outweigh its harms for the proposed use, and to examine adverse events in a larger population.[39] Phase 4 trials are done after marketing to study

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33. 21 U.S.C. § 355 (making proof of safety and efficacy a condition of new small molecule drug approval); 42 U.S.C. § 262 (making proof of safety, purity, and potency a condition of new biologic drug approval); *see also* 21 U.S.C. § 360bbb-3 (defining an emergency drug, device, and biological product authorization process that also requires scientific evidence, such as data from controlled trials). The emergency use authorization (EUA) process was rarely used prior to the present COVID-19 emergency and is not the focus of our discussion here.

34. *See* Kapczynski, *Dangerous Times*, *supra* note 10, at 2357–58 (describing the common arguments that the FDA operates as a "certifier" of information, or paternalistically to protect the public from dangerous products, and describing why instead its framework statutes establish it as primarily addressing a problem of information production and validation); *see also* Eisenberg, *Innovation Policy*, *supra* note 19; Erika Lietzan, *Access Before Evidence and the Price of the FDA's New Drug Authorities*, 53 U. RICH. L. REV. 1243, 1285, 1295 (2019).

35. *See* Kapczynski, *Dangerous Times*, *supra* note 10, at 2363–64 (describing the information production problem and noting that competitors have insufficient incentive to generate negative information because of free rider problems).

36. 21 C.F.R. § 201 (2019).

37. *See* Thomas J. Moore, Hanzhe Zhang, Gerard Anderson & G. Caleb Alexander, *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016*, 178 JAMA INTERNAL MED. 1451 (2018).

38. *See* GRAHAM L. PATRICK, AN INTRODUCTION TO MEDICINAL CHEMISTRY 274, 277 (5th ed. 2013) ("[A] drug has to be tested to ensure that it is safe and effective, and can be administered in a suitable fashion. This involves preclinical and clinical trials covering toxicity, drug metabolism, stability, formulation, and pharmacological tests. . . . Once the preclinical studies . . . have been completed, the company decides whether to proceed to clinical trials.").

39. *Step 3: Clinical Research, Clinical Research Phase Studies*, FDA, https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#Clinical_Research_Phase_Studies [https://perma.cc/5V65-MRQG]. The FDA has become more flexible about the quantity and kind of safety and efficacy evidence upon which it will approve a

longer-term safety and effectiveness, new uses of the drug, and other outstanding questions not resolved at approval.[40]

To market a drug, companies must provide data from such trials to the FDA in a formal application: New Drug Application (NDA) for small molecule drugs or Biologics License Application (BLA) for biologic drugs, including vaccines.[41] The most important trials described in NDAs and BLAs, commonly called "pivotal" trials, are those for which drug companies submit *complete* data sets to the FDA. It is primarily based on this safety and efficacy evidence that the FDA decides whether to approve the application (and thereby permit the drug onto the market).[42]

As a result, the FDA "houses the largest known repository of clinical data" in the world.[43] This data is of enormous significance to public health but is not routinely shared or made available to researchers. Traditionally, data remains only with the FDA and the entity that conducts and/or sponsors the study, and outside reviewers have little opportunity to access it.[44]

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drug. *See* Audrey D. Zhang, Jeremy Puthamana, Nicholas S. Downing, Nilay D. Shah, Harlan M. Krumholz & Joseph S. Ross, *Assessment of Clinical Trials Supporting US Food and Drug Administration Approval of Novel Therapeutic Agents, 1995–2017*, JAMA NETWORK OPEN (2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764603 [https://perma.cc/ZV9B-SVAQ] ("[T]he quantity and quality of evidence supporting recent drug approvals is variable, both in terms of the number of pivotal trials and their design features, such as randomization, blinding, choice of comparators and end points, number of treated patients, and trial duration."). The agency has, in addition, indicated an openness to reliance on "phase 2/3" trials (which blend aspects of phases 2 and 3 in a single trial) and "adaptive" trials (in which the trial design changes during the trial, in prospectively planned ways, based on data accumulated along the way). *See, e.g.*, U.S. DEP'T HEALTH & HUM. SERVS., FDA, ADAPTIVE DESIGNS FOR CLINICAL TRIALS OF DRUGS AND BIOLOGICS: GUIDANCE FOR INDUSTRY (2019), https://www.fda.gov/media/78495/download [https://perma.cc/S73K-RGN2].

40. Phase 4 trials are also called post-market or post-marketing trials. *See Biologics Post-Market Activities*, FDA (Sept. 18, 2018), https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-post-market-activities [https://perma.cc/DP5C-WVET] (referencing "post-marketing study commitments (also known as Phase IV studies)").

41. *See* 21 U.S.C. § 355(b) (NDAs); 42 U.S.C. § 262(a) (BLAs).

42. *See* 21 C.F.R. §§ 314.50(d)(5) (2019) (requiring submission of safety and efficacy data in NDAs); 601.2(a) (requiring "safety, purity, and potency" for BLAs); *see also* Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions, 83 Fed. Reg. 7043 (Feb. 16, 2018) (requiring "electronic submissions of data and information from all major (i.e., pivotal) studies"). Data from non-pivotal trials is not always submitted to the FDA, and data from some Phase 4 trials are likewise never submitted to the FDA. *See, e.g.*, Steven Woloshin, Lisa M. Schwartz, Brian White & Thomas J. Moore, *The Fate of FDA Postapproval Studies*, 377 NEW ENG. J. MED. 1114, 1116 (2017). While the clinical trial data publicity regime we propose in this Article is, in our view, the single best way to expand public access to clinical trial data on FDA-approved drugs, more work can and should be done to expand the universe of data that the FDA itself holds.

43. FDA, DRIVING BIOMEDICAL INNOVATION: INITIATIVES TO IMPROVE PRODUCTS FOR PATIENTS 22 (2011), https://www.celebrationofscience.org/assets/Uploads/DrivingBiomedicalInnovation-ImprovingProductsforPatients.pdf [https://perma.cc/U2XC-XHGA].

44. *See* Joseph S. Ross, Richard Lehman & Cary P. Gross, *The Importance of Clinical Trial Data Sharing: Toward More Open Science*, 5 CIRCULATION: CARDIOVASCULAR QUALITY & OUTCOMES 238 (2012).

"Safety" and "efficacy" of medicines cannot be determined independently of one another; they must be understood together. No drug is without side effects, and medicines can also cause harm indirectly by displacing other remedies. A drug is considered acceptably "safe" only if its known therapeutic benefits outweigh its known harms.[45] This weighing of benefits and harms is invariably specific to a particular use in a particular patient population—what doctors and the FDA refer to as an "indication."[46] For example, a drug might be proved safe and effective, and thus be FDA-approved, for the specific indication of slowing tumor growth in people with a particular kind of lung cancer, or for patients with severe, but not mild, rheumatoid arthritis. The link between safety and efficacy means that a drug that is shown to be entirely ineffective—that is, that has no therapeutic benefits—is per se "unsafe." Because safety can only be understood in relation to efficacy and vice versa, we refer to "safety and efficacy data" collectively throughout this Article.

Recent research has documented the problems associated with secrecy in safety and efficacy data. We now know, for example, that many clinical trials are not published in a timely fashion.[47] Publication bias is also a deep problem for trials conducted by the industry, government, and academia alike: negative studies are significantly less likely to be published than positive ones, and when trials *are* published, key information may be omitted or the study's results may be mischaracterized.[48] One recent article compared the FDA's summary reviews of trials with the published literature for antidepressant drugs and showed that very few of the trials the FDA considered negative were published while almost

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45. *FDA's Drug Review Process: Continued*, FDA, https://www.fda.gov/drugs/drug-information-consumers/fdas-drug-review-process-continued [https://perma.cc/94LB-SRR3] ("Once a new drug application is filed, an FDA review team--medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts--evaluates whether the studies the sponsor submitted show that the drug is safe and effective for its proposed use. No drug is absolutely safe; all drugs have side effects. 'Safe' in this sense means that the benefits of the drug appear to outweigh the known risks.").

46. *See* Omudhome Ogbru, *Indications for Drugs (Uses), Approved vs. Non-Approved*, MEDICINENET, https://www.medicinenet.com/indications_for_drugs__approved_vs_non-approved/views.htm [https://perma.cc/QNJ3-AJ76] (explaining indications); Spectrum Pharm., Inc. v. Burwell, 824 F.3d 1062, 1069 (D.C. Cir. 2016) ("FDA's approval of a drug application shows that the agency concluded that the drug in its anticipated form is safe and effective *for the indication sought*." (emphasis added)).

47. Joseph S. Ross, Tony Tse, Deborah A. Zarin, Hui Xu, Lei Zhou & Harlan M. Krumholz, *Publication of NIH Funded Trials Registered in ClinicalTrials.gov: Cross Sectional Analysis*, BRIT. MED. J., Jan. 2012, at 14 (finding that despite recent improvement in timely publication, "[f]ewer than half of NIH funded trials are published in a peer reviewed biomedical journal indexed by Medline within 30 months of trial completion").

48. An-Wen Chan, Asbjørn Hróbjartsson, Mette T. Haahr, Peter C. Gøtzsche & Douglass G. Altman, *Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials: Comparison of Protocols to Published Articles*, 291 JAMA 2457 (2004); *see also* Charles Piller, *FDA and NIH Let Clinical Trial Sponsors Keep Results Secret and Break the Law*, SCIENCE (Jan. 13, 2020), https://www.sciencemag.org/news/2020/01/fda-and-nih-let-clinical-trial-sponsors-keep-results-secret-and-break-law [https://perma.cc/KBV2-R9NQ] (showing that many U.S. universities and federal laboratories have failed to publish the results of clinical trials they sponsored).

all of the positive trials were published.[49] Of the few negative studies published, most were misleadingly described in print as having positive results.[50] This publication bias means that doctors may have an inaccurately rosy view of a medicine's benefits. Importantly, the "meta-studies" that are used to collate evidence and guide clinical practice are also undermined by secrecy because the FDA review teams typically only have access to the published literature. In rare cases of effective data publicity, when teams have been able to access more complete data sets, the results and recommendations of their reviews have sometimes been reversed.[51]

For patients, the implications of hidden data are sometimes grave. For example, in its few years on the market, rofecoxib (Vioxx) was estimated to have caused 88,000 to 140,000 serious cardiac events, leading to tens of thousands of deaths.[52] Paroxetine (Paxil) offers another example. The antidepressant was never approved for use in pediatric populations but became a popular pediatric treatment—with over two million prescriptions for children per year—on the basis of a medical journal article that claimed that the medicine was "generally well tolerated and effective" in young patients.[53] In fact, paroxetine caused suicidal thinking and suicide in a substantial portion of young people.[54] When independent researchers gained access to the study underlying the published

49. Erick H. Turner, Annette M. Matthews, Eftihia Linardatos, Robert A. Tell & Robert Rosenthal, *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 256 (2008) (showing that 97% of trials with positive results were published in the medical literature, compared to only 33% of trials with negative results).

50. *Id.* (showing, out of twenty-four total negative studies in the data set, sixteen unpublished negative studies (67%), five published negative studies that conflicted with the FDA's analysis (21%), and only three published negative studies that agreed with the FDA's analysis (12%)).

51. Tom Jefferson et al., *Neuraminidase Inhibitors for Preventing and Treating Influenza in Adults and Children*, COCHRANE DATABASE SYSTEMATIC REVS., Apr. 2014, at 3, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008965.pub4/full ("We have used data from 46 trials . . . in this review. We identified problems in the design of many of the studies that we included, which affects our confidence in their results."); Tom Jefferson, Mark Jones, Peter Doshi & Chris Del Mar, *Neuraminidase Inhibitors for Preventing and Treating Influenza in Healthy Adults: Systematic Review and Meta-Analysis*, 339 BRIT. MED. J. b5106 (2009), https://www.bmj.com/content/339/bmj.b5106 [https://perma.cc/Q4VG-HDWN] ("Evidence on the effects of oseltamivir in complications from lower respiratory tract infections, reported in our 2006 Cochrane review, may be unreliable."). The researchers were only able to access the data after years of requests and a public campaign for the release of the data conducted by the British Medical Journal.

52. *See* Graham et al., *supra* note 15; *see also* Abraham, *supra* note 15 ("[A]nywhere from 39,000 to 61,000 deaths in the United States could be linked to Vioxx."); Harlan Krumholz et al., *What Have We Learnt from Vioxx?*, 334 BRIT. MED. J. 120, 120 (2007).

53. Peter Doshi, *No Correction, No Retraction, No Apology, No Comment: Paroxetine Trial Reanalysis Raises Questions About Institutional Responsibility*, BRIT. MED. J. (Sept. 16, 2015), at 1, https://www.bmj.com/content/351/bmj.h4629 [https://perma.cc/RG6F-BL6L].

54. FDA, FDA TALK PAPER T03-43: FDA STATEMENT REGARDING THE ANTI-DEPRESSANT PAXIL FOR PEDIATRIC POPULATION (2003), https://ahrp.org/fda-statement-regarding-anti-depressant-paxil-for-children/ [https://perma.cc/B552-JK7J].

article, they found that it showed the risks quite clearly.[55] GlaxoSmithKline ultimately pled guilty to fraud.[56]

Medical ethicists support data publicity because it reduces risk to patients and promotes efficient use of resources. Because patients undergo risks in clinical trials, the scientific community has an obligation to make the best possible use of the results and prevent unknowing duplication of studies.[57]

Clinical trial data publicity can also help affirm the credibility of properly conducted studies and help us better direct our health care spending.[58] Drug prices and overall spending on "innovative" new drugs have ballooned in recent years, sometimes without evidence that these expensive treatments provide meaningful therapeutic benefits over older, cheaper alternatives.[59] For example, data access helped researchers show that governments have likely wasted billions of dollars stockpiling ineffective influenza treatments.[60] Independent analyses have also repeatedly identified approved medicines that are significantly overpriced given their true therapeutic benefits.[61] In some cases,

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55. *See* Joanna Le Noury, John M Nardo, David Healy, Jon Jureidini, Melissa Raven, Catalin Tufanaru & Elia Abi-Jaoude, *Restoring Study 329: Efficacy and Harms of Paroxetine and Imipramine in Treatment of Major Depression in Adolescence*, BRIT. MED. J. (Aug. 3, 2015), https://www.bmj.com/content/351/bmj.h4320 [https://perma.cc/7APM-BGYX].

56. Katie Thomas & Michael S. Schmidt, *Glaxo Agrees to Pay $3 Billion in Fraud Settlement*, N.Y. TIMES (July 2, 2012), https://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html [https://perma.cc/3VJ6-E9MW].

57. *See* Jeffrey M. Drazen, *Sharing Individual Patient Data from Clinical Trials*, 372 NEW ENG. J. MED. 201 (2015); *see also* Doshi & Jefferson, *supra* note 19.

58. *See* Joseph S. Ross & Harlan M. Krumholz, *Ushering in a New Era of Open Science Through Data Sharing: The Wall Must Come Down*, 309 JAMA 1355 (2013).

59. Alison Kodjak, *Prescription Drug Costs Driven by Manufacturer Price Hikes, Not Innovation*, NPR (Jan. 7, 2019), https://www.npr.org/sections/health-shots/2019/01/07/682986630/prescription-drug-costs-driven-by-manufacturer-price-hikes-not-innovation [https://perma.cc/2BPW-B4PE] ("The skyrocketing cost of many prescription drugs in the U.S. can be blamed primarily on price increases, not expensive new therapies or improvements in existing medications as drug companies frequently claim, a new study shows." (citing Inmaculada Hernandez, Chester B. Good, David M. Cutler, Walid F. Gellad, Natasha Parekh & William H. Shrank, *The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Costs of Drugs*, 38 HEALTH AFFS. 76 (2019))).

60. In the 2000s and early 2010s, governments around the world spent billions stockpiling oseltamivir (Tamiflu) and zanamivir (Relenza) to fight seasonal and pandemic flu viruses. After years of digging, a group of researchers associated with the Cochrane Collaboration obtained unpublished clinical trial data and, in 2014, revealed that these expensive drugs failed to prevent the spread of the flu, reduce hospital admissions, or minimize complications. Richard Van Noorden, *Report Disputes Benefit of Stockpiling Tamiflu*, NATURE (Apr. 10, 2014), https://www.nature.com/news/report-disputes-benefit-of-stockpiling-tamiflu-1.15022 [https://perma.cc/6NHW-E664].

61. Eteplirsen (Exondys 51), a drug approved by the FDA in 2016 for treatment of a rare form of muscular dystrophy, costs close to $1 million per year per patient. Katie Thomas & Reed Abelson, *The $6 Million Drug Claim*, N.Y. TIMES (Aug. 25, 2019), https://www.nytimes.com/2019/08/25/health/drug-prices-rare-diseases.html [https://perma.cc/372Z-QKMV]. Yet an exhaustive independent analysis of eteplirsen's cost-effectiveness by the independent Institute for Clinical and Economic Review (ICER) concluded that there was no concrete evidence of clinical benefit or cost-effectiveness at any price, let alone $1 million. *See* Kyle Blankenship, *Want Bang for Your Buck? Don't Look to Sarepta's Pricey DMD Therapy Exondys, ICER Says*, FIERCE PHARMA (May 23, 2019), https://www.fiercepharma.com/pharma/want-bang-for-your-buck-don-t-look-to-

companies have deliberately obscured evidence that only a narrow population will benefit from a drug to generate greater sales.[62] Data sharing can help improve treatment guidelines and prevent wasteful spending by governments and insurers.[63] This can help incentivize better innovation too.[64]

Finally, data publicity can help identify and correct problems in regulatory and industry practices. For example, a group of researchers at Johns Hopkins, in part with our assistance, recently obtained detailed, internal FDA data on the oversight of fast-acting fentanyl products.[65] Based on this data, the Hopkins researchers revealed flaws in the agency's Risk Evaluation and Mitigation Strategy (REMS) program.[66] These flaws allowed the drugs to be widely prescribed to patients for whom the risk of addiction and overdose was unacceptably high, exacerbating the opioid epidemic.[67] The revelations sparked

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sarepta-s-pricey-dmd-therapy-exondys-icer-says [https://perma.cc/4F62-4RHZ] (citing INST. FOR CLINICAL & ECON. REV., DEFLAZACORT, ETEPLIRSEN, AND GOLODIRSEN FOR DUCHENNE MUSCULAR DYSTROPHY: EFFECTIVENESS AND VALUE (2019), https://icer.org/wp-content/uploads/2020/10/ICER_DMD_Evidence_Presentation_072519-x1Aug2017-1-2.pdf [https://perma.cc/B5DY-AXUV]). *See also* Tracy Rupp & Diana Zuckerman, *Quality of Life, Overall Survival, and Costs of Cancer Drugs Approved Based on Surrogate Endpoints*, 177 JAMA INTERNAL MED. 276 (2017) (describing similar concerns regarding cancer); Peter B. Bach, *Insights into the Increasing Costs of Cancer Drugs*, 17 CLINICAL ADVANCES HEMATOLOGY & ONCOLOGY 287 (2019) (same).

62. *See, e.g.*, Melody Petersen, *This $7,800-a-Month Cancer Drug Caused Rashes and Rarely Worked. Now Trump Could Make FDA Approvals Even Easier*, L.A. TIMES (Feb. 4, 2017), https://www.latimes.com/business/la-fi-fda-tarceva-approval-20170204-htmlstory.html [https://perma.cc/RW8N-6ZV6].

63. For example, by pooling individual participant data from a wide range of settings, malaria researchers were recently able to revise treatment guidelines for children. They estimated that a small dosage increase in one drug would significantly cut the risk of treatment failure and still cure 95% of cases, saving both resources and lives in the process. WorldWide Antimalarial Resistance Network (WWARN) DP Study Group, *The Effect of Dosing Regimens on the Antimalarial Efficacy of Dihydroartemisinin-Piperaquine: A Pooled Analysis of Individual Patient Data*, PLOS MED. (Dec. 3, 2013), at 10–11, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3848996/ [https://perma.cc/F22F-JA2T].

64. Richard G. Frank, Jerry Avorn & Aaron S. Kesselheim, *What Do High Drug Prices Buy Us?*, HEALTH AFFS. BLOG (Apr. 29, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200424.131397/full/ [https://perma.cc/KY9W-T753] ("[I]f the [U.S.] government negotiated for prices based on a drug's real advantage over existing products, it could provide a better incentive for more useful innovation as well as improve the affordability of prescription drugs.").

65. Jeffrey E. Rollman, James Heyward, Lily Olson, Peter Lurie, Joshua Sharfstein & G. Caleb Alexander, *Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products*, 321 JAMA 676, 677 (2019). The researchers obtained this data via a multi-year FOIA-based investigation with the assistance of the author AK and others at Yale's Collaboration for Research Integrity and Transparency. *See MFIA/CRIT Team Supports Johns Hopkins Investigation of FDA Oversight of Fentanyl Products*, YALE L. SCH. (Feb. 22, 2019), https://law.yale.edu/yls-today/news/mfiacrit-team-supports-johns-hopkins-investigation-fda-oversight-fentanyl-products [https://perma.cc/P72K-E4DA].

66. Rollman et al., *supra* note 65.

67. *Id.*

high-profile media coverage,[68] attention from Congress,[69] a hearing at the FDA,[70] and, ultimately, agency changes to the REMS program, which tightened prescription rules to reduce inappropriate use.[71]

Data publicity can also shed light on bad industry practices—practices that are constantly evolving. For example, data released in conjunction with lawsuits helped show the emergence of the "ghostwriting" phenomenon, where companies pay prominent researchers to put their names on studies in which they played no part,[72] and "seeding trials," where companies engage in otherwise prohibited marketing under the guise of running clinical trials.[73]

As these examples show, a robust ecology of researchers and organizations has been able to generate important new health insights in high-stakes instances and connect those insights to changes in practice. This is the result of a broader political economy that includes not just industry-funded researchers but also strong public and publicly funded academic health research. Over decades, with hundreds of billions of dollars of support from public funders like the National Institutes of Health (NIH), academic science has evolved a network of institutions and practices—including academic journals, independent, non-profit health technology assessment organizations, norms about conflict of interest, and norms of priority and disclosure that underpin the "open science" model.[74] A healthy ecosystem of independent researchers is critical because validating

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68. *See, e.g.*, Emily Baumgaertner, *F.D.A. Did Not Intervene to Curb Risky Fentanyl Prescriptions*, N.Y. TIMES (Aug. 2, 2018), https://www.nytimes.com/2018/08/02/health/fda-fentanyl-opioid-epidemic-overdose-cancer.html [https://perma.cc/B8EC-JHWE].

69. *See, e.g.*, Letter from Hon. Edward J. Markey, U.S. Sen., to Hon. Scott Gottlieb, FDA Comm'r (Aug. 17, 2018), https://www.markey.senate.gov/imo/media/doc/FDA%20REMS%20and%20fentanyl%2008.17.18.pdf [https://perma.cc/K37X-WH3P].

70. *See, e.g.*, G. Caleb Alexander & Joshua M. Sharfstein, Testimony for the Record Submitted to the U.S. Food and Drug Administration for the Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee, Dkt. No. FDA-2018-N-1917 (Aug. 3, 2018), https://int.nyt.com/data/documenthelper/123-fda-opioid-overdose-cancer/4be5694a2729eb5b522d/optimized/full.pdf [https://perma.cc/GS8X-TERK].

71. *See* Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Strengthen Agency's Safety Requirements Aimed at Mitigating Risks Associated with Transmucosal Immediate-Release Fentanyl Products (Mar. 27, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-strengthen-agencys-safety-requirements-aimed [https://perma.cc/HC49-UBPS].

72. *See* PLoS Medicine Editors, *Ghostwriting: The Dirty Little Secret of Medical Publishing That Just Got Bigger*, 6 PLOS MED. e1000156 (2009).

73. Kevin P. Hill, Joseph S. Ross, David S. Egilman & Harlan M. Krumholz, *The ADVANTAGE Seeding Trial: A Review of Internal Documents*, 149 ANNALS INTERNAL MED. 251, 251 (2008). For more bad practices in the pharmaceutical industry, see Alexander C. Egilman, Aaron S. Kesselheim, Harlan M. Krumholz, Joseph S. Ross, Jeanie Kim & Amy Kapczynski, *Confidentiality Orders and Public Interest in Drug and Medical Device Litigation*, 180 JAMA INTERNAL MED. 292 (2020).

74. *See* Kapczynski, *Order Without Intellectual Property Law*, *supra* note 25, at 1591–95; *see also* Fan, *supra* note 22, at 199 (describing public health researchers and suggesting that "trained professionals such as researchers who are ethically obligated to comply with data-use and protection safeguards and attorneys who are ethically bound to abide by limitations on disclosure" are "better suited to maximize the value of disclosure by using their expertise to detect potential threats to public safety").

clinical trial data is an enormously time- and resource-intensive exercise that requires dedication to scientific craft. Private markets provide inadequate incentives for this critical validation work; innovators do not benefit from publicizing negative studies, and their competitors face free-rider dynamics and misaligned incentives.[75] Public funding for such reanalysis may need to grow as we make more data available.

This ecosystem of independent researchers strengthens the FDA's role as the arbiter of the safety and efficacy of medicines, devices, and vaccines.[76] Validation of the FDA's work helps protect the agency from undue pressure from the pharmaceutical industry, patient groups, politicians, and other stakeholders, and usually confirms the soundness of the agency's decisions.[77] When independent reviewers do occasionally detect mistakes in the FDA's decision-making—as they did in 2005, helping to avert FDA approval of a diabetes drug, muraglitazar, because of excess cardiovascular risk that the agency and its advisory committee missed[78]—they generally help conserve the FDA's resources by helping it detect and address problems quickly, and protect its credibility by averting more serious regulatory failures.

Safety and efficacy data on prescription drugs would ideally be shared at the moment of FDA approval or very shortly thereafter. The deadly and costly regulatory failures we describe above, like those related to rofecoxib (Vioxx) and fentanyl, highlight a major drawback of our current system. If relevant data reaches independent researchers, it usually does so *years* after approval, by which time much damage has already been done. Safety and efficacy data is most valuable in the months immediately following approval of a new drug, as it is

75. *See* Kapczynski, *Dangerous Times*, *supra* note 10.

76. For an analysis of the FDA's role, not just in keeping unsafe and ineffective drugs off the market, but in generating, validating, and disseminating evidence of safety and efficacy, see Kapczynski, *Dangerous Times*, *supra* note 10, at 2373–74. *See generally* DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA (2010) (discussing the FDA's substantial powers and its role as gatekeeper in the American pharmaceutical marketplace).

77. Notice: FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration; Availability, 75 Fed. Reg. 28,622-02, 28,622 (May 21, 2010) ("Transparency in FDA's activities and decisionmaking allows the public to better understand the agency's decisions, increasing credibility and promoting accountability."); *see* Sachs & Hwang, *supra* note 19, at 189 ("FDA disclosure [of certain safety and efficacy data] could serve as a check on corporate misconduct"); Sharfstein et al., *supra* note 19, at 7–8 (suggesting that "greater transparency in the regulatory process" will lead to "[g]reater public understanding and confidence in the activities of the FDA"); Margaret A. Hamburg & Joshua M. Sharfstein, *The FDA as a Public Health Agency*, 360 NEW ENG. J. MED. 2493, 2495 (2009) (FDA Commissioner and Deputy Commissioner stating that "[t]ransparency is a potent element of a successful strategy to enhance the work of the FDA and its credibility with the public").

78. Submission of Dr. Agnes Vitry, Senior Research Fellow, to the Therapeutic Goods Admin. of Australia, *Improving Transparency of the Therapeutic Goods Administration*, https://www.tga.gov.au/sites/default/files/review-tga-transparency-1101-submission-agnes-vitry.pdf [https://perma.cc/Q82H-NLHZ]; Steven E. Nissen, *The Rise and Fall of Rosiglitazone*, 31 EUR. HEART J. 773 (2010).

during this time that various stakeholders make important decisions.[79] This is when insurers decide whether to place the new drug on their formularies,[80] medical associations update treatment guidelines,[81] and individual prescribers and patients typically begin seeing advertisements[82] and must decide whether the new drug is right for them. Effective data publicity could create a virtuous feedback loop: if useful safety and efficacy data were made available at the time of approval, the ecosystem of researchers reviewing and interpreting this data would grow larger and stronger, and their insights and recommendations would reinforce the value of data publicity.

While data on unapproved drugs is important for research (for example, because it can speed up research on the same or similar compounds), we focus on the data needed to assess the quality of drugs that are currently on the market because this data is particularly urgent for patients and providers.[83] Several different categories of data from trials of FDA-approved drugs should be shared to benefit patients, clinicians, researchers, and insurers. Clinical trial data can be thought of as falling into three broad categories: (1) metadata, which is data *about* the data that includes protocols, statistical analysis plans, and analytic code; (2) summary data, which is any summary that highlights and explains key results made by companies, regulators, and researchers; and (3) individual participant data, which includes raw data collected from trial participants,

79. *See* Aaron Kesselheim, *Improving Competition to Lower U.S. Prescription Drug Costs*, *in* VISION 2020: EVIDENCE FOR A STRONGER ECONOMY 21, 25 (Wash. Ctr. for Equitable Growth ed., 2020), https://equitablegrowth.org/improving-competition-to-lower-u-s-prescription-drug-costs/ [https://perma.cc/J9LR-GCXF] ("The United States needs a [governmental value-based assessment] body operating at the national government level that can make such a determination within the first year after approval . . . .").

80. Cole Werble, *Prescription Drug Pricing #11: Formularies*, HEALTH AFFS. (Sept. 14, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000177/full/ [https://perma.cc/667H-ZN42].

81. Paul G. Shekelle, *Updating Practice Guidelines*, 311 JAMA 2072, 2072 (2014) (noting that medical organizations have developed systems for updating clinical practice guidelines based on the occurrence of "triggers," including the release of a new drug); *see also* Kim Peterson, Marian S. McDonagh & Rongwei Fu, *Decisions to Update Comparative Drug Effectiveness Reviews Vary Based on Type of New Evidence*, 64 J. CLINICAL EPIDEMIOLOGY 977, 978 (2011) (finding the emergence of a new drug to be a "significant predictor[] of decisions to update" comparative drug effectiveness reviews).

82. Julie M. Donohue, Marisa Cevasco & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 678 (2007) ("Advertising campaigns generally begin within a year after the introduction of a pharmaceutical product . . . .").

83. For a more comprehensive list of types of data that the FDA could and should make available, including data on unapproved drugs, see Sharfstein et al., *supra* note 19. We do not mean to suggest that important clinical data on unapproved products—in Investigational New Drug (IND) applications, in unapproved New Drug Applications (NDAs) and Biologic License Applications (BLAs), in complete response letters from the FDA, and so on—should not be disclosed proactively. However, the legal case for their proactive disclosure traverses different questions, putting these forms of data beyond the scope of this Article. Among the differences, some of the FDA's existing statutory authority to disclose clinical data is limited to approved products, and claims of confidentiality may be stronger as to data on unapproved products. We note, however, that our proposal to impose data use agreements on data users could address the need for legitimate protection of confidences for other forms of clinical trial data, as well as data from other industries.

including in executable data sets and adverse event reports.[84] Each form of data is important.[85]

First, metadata is needed to understand how to interpret the data produced by a clinical trial. The most important metadata is the study protocols, which set forth how investigators plan to proceed, include a statistical analysis plan, and identify the endpoints the study will evaluate. Having access to protocols allows researchers to put trial results into context. It also helps researchers spot selective reporting or alteration of clinical trial outcomes, which can generate spurious results.[86] For example, after a study is conducted, finding some pattern in the data is almost inevitable if one "dredges" for a pattern. This stems from the nature of the test for statistical significance, which is conventionally established when there is a less than 5 percent likelihood that an outcome was the result of chance.[87] This means that one in every twenty comparisons that one makes with a data set will produce falsely significant results. If one repeatedly tests data for associations with, say, zodiac sign or hair color, one will eventually be able to produce a positive result, but that result cannot be treated as reliable.[88] It is rare for investigators to fully report all of their outcomes and justify any and all deviations from their protocols in publications.[89] This was a key part of the paroxetine (Paxil) story. On reanalysis, independent researchers discovered that all of the planned study endpoints were negative, but the authors who published the initial misleading study simply switched to different outcomes that generated flattering results.[90] The FDA typically requires drug companies to prespecify the study protocols, including the statistical analysis plans used in the trials relied on

84. *See* INST. OF MED. OF THE NAT'L ACADS., *supra* note 18.

85. The set of metadata, summary data, and individual participant data that we recommend here is non-exhaustive. The FDA could undertake proactive disclosure of additional valuable data from trials of FDA-approved products, such as FDA inspection reports on irregularities and misconduct in clinical trials. *See* Rafael Dal-Ré, Aaron S. Kesselheim & Florence T. Bourgeois, *Increasing Access to FDA Inspection Reports on Irregularities and Misconduct in Clinical Trials*, 323 JAMA 1903 (2020).

86. *See* John PA Ioannidis, Arthur L Caplan & Rafael Dal-Ré, *Outcome Reporting Bias in Clinical Trials: Why Monitoring Matters*, BRIT. MED. J. (Feb. 14, 2017). https://www.bmj.com/content/356/bmj.j408 [https://perma.cc/J2Q9-4LSG].

87. *See* James L. Mills, *Data Torturing*, 329 NEW ENG. J. MED. 1196, 1197 (1993). The phenomenon of study investigators "dredging" data to identify correlations that appear statistically significant is also referred to as "p-hacking." *See* Christie Aschwanden, *We're All 'P-Hacking' Now*, WIRED (Nov. 26, 2019), https://www.wired.com/story/were-all-p-hacking-now/ [https://perma.cc/3LL9-59EF].

88. *See* Mills, *supra* note 87; Aschwanden, *supra* note 87. "Improper data dredging" has led to at least one FDA approval. *See* Jonathan Kahn, *Race in a Bottle*, SCI. AM., Aug. 2007, at 40, https://msu.edu/~pennock5/courses/484%20materials/Kahn_Race_in_Bottle.pdf [https://perma.cc/GW97-K8LJ].

89. Ioannidis et al., *supra* note 86.

90. YALE COLLABORATION FOR RSCH. INTEGRITY & TRANSPARENCY, PROMOTING TRANSPARENCY IN CLINICAL RESEARCH: WHY AND HOW 9 (2017), https://law.yale.edu/sites/default/files/area/center/crit/crit_white_paper_november_2017_best_promoting_transparency_in_clinical_research_why_and_how.pdf [https://perma.cc/65WB-MCVJ].

for approval,[91] but it has been criticized for approving a drug despite alleged data dredging.[92] As such, metadata is essential to interpret clinical trial results.

Second, summary data is also critical to validate research. Two kinds of summary data that are not generally made public but are especially critical for research validation are clinical study reports and internal assessments done by the FDA, including scientific reviews generated by individual reviewers or teams. A clinical study report (CSR) is a report summarizing a clinical trial prepared by a manufacturer and submitted to the FDA, often running into the thousands of pages.[93] Clinical study reports are currently not routinely disclosed by the FDA,[94] though some have been made available through FOIA litigation, including litigation over Gilead's Hepatitis C drug, sofosbuvir.[95] The European Medicines Association (EMA) has adopted a process for disclosing CSRs with minimal redactions, although its implementation has been suspended.[96] When such CSRs have been made available, they have spurred important new insights

91. *See, e.g.*, 21 C.F.R. § 314.50(d)(6) (2019) (requiring that NDAs contain a statistical section).

92. Sharon Begley, *Exclusive: Questionable Data Propped up Cancer Drug Provenge*, REUTERS (Oct. 11, 2012), https://www.reuters.com/article/us-drugs-dendreon-provenge/exclusive-questionable-data-propped-up-cancer-drug-provenge-idUSBRE89A15420121011 [https://web.archive.org/web/20200907230908/https://www.reuters.com/article/us-drugs-dendreon-provenge/exclusive-questionable-data-propped-up-cancer-drug-provenge-idUSBRE89A15420121011].

93. Sharfstein et al., *supra* note 19, at 17.

94. The FDA announced in January of 2018 that it would begin a pilot program to release portions of CSRs for FDA-approved drugs, including "the study report body, the protocol and amendments, and the statistical analysis plan for each of the participating product's pivotal studies." Press Release, FDA, FDA Comm'r Scott Gottlieb, M.D., on New Steps FDA Is Taking to Enhance Transparency of Clinical Trial Information to Support Innovation and Scientific Inquiry Related to New Drugs (Jan. 16, 2018), https://www.fda.gov/news-events/press-announcements/fda-commissioner-scott-gottlieb-md-new-steps-fda-taking-enhance-transparency-clinical-trial [https://perma.cc/88ZH-ZE4C]. The program depended on industry consent, and the FDA promised it would "continue to protect patient privacy, trade secret, and confidential commercial information in the CSRs [it] release[d] as part of the pilot." *Id.* The FDA's pilot program was officially discontinued in March 2020 after only one industry sponsor, Janssen, agreed to participate. *See* Zachary Brennan, *FDA Plots Shift Away from CSR Pilot to Forge New Transparency on Drug Approval Process*, REGUL. AFFS. PROF'LS. SOC'Y (June 26, 2019), https://www.raps.org/news-and-articles/news-articles/2019/6/fda-plots-shift-away-from-csr-pilot-to-forge-new-t [https://perma.cc/UB27-Q2NB]; Press Release, FDA, FDA Continues to Support Transparency and Collaboration in Drug Approval Process as the Clinical Data Summary Pilot Concludes (Mar. 26, 2020), https://www.fda.gov/news-events/press-announcements/fda-continues-support-transparency-and-collaboration-drug-approval-process-clinical-data-summary [https://perma.cc/8CVP-RTCB].

95. *GHJP Closes Two-Year FOIA Case Against Drug Manufacturer*, YALE SCH. MED. (Sept. 19, 2017), https://medicine.yale.edu/news-article/15794/ [https://perma.cc/V26J-J5Y5]. One of the authors participated in this litigation.

96. *Clinical Data Publication*, EUR. MEDS. AGENCY, https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication [https://perma.cc/SW4N-THN4]; *European Medicines Agency Backtracks on Transparency Pledges, Restricts Access to Key Documents*, TRANSPARIMED (Aug. 19, 2018), https://www.transparimed.org/single-post/2018/08/19/European-Medicines-Agency-backtracks-on-transparency-pledges-restricts-access-to-key-drug-safety-documents [https://perma.cc/2WMY-X97T] (explaining that the EMA permanently restricted access to older CSRs). For more on the EMA's clinical data sharing policy, see *infra* Part II.B.

into risks, leading to new black-box warnings (the most serious kind) and, in some jurisdictions, to the withdrawal of medicines.[97]

The other critical kind of summary data is internal assessments conducted by the FDA. Expert FDA reviewers undertake careful analysis of medicines before they are approved,[98] and the published assessments of senior FDA officials and individual scientific review teams within the FDA—clinical/medical, toxicological, statistical, chemical, etc.—provide important indications of agency concerns.[99] These assessments are published as part of the "approval package" that the FDA publishes on the "Drugs@FDA" site every time it approves a new drug or new indication of an existing drug. The assessments contain a variety of important information not often found in the medical literature, such as details from clinical trial protocols and statistical analysis plans, more complete sets of efficacy endpoints and adverse events, comparisons of FDA and sponsor analyses of the same data, important details about postmarketing study requirements, and each individual FDA reviewer's (or review team's) view on whether the drug application should be approved.[100] Summary evidence of this kind helps researchers understand where they might want to dig deeper.[101] Unfortunately, in June 2019, the FDA announced that it plans to discontinue publication of the assessments of individual reviewers and review teams and shift to publication of a single consolidated "integrated review."[102] This is problematic because it allows others less insight into differing

97. YALE COLLABORATION FOR RSCH. INTEGRITY & TRANSPARENCY, *supra* note 90, at 12–13 (describing how the diabetes drug rosiglitazone (Avandia) received a black-box warning in the U.S. and is no longer sold in the European Union).

98. *See FDA's Drug Review Process: Continued*, *supra* note 45. For a minority of drugs, the FDA convenes a panel of outside experts—an "advisory committee"—to advise on whether to approve the drug. The FDA releases advisory committee materials which reveal the basis of evidence that those experts use to make a recommendation on approval. *See* Peter Lurie & Allison Zieve, *Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at the FDA*, 69 L. & CONTEMP. PROBS. 85, 91 (2006) (describing advisory committee materials and the FOIA/FACA case that required release). Advisory committee materials typically include some metadata and summary data, which has proven valuable to independent researchers. *See, e.g.*, Clifford J. Rosen, *The Rosiglitazone Story—Lessons from an FDA Advisory Committee Meeting*, 357 NEW ENG. J. MED. 844 (2007); Aaron S. Kesselheim & Jerry Avorn, *Approving a Problematic Muscular Dystrophy Drug: Implications for FDA Policy*, 316 JAMA 2357 (2016). However, advisory committees are convened only occasionally, to consider specific questions on a relatively small of drugs, and the data disclosed is also incomplete.

99. *See* Lisa M. Schwartz & Steven Woloshin, *Lost in Transmission – FDA Drug Information That Never Reaches Clinicians*, 361 NEW ENG. J. MED. 1717, 1719 (2009); Matthew Herder, *Toward a Jurisprudence of Drug Regulation*, 42 J.L. MED. & ETHICS 244, 256 (2014); Matthew Herder Christopher J. Morten & Peter Doshi, *Integrated Drug Reviews at the US Food and Drug Administration—Legal Concerns and Knowledge Lost*, 180 JAMA INTERNAL MED. 629 (2020).

100. *See* Herder et al., *supra* note 99; Schwartz & Woloshin, *supra* note 99.

101. *See* Herder et al., *supra* note 99.

102. *See* Notice: New Drugs Regulatory Program Modernization: Improving Approval Package Documentation and Communication, 84 Fed. Reg. 30,733 (June 27, 2019), https://www.regulations.gov/document?D=FDA-2019-N-2012-0001 [https://perma.cc/78LY-NFT9].

interpretations and debates inside the agency and may even suppress dissent within the FDA.[103]

Finally, individual patient-level data is extremely valuable to researchers. This includes raw data collected for each trial patient, and to be practically usable, data must be made available in executable (analyzable) form (i.e., in a form that can be analyzed using appropriate analytic software, such as Excel).[104] Granular data of this sort is rarely available to researchers, but pilot projects that have made it available on a voluntary basis show both that there is demand for the data and that important research insights can be gleaned from reanalysis of patient-level data.[105] For example, researchers reviewed previously unavailable individual patient data from thirty-three clinical trials of the once-blockbuster, now deprecated[106] drug rosiglitazone (Avandia) and identified serious discrepancies between the safety profile embedded in that individual patient data and previous depictions in summary data, including significantly higher risk of myocardial infarction (heart attack).[107] Some of the most important individual patient data emerge from the "pivotal" trials that are used to support approval of the drug. Individual adverse event reports are also valuable, but the need is less pressing as this data is currently available in redacted form from the FDA.[108]

There is a growing movement toward sharing all of this important safety and efficacy data. A consensus is emerging among medical experts that more data sharing is essential to protect public health,[109] and patients widely support

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103. *See* Letter from Peter Doshi et al. re: Docket No. FDA-2019-N-2012 ("New Drugs Regulatory Program Modernization: Improving Approval Package Documentation and Communication") (Aug. 23, 2019), https://www.regulations.gov/contentStreamer?documentId=FDA-2019-N-2012-0010&attachmentNumber=1&contentType=pdf [https://perma.cc/3HQD-GV6N]; *see also* Herder et al., *supra* note 99.

104. Perry Nisen & Frank Rockhold, *Access to Patient-Level Data from GlaxoSmithKline Clinical Trials*, 369 NEW ENG. J. MED. 475, 476 (2013) (describing these two kinds of patient-level data, raw and analysis-ready, and GSK's efforts to make them more available to researchers).

105. Joseph S. Ross et al., *Overview and Experience of the YODA Project with Clinical Trial Data Sharing After 5 Years*, 5 SCI. DATA 1 (2018), https://www.nature.com/articles/sdata2018268 [https://perma.cc/JR38-EE4D] (noting one hundred requests for data, and requests for almost 70% of all trials available on the site, with 13% already resulting in a publication); *see also* Letter from Matthew Herder, Director, Health L. Inst., et al., An Open Letter in Support of FDA's Clinical Study Report Pilot Project (Jan. 16, 2019) https://cspinet.org/sites/default/files/attachment/FDA-CSR-pilot-open-letter-FINAL.pdf [https://perma.cc/R4F5-DY26] (describing the benefits of sharing clinical study reports, which contain individual patient data, with researchers).

106. Nissen, *supra* note 78.

107. Joshua D. Wallach et al., *Updating Insights into Rosiglitazone and Cardiovascular Risk Through Shared Data: Individual Patient and Summary Level Meta-Analyses*, 368 BRIT. MED. J. 1 (2020), https://www.bmj.com/content/368/bmj.l7078 [https://perma.cc/LG9X-X7TL].

108. The FDA's Adverse Event Reporting System (FAERS) publishes anonymized individual adverse event reports as well as medication error reports and product quality complaints resulting in adverse events. *See Questions and Answers on FDA's Adverse Event Reporting System (FAERS)*, FDA (June 4, 2018), https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers [https://perma.cc/D7QZ-S5YV].

109. *See* INST. OF MED. OF THE NAT'L ACADS., *supra* note 18, at ix; *Developing Global Norms for Sharing Data and Results During Public Health Emergencies*, WORLD HEALTH ORG. (Sept. 2015), http://www.who.int/medicines/ebola-treatment/data-sharing_phe/en/ [https://perma.cc/PEN6-86U4];

more sharing as well.[110] Data sharing also supports the FDA's primary purposes: information production and validation. These functions are negated if much of the information produced under its influence remains unavailable to researchers, doctors, and the public.[111] Many new and emerging initiatives to promote data sharing show that more access to data can facilitate better science and protect patients.[112] But existing approaches have not yet solved the problem.

B. Insufficiency of Existing Approaches

There are existing sources of clinical trial data, but none are comprehensive or responsive enough to provide the necessary access and accountability. In this Section, we summarize several leading approaches to obtain clinical trial data: access through the public ClinicalTrials.gov website, litigation against drug companies and encouraging voluntary data sharing by drug companies, access through foreign drug regulators' safety and efficacy data sharing programs, and FOIA requests to the FDA. We explain the limitations of each, which underscore the need for more comprehensive data publicity.

1. ClinicalTrials.gov

Although companies are required to report clinical studies to the NIH, the required disclosures are partial, and compliance is incomplete. Existing law requires anyone who conducts a Phase 2, 3, or 4 clinical trial of an FDA-approved drug or medical device to disclose information on that trial via the ClinicalTrials.gov website, which is administered by the NIH.[113] Each trial must be registered before it begins and must report a summary of trial results when completed.[114] Since 2017, drug companies and other trial sponsors have been required to submit full trial protocol documents after trials are completed.[115] But

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Kathy L. Hudson & Francis S. Collins, *Sharing and Reporting the Results of Clinical Trials*, 313 JAMA 355 (2015) (describing the NIH view); Darren B. Taichman et al., *Sharing Clinical Trial Data—A Proposal from the International Committee of Medical Journal Editors*, 374 NEW ENG. J. MED. 384 (2016); Aaron S. Kesselheim & Michelle M. Mello, *Confidentiality Laws and Secrecy in Medical Research: Improving Public Access to Data on Drug Safety*, 26 HEALTH AFFS. 483, 490 (2007); Drazen, *supra* note 57; Ross et al., *supra* note 105, at 2.

110. *See* Michelle M. Mello, Van Lieou & Steven N. Goodman, *Clinical Trial Participants' Views of the Risks and Benefits of Data Sharing*, 378 NEW ENG. J. MED. 2202 (2018).

111. Kapczynski, *Dangerous Times*, *supra* note 10; Lietzan, *Access Before Evidence*, *supra* note 34, at 1288 ("The best way to describe the information-mediating aspect of the FDA's gatekeeping function is thus to say it ensures that high quality information about a new drug is generated and disclosed.").

112. Ross et al., *supra* note 105; Deborah A. Zarin, Kevin M. Fain, Heather D. Dobbins, Tony Tse & Rebecca J. Williams, *10-Year Update on Study Results Submitted to ClinicalTrials.gov*, 381 NEW ENG. J. MED. 1966 (2019).

113. *See* 42 U.S.C. § 282(j); 42 C.F.R. § 11.2 (2019). Many trials of unapproved products must also register and report results to ClinicalTrials.gov. *See FDAAA 801 and the Final Rule*, NIH U.S. NAT'L LIBR. MED., https://clinicaltrials.gov/ct2/manage-recs/fdaaa [https://perma.cc/C2R7-SR3T].

114. For a summary of ClinicalTrials.gov and trial sponsors' reporting requirements, see Zarin et al., *supra* note 112, at 1968.

115. Zarin et al., *supra* note 112, at 1966.

compliance with ClinicalTrials.gov requirements is spotty, especially when it comes to reporting results after trials are completed: according to multiple studies, only about two-thirds of completed trials had reported results as of 2019, raising concerns that drug companies and other trial sponsors are selectively reporting some results and withholding others.[116] NIH and FDA have not enforced the law's reporting requirements, and few expect them to do so.[117] Moreover, ClinicalTrials.gov's requirements are partial: sponsors need not report complete metadata or summary data, nor individual patient data.[118] Useful and important as it is, the ClinicalTrials.gov website is an inadequate source of safety and efficacy data.[119]

2. Litigation and Voluntary Data Sharing

In the United States, a small but vital stream of safety and efficacy data on prescription drugs is unearthed via discovery in tort and other litigation.[120] But only a subset of drugs become the subject of litigation, and the relevant data often remains secret pursuant to protective or sealing orders.[121] While some companies have voluntarily committed to clinical trial data sharing, and efforts by independent and academic researchers to expand voluntary data sharing like the Good Pharma Scorecard[122] are gaining traction, a majority of drug companies still decline to share their data fully.[123] Gaps may be particularly likely where

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116. *See id.* at 1969 (66% of completed trials had reported results as of May 2019); Nicholas J. DeVito, Seb Bacon & Ben Goldacre, *Compliance with Legal Requirement to Report Clinical Trial Results on ClinicalTrials.gov: a Cohort Study*, 395 LANCET 361, 365 (2020) (finding that 63.8% of completed trials had reported results as of September 16, 2019); Piller, *supra* note 48 ("Few trial sponsors have consistently [reported results to ClinicalTrials.gov], even after a 2007 law made posting mandatory for many trials registered in the database.").

117. *See, e.g.*, Piller, *supra* note 48 ("NIH and FDA officials do not seem inclined to apply that pressure.").

118. *How to Submit Your Results*, NIH U.S. NAT'L LIBR. OF MED.: CLINICALTRIALS.GOV, https://clinicaltrials.gov/ct2/manage-recs/how-report#ScientificInformation [https://perma.cc/QF47-ADCD] (defining data reported on ClinicalTrials.gov).

119. The same is true of the FDA assessments published on the FDA's Drugs@FDA website as part of a drug's approval package, described *supra* Part I.A: some important metadata and summary data is disclosed, but not comprehensively, and not enough to prevent cases like those described above. For discussion of the information historically and currently available on the Drugs@FDA website, see Herder et al., *supra* note 99, and Lisa M. Schwartz, Steven Woloshin, Eugene Zheng, Tonsy Tse & Deborah A. Zarin, *ClinicalTrials.gov and Drugs@FDA: A Comparison of Results Reporting for New Drug Approval Trials*, 165 ANNALS INTERNAL MED. 421, tbl.1 (2016) (comparing safety and efficacy data available at Drugs@FDA to data available at ClinicalTrials.gov, as of 2015).

120. Kesselheim & Avorn, *supra* note 12.

121. Egilman et al., *supra* note 73, at 293.

122. *Good Pharma Scorecard*, BIOETHICS INT'L, https://bioethicsinternational.org/good-pharma-scorecard/ [https://perma.cc/CES8-K9DD].

123. *See* Jennifer Miller, Joseph S Ross, Marc Wilenzick & Michelle M Mello, *Sharing of Clinical Trial Data and Results Reporting Practices Among Large Pharmaceutical Companies: Cross Sectional Descriptive Study and Pilot of a Tool to Improve Company Practices*, BRIT. MED. J., 2019, at 1, https://www.bmj.com/content/366/bmj.l4217 [https://perma.cc/7SYN-36K] (noting that as of Spring 2018, only "25% of large pharmaceutical companies fully met the data sharing standard," although "the

the data is most consequential, and in notable cases, companies have refused to disclose despite repeated requests and even legal action initiated by researchers.[124]

3. Reliance on Foreign Drug Regulators

In Europe and Canada, regulatory authorities have taken significant steps toward data publicity.[125] Both are important examples, but reliance on foreign regulators will always be an imperfect solution. Each policy is limited in certain ways—for example, applying only prospectively or limiting the persons who may apply. In addition, drugs are often approved in the United States before they are approved anywhere else,[126] and some drugs are never approved anywhere but the United States.[127] We also do not know if companies submit the same data to different regulatory agencies, and it is plausible that the FDA, which is the most robust drug regulatory agency in the world, has more data, particularly in controversial cases, than do other regulators.

European and Canadian policies do, however, provide some access to important data and represent significant examples of successful data disclosure programs. The European Union's European Medicines Agency (EMA) has

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proportion increased to 33% when companies were given an opportunity to improve their policies and practices").

124. As a vivid example, the drug company Sarepta Therapeutics refuses to share data on its FDA-approved drug eteplirsen with an independent journalist despite years of FOIA litigation. *See infra* notes 177–185 and accompanying text; Charles Seife, *Is the Food and Drug Administration Withholding Drug Trial Data to Protect the Corporate Secrets of Pharmaceutical Companies?*, SCI. AM., Feb. 2018, at 38, 42.

125. *See, e.g.*, Alexander C. Egilman, Amy Kapczynski, Margaret E. McCarthy, Anita T. Luxkaranayagam, Christopher J. Morten, Mathew Herder, Joshua D. Wallach & Joseph S. Ross, *Transparency of Regulatory Data Across the European Medicines Agency, Health Canada, and US Food and Drug Administration*, J.L. MED. & ETHICS (forthcoming 2021); Arti K. Rai, *Risk Regulation and Innovation: The Case of Rights-Encumbered Biomedical Data Silos*, 92 NOTRE DAME L. REV. 1641, 1660–63 (2017).

126. *See* Nicholas S. Downing, Jerenius A. Aminawung, Nilay D. Shah, Joel B. Braunstein, Harlan M. Krumholz & Joseph S. Ross, *Regulatory Review of Novel Therapeutics — Comparison of Three Regulatory Agencies*, 366 NEW ENG. J. MED. 2284, 2292 (2012); Nicholas S. Downing, Audrey D. Zhang & Joseph S. Ross, *Regulatory Review of New Therapeutic Agents — FDA versus EMA, 2011–2015*, 376 NEW ENG. J. MED. 1386, 1386–87 (2017).

127. For example, one study showed that 26% of orphan drugs approved in the United States between 1997 and 2012 were not approved in Canada. *See* Matthew Herder & Timothy Mark Krahn, *Some Numbers Behind Canada's Decision to Adopt an Orphan Drug Policy: US Orphan Drug Approvals in Canada, 1997–2012*, 11 HEALTHCARE POL'Y 70, 75 (2016); *see also* Mark Terry, *Going its Own Way, European Regulators Reject Sarepta's Exondys 51 for DMD*, BIOSPACE (Sept. 21, 2018), https://www.biospace.com/article/going-its-own-way-european-regulators-reject-sarepta-s-exondys-51-for-dmd-fd1a-/ [https://perma.cc/NLW9-2C6Y] (describing a controversial muscular dystrophy drug that was approved in the United States but not approved in Europe, Canada, or elsewhere). Other common medicines, including artemisinin (anti-malarial) and ivermectin (anti-parasitic), have only been approved by Health Canada in very limited circumstances. *See* Adam R. Houston, Elizabeth Rea & Stan Houston, *Why Some Essential Medicines Are Unavailable in Canada*, POL'Y OPS. POLITIQUES (July 4, 2017), https://policyoptions.irpp.org/magazines/july-2017/why-some-essential-medicines-are-unavailable-in-canada/ [https://perma.cc/3V74-BHXM].

permitted release of clinical trial data upon request since 2010, via "Policy 0043." The policy is broad, potentially covering any documents held by the agency, but requesters must be European citizens or residents.[128] The agency may withhold commercially confidential information but has taken a narrow view of that exception.[129] It has released clinical study reports with very minimal redactions, an approach recently upheld by the Court of Justice of the European Union (CJEU) against a drug company's objection that this violated its intellectual property interests.[130] Reactive data disclosures, however, can be slow and limited – in its first six years, the policy apparently released fewer than four hundred thousand pages of documents.[131]

In 2015 the EMA also implemented a proactive policy, "Policy 0070," for releasing the types of trial data discussed here: summary data, metadata, and (eventually) individual patient data.[132] But the policy applies only prospectively, to drug applications submitted after 2015,[133] and it was suspended in 2018 and remains suspended as of late 2020.[134] Policy 0070 is an important precedent: the EMA made data for over 130 drugs available[135] with no obvious ill effect on the industry. The EMA's redaction policy here too was extremely narrow, and the agency regulations detail the many kinds of safety and efficacy data, such as trial

128. EUR. MEDS. AGENCY, *European Medicines Agency Policy on Access to Documents: POLICY/0043*, at 4.1.1, https://www.ema.europa.eu/documents/other/policy/0043-european-medicines-agency-policy-access-documents_en.pdf [https://perma.cc/2D95-3SMK] ("Citizens of the EU and natural or legal persons residing or having their registered office in an EU Member State have the right of access to EMA documents . . . . EMA is no longer in a position to process access to documents requests issued from outside the EU.").

129. *See infra* Part II.A.

130. Judgment in Case C-175/18, PTC Therapeutics Int'l Ltd. v. Eur. Meds. Agency, ECLI:EU:C:2020:23, ¶ 64 (Jan. 22, 2020). (describing the very limited redactions); *see also id.* at ¶¶ 82, 91, 97 (rejecting the challenge to the release of clinical trial documents, concluding that the agency had broad discretion to release data, and that the company had not made a specific showing that the release would undermine its legitimate interests).

131. Jean-Marc Ferran & Sarah J. Nevitt, *European Medicines Agency Policy 0070: An Exploratory Review of Data Utility in Clinical Study Reports for Academic Research*, BMC MED. RSCH. METHODOLOGY, Nov. 5, 2019, at 1, 3 fig.1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6833240/ [https://perma.cc/RZ2W-BHQ3].

132. *See id.* at 2; *Clinical Data Publication*, *supra* note 96. The EMA's Policy 0070 disclosed highly useful summary data and metadata—including trial protocols, clinical study reports, clinical summaries, and documentation of statistical methods—as well as a relatively small amount of individual patient data. A planned future "Phase 2" of Policy 0070 will make more anonymized individual patient data available. *See European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use*, EUR. MEDS. AGENCY 7 (Mar. 21, 2019), https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf [https://perma.cc/LRP7-QMYG].

133. *See Clinical Data Publication*, *supra* note 96.

134. *See* Peter Doshi, *EMA Scales Back Transparency Initiatives Because of Workload*, BRIT. MED. J. (Aug. 14, 2018), https://www.bmj.com/content/362/bmj.k3513 [https://perma.cc/Z5H3-FFVN]; *Clinical Data Publication*, *supra* note 96.

135. Barbara Mantel, *Canada's Decision to Make Public More Clinical Trial Data Puts Pressure on FDA*, NPR (Oct. 11, 2019), https://www.npr.org/sections/health-shots/2019/10/11/769348119/canadas-decision-to-make-public-more-clinical-trial-data-puts-pressure-on-fda [https://perma.cc/VV7Y-5LW3].

endpoints and statistical data, that are defined, by their nature, as not confidential commercial information.[136]

In Canada, a proactive disclosure policy modeled on the EU's launched in early 2019 and, like the EU's, includes most but not all of the data that is important here.[137] Health Canada also announced that it would release historical data on earlier-approved drugs "upon receipt of a request from the public and within the limits of [the agency's] administrative capacity."[138] Proactive disclosure has proceeded gradually: as of August 2020, data from only about sixty-five drugs had been posted;[139] Health Canada has said it will prioritize release of data on first-in-class drugs before expanding to all new drug submissions in 2020 or 2021.[140] Given the limits of the EU and Canadian policies and the scope of the FDA's data holdings, comprehensive data publicity will require action in the United States. However, as we describe later, drawing on these foreign examples can facilitate this work.[141]

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136. EUR. MEDS. AGENCY, EXTERNAL GUIDANCE ON THE IMPLEMENTATION OF THE EUROPEAN MEDICINES AGENCY POLICY ON THE PUBLICATION OF CLINICAL DATA FOR MEDICINAL PRODUCTS FOR HUMAN USE 49–52 (2018), https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data_en-3.pdf [https://perma.cc/28UL-6ZQK] (detailing lists of administrative, quality-related, and non-clinical information that are not considered Confidential Commercial Information (CCI)). The EMA also will release data that is CCI if it deems it to be in the public interest. *Id.* at 52.

137. *See generally* Margaret E. McCarthy & Joseph S. Ross, *FDA and Health Canada: Similar Origins, Yet Divergent Paths and Approaches to Transparency* (forthcoming) (on file with authors); *see also Public Release of Clinical Information: Guidance Document*, HEALTH CAN., https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/profile-public-release-clinical-information-guidance.html [https://perma.cc/S5UH-UPN9] (disclosing trial protocols, clinical study reports, clinical summaries, documentation of statistical methods, and clinical overviews, but limited patient-level data). Health Canada has designed the set of data disclosed to be identical, or nearly so, to that disclosed under EMA Policy 0070. *See, e.g.*, *Public Release of Clinical Information: Guidance Document*, *supra*, at 4.4: Submissions of Annotated Documents with Proposed CBI Redaction(s) and Anonymization ("With appropriate certification, the manufacturer may submit to Health Canada final redacted documents of drug submission that were previously accepted by the European Medicines Agency . . . [T]he clinical information in scope of Health Canada's Public Release of Clinical Information [must be] identical to the clinical information published under EMA Policy 0070."). Like the EMA, Health Canada applies a narrow definition of CCI. *See* Matthew Herder, *Transparency by Sleight of Hand?*, CRITICAL THINKING BLOG (Jan. 3, 2018), https://law.yale.edu/centers-workshops/collaboration-research-integrity-and-transparency-crit/critical-thinking-blog/transparency-sleight-hand [https://perma.cc/FZ3V-9LN7].

138. *See Public Release of Clinical Information: Guidance Document*, *supra* note 137, at 2.2: Clinical Information in Drug Submissions.

139. *Search for Clinical Information on Drugs and Medical Devices*, HEALTH CAN., https://clinical-information.canada.ca/search/ci-rc [https://perma.cc/K3UD-HVDP].

140. *See Public Release of Clinical Information: Guidance Document*, *supra* note 137, at 3.3: Information Schedule for the Proactive Disclosure of Clinical Information in Drug Submissions and Medical Device Applications.

141. *See infra* Part II.B.

4. The Freedom of Information Act

FOIA is currently the most important approach for independent researchers to obtain clinical data from the FDA regarding approved drugs.[142] On its plain text, FOIA might seem like a reasonable way to obtain safety and efficacy data from the FDA. FOIA generally requires a federal agency to make information—"records"—within its possession "promptly available" to "any person"[143] who requests that information.[144] A naïve researcher might reasonably file a FOIA request with the FDA for all of the safety and efficacy data it possesses on a drug of interest and eagerly await the FDA's "prompt" release of that data, as contemplated by the statute. But our naïve researcher is very likely to be disappointed.

FOIA at the FDA has four key flaws: FOIA requests are (1) reactive and require the requester to know precisely what information she seeks before she asks, (2) slow, (3) resource intensive for requesters, and (4) highly deferential to the pharmaceutical industry. We will describe each in detail and explain how they together buttress the data secrecy regime.

First, to ensure processing, a FOIA requester must request a limited set of specific, clearly defined data.[145] The requester generally cannot simply ask for data from a particular clinical trial but must identify the precise metadata, summary data, and individual patient data she needs to perform an independent analysis of each trial. This creates an information asymmetry problem, the "requester's paradox": how can a requester request a specific record if she does

142. 5 U.S.C. § 552. *See* Kesselheim & Mello, *supra* note 109, at 487 ("FOIA requests are generally the only avenue available to consumer groups, researchers, and physicians seeking to access information not released by the FDA."); *see also* Lurie & Zieve, *supra* note 98, at 89 (identifying advisory committee materials and FOIA requests as the two approaches "that have provided the greatest access to pharmaceutical data"). For other analysis of FOIA at the FDA, see Laurence Tai, *A Tale of Two Transparency Attempts at FDA*, 69 FOOD & DRUG L.J. 423 (2013); Amy Kapczynski & Jeanie Kim, *Clinical Trial Transparency: The FDA Should and Can Do More*, J.L. MED. & ETHICS, Winter 2017, at 33; Mathew Herder, *Reviving the FDA's Authority to Publicly Explain Why New Drug Applications Are Approved or Rejected*, 178 JAMA INTERNAL MED. 1013, 1013 (2018); Alexander C. Egilman, Joshua D. Wallach, Christopher J. Morten, Peter Lurie & Joseph S. Ross, *Systematic Overview of Freedom of Information Act Requests to the Department of Health and Human Services from 2008 to 2017*, 4 RSCH. INTEGRITY & PEER REV. 26 (2019).

143. For purposes of making a FOIA request, a "person" can be any individual or organization, commercial or noncommercial, citizen or noncitizen, located anywhere in the world. *See* 110 AM. JURIS. TRIALS 367 § 5 (2008).

144. 5 U.S.C. § 552.

145. 5 U.S.C. § 552(a)(3)(A) (requiring requesters to "reasonably describe[]" the records they seek). Agencies have interpreted this statutory language as permitting them to refuse to process FOIA requests unless those requests identify with specificity or "particularity" the individual records sought, and courts have upheld this practice. *See, e.g.*, Assassination Archives & Rsch. Ctr. v. CIA, 720 F. Supp. 217, 219 (D.D.C. 1989). Even if specific, readily identifiable records are requested, the FDA may also refuse to process a FOIA request it deems "unreasonably burdensome," another agency practice that courts have upheld. *See, e.g.*, Am. Fed'n Gov't Emps, Local 2782 v. U.S. Dep't of Commerce, 907 F.2d 203, 209 (D.C. Cir. 1990).

not know how to describe the record, for example, because she is unaware it exists?[146]

Second, if the FDA did process our requester's request, the FDA would take months or years to release any information.[147] The FDA's FOIA office is backlogged, with over three thousand FOIA requests outstanding at the end of 2018, and the agency routinely fails to meet the statutory requirements for speed of response.[148] In our experience making and litigating FOIA requests,[149] obtaining clinical data from the FDA takes years, which includes time spent negotiating page-by-page with the FDA over release of individual documents along with long stretches of waiting. Expedited processing is theoretically available[150] but is almost always denied by the agency.[151]

Third, FOIA is not only slow but also resource intensive. Successful use of FOIA to obtain clinical data from the FDA requires money and some legal sophistication.[152] Even FOIA requests processed without litigation may require the help of a lawyer to negotiate document productions. The FDA charges fees

146. *See, e.g.*, Ari Schwartz, *Using Open Internet Standards to Provide Greater Access in a Post-9/11 World*, 2 I/S: J.L. POL'Y 125, 128 (2005) (describing "the 'requester's paradox': how can I know to request a specific document, when I don't even know that the document exists?").

147. *See* Egilman et al., *supra* note 142, at 4 (finding that between 2008 and 2017, FDA took more than sixty days to fulfill most FOIA requests, even those deemed simple). Requests for clinical trial data contained in INDs, NDAs, and BLAs are routinely assigned to the complex queue where processing times are longer still – an average of 127 days in 2018, by the FDA's own estimates. Telephone Interview with Darshini Satchi, Ctr. for Drug Evaluation & Rsch. Point of Contact, FDA FOIA Office (Nov. 13, 2019) (notes on file with author); *HHS Fiscal Year 2018 Freedom of Information Annual Report*, HHS.gov, at tbl.VII.A, https://www.hhs.gov/foia/reports/annual-reports/2018/index.html [perma.cc/F3UN-ZMVC]. About 15% of requests on the complex queue take over 400 days to process. *Id.* at tbl.VII.C (685 of 4,446 processed complex requests had a response time of over 400 days).

148. *HHS Fiscal Year 2018 Freedom of Information Annual Report*, *supra* note 147, at tbl.V.A. Kwoka has shown that this backlog is attributable to the enormous number of FOIA requests that FDA receives from commercial requesters. *See* Kwoka, *FOIA, Inc.*, *supra* note 23.

149. *GHJP Closes Two-Year FOIA Case Against Drug Manufacturer*, *supra* note 95; *Sarepta*, YALE L. SCH. MEDIA FREEDOM & INFO. ACCESS CLINIC, https://law.yale.edu/mfia/projects/open-data/sarepta [https://perma.cc/63D2-MHRA]; *MFIA/CRIT Team Supports Johns Hopkins Investigation of FDA Oversight of Fentanyl Products*, *supra* note 65.

150. By regulation, the FDA limits it to requesters who demonstrate an imminent threat to life or safety or an urgent need to inform the public of actual or alleged agency misconduct. *See* 21 C.F.R. § 20.44(a) (2019).

151. *HHS Fiscal Year 2018 Freedom of Information Annual Report*, *supra* note 147, at tbl.VIII.A (indicating that in Fiscal Year 2018, FDA denied 449 requests for expedited processing and granted zero).

152. *See* David E. Pozen, *Freedom of Information Beyond the Freedom of Information Act*, 165 U. PA. L. REV. 1097, 1113 (2017) (noting that effective use of FOIA requires "the wherewithal to negotiate with FOIA staff and to litigate denials under unfavorable conditions"); Seth F. Kreimer, *The Freedom of Information Act and the Ecology of Transparency*, 10 U. PA. J. CONST. L. 1011, 1020 (2008) ("To press a recalcitrant administration for disclosure under FOIA requires time, money, and expertise.").

for searching, reviewing, and duplicating documents that can run to the tens of thousands of dollars for large productions of data.[153]

Fourth, and perhaps most importantly, out of deference to the pharmaceutical industry, the FDA will likely heavily redact whatever data it does release. Therefore, this data will have limited value. One of FOIA's exemptions, Exemption 4, permits an agency to withhold trade secrets and a broader category of confidential commercial information (CCI) from a FOIA requester.[154] The agency has adopted a fairly expansive definition of CCI.[155] Although FOIA is a *permissive* statute that allows agencies to voluntarily release information, even if the information qualifies as a trade secret or as CCI,[156] the FDA's own rules in fact *prohibit* the agency from disclosing such information.[157] Additional FDA regulations also create default rules that make much of the safety and efficacy data in new drug applications presumptively secret until, or perhaps even after, the moment of FDA approval.[158] Under these rules, if the existence of the

153. *FOIA Fees*, FDA, https://www.fda.gov/regulatory-information/freedom-information/foia-fees [https://perma.cc/P563-Q3ZG]. While fee waivers are available, see 21 C.F.R. § 20.46 (2019), the burden is on the requester to prove eligibility (demanding further legal expertise), and there is no guarantee the FDA will grant the waiver.

154. *See* 5 U.S.C. § 552(b)(4).

155. *See* 21 C.F.R. § 20.61(b) (2019) ("Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.").

156. *See infra* Part I.A.

157. *See* 21 C.F.R. § 20.61(c) (2019); *see also id.* § 20.82(b).

158. *See id.* § 314.430 (small molecule NDAs); *id.* § 601.51 (biologic BLAs). Once an NDA is approved, 21 C.F.R. § 314.430(e) explicitly makes certain summary data available for disclosure. Once certain later milestones are reached—e.g., the FDA approves a generic application that references the NDA—then "[a]ll safety and effectiveness data and information which have been submitted in an application and which have not previously been disclosed to the public [become] available to the public, upon request." *Id.* § 314.430(f). The FDA has interpreted this rule as meaning that complete safety and efficacy data is *not* disclosable to FOIA requesters at the moment of approval but only becomes disclosable when a milestone event enumerated in subsection (f) occurs. *See, e.g.*, 50 Fed. Reg. 7452, 7490 (1985) (stating that under 314.430(f), "safety and effectiveness data and information . . . are publicly disclosable as soon as an abbreviated [generic] application under section 505(j) of the act for the product can be made effective . . . ."); *Frequently Asked Questions on Botanical Drug Development*, FDA, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/frequently-asked-questions-botanical-drug-product-development [https://perma.cc/WP9A-V6TF] ("What kind of IND and NDA data may be released without prior permission from the sponsor? . . . Once an NDA is approved, FDA may release certain safety and efficacy information (§ 314.430(e))."); Defendants' Supplemental Memorandum of Law in Support of Motion for Summary Judgment at 12–13, Seife v. FDA, No. 1:17-cv-03960 (JMF), 2020 WL 5913525 (S.D.N.Y. Oct. 6, 2020), ECF No. 146 (stating that "any information [in an NDA] that did not appear in the SBA [i.e., the action package posted on Drugs@FDA] after approval was considered confidential and would remain so unless previously disclosed to the public"). Contrary to the FDA's interpretation, the rule's text does not explicitly state that full results *cannot* be made public *before* the identified milestone events but rather that such results *will* be released *after* such events. The plain text thus leaves room for discretionary disclosure, though it does not require mandatory disclosure. The regulations for biologic drugs (including vaccines) differ in a manner that supports this interpretation. Under 21 C.F.R. § 601.51, the FDA has bound itself to disclose all safety and efficacy data in a BLA from the moment of approval. 21 C.F.R. § 601.51(e) (2019) ("After a license has been issued, the following data and information in the biological product

application in question has not been made public, no data is available.[159] However, if the application's existence has been made public, then the FDA has discretion to "disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue."[160]

Moreover, the FDA's current process gives drug companies, not agency officials, the first opportunity to determine which clinical data on their products to disclose and which to keep secret. The agency permits companies to designate data and other information as CCI upon submission,[161] notifies companies of FOIA requests, and permits them to propose withholding of that data before it is released to the FOIA requester.[162] While the FDA has an obligation to independently verify the submitters' proposed withholding and redaction,[163] it does not always do so,[164] perhaps because of the agency's limited resources, deep backlog of FOIA requests, or desire to avoid confrontation with the industry. Between 2008 and 2017, the FDA most frequently cited FOIA

file are immediately available for public disclosure unless extraordinary circumstances are shown . . . ."). All of the disclosure provisions of both sections 314.430 and 601.51 are subject to a proviso: if the drug company can show "extraordinary circumstances," then data can remain secret for longer. As Eisenberg has noted, "industry has successfully resisted a plain meaning interpretation" of these provisions, and the FDA does not regularly disclose additional safety and efficacy data even when a drug goes generic. Eisenberg, *The Role of the FDA*, *supra* note 19, at 381. Lietzan has suggested that the FDA has concluded that "extraordinary circumstances" apply any time that the clinical data in question retains any competitive value, even overseas, such that "as a practical matter it does not release the content in question." Lietzan, *A New Framework*, *supra* note 21, at 43. However, we have not found any instance in which the FDA publicly committed itself to that definition.

159. 21 C.F.R. §§ 314.430, 601.51 (2019).

160. *Id.* §§ 314.430(b)–(d), 601.51(b)–(d).

161. *Id.* § 20.61(d).

162. *Id.* § 20.61(e)(3). This rule implements a Reagan-era executive order requiring federal agencies to notify submitters of CCI before disclosing that CCI to FOIA requesters. *See* Exec. Order No. 12,600, 52 C.F.R. 23,781 (June 23, 1987).

163. 21 C.F.R. § 20.61(e) (2019).

164. In a number of FOIA cases, the FDA has initially withheld documents under Exemption 4, deeming the documents to be CCI without having independently or properly verified their status, only to release them later as non-CCI upon court order or negotiation with the FOIA requester. *See, e.g.*, Seife v. FDA, No. 17-cv-03960 (JMF), 2020 WL 5913525, at *2 (S.D.N.Y. Mar. 27, 2019) (holding that "the FDA's redactions [under Exemption 4] are overbroad" and ordering the FDA to "re-review and, as necessary re-redact, the documents that are in dispute"); Order re: Defendant's Motion for Summary Judgment at 21, AIDS Healthcare Foundation v. FDA, No. 11-cv-07925-MMM (JEMx), 2014 WL 10983763 (C.D. Cal. Aug. 6, 2013), ECF No. 60 (holding that the FDA "has failed to demonstrate that the safety and efficacy records that have been withheld are 'confidential' financial and commercial records" and "order[ing] the FDA to produce complete and unredacted copies of the safety and efficacy records to" the FOIA requester); *Public Citizen HRG v. FDA (Bextra)*, PUB. CITIZEN, https://www.citizen.org/litigation/public-citizen-hrg-v-fda-bextra/ [https://perma.cc/PSK9-3H28] (explaining that Public Citizen made a FOIA request to the FDA for certain metadata concerning the drug valdecoxib (Bextra), which was initially withheld but then released after Public Citizen filed a complaint). *See generally*, Lurie & Zieve, *supra* note 98 (describing multiple cases in which the FDA did not properly review redactions by submitters and later released these documents after FOIA requests or threats of lawsuits).

Exemption 4—the trade secrets and CCI exemption—to withhold information from FOIA requesters.[165]

The FDA's deference to the pharmaceutical industry would be less problematic if the FDA and other federal agencies were required to weigh the public interest in the information being sought against the corporate interest in ongoing secrecy. Such balancing tests are standard in many countries' freedom of information laws,[166] but U.S. courts and agencies have only occasionally embraced them.[167] The FDA has not embraced a balancing test.[168]

Lower courts have rejected broad claims that safety and efficacy data is "confidential" under the FOIA statute,[169] but a recent Supreme Court case, *Food Marketing Institute v. Argus Leader* ["*FMI*"], exacerbates the problem of FDA deference to the industry's view of what constitutes CCI. In *FMI*, the Court significantly expanded the scope of information and data that is withholdable as CCI, at least with respect to FOIA requests filed prior to the amendment of FOIA

165. Egilman et al., *supra* note 142, at 4 tbl.3.

166. *See By Indicator Detail*, RTI RATING, https://www.rti-rating.org/country-data/by-indicator/31/ [https://perma.cc/QNX7-94HU] (showing various countries' rules for weighing the public interest). The EMA adopts such a balancing test. *See* EUR. MEDS. AGENCY, *supra* note 136, at 56.

167. *See* Pub. Citizen Health Rsch. Grp. v. FDA, 185 F.3d 898, 909 (D.C. Cir. 1999) (Garland, J., concurring); GC Micro Corp. v. Def. Logistics Agency, 33 F.3d 1109, 1115 (9th Cir. 1994), *overruled on other grounds by* Animal Legal Def. Fund v. FDA, 836 F.3d 987 (9th Cir. 2016) (requiring courts to "balance the strong public interest in favor of disclosure against the right of private business to protect sensitive information"); Martin v. Lauer, 686 F.2d 24, 33 (D.C. Cir. 1982) (requester's "speech interests . . . are deserving of rigorous protection").

168. *See* Defendants' Memorandum of Law in Opposition to Plaintiff's Renewed Cross-Motion for Summary Judgment and Reply Brief in Further Support of Defendants' Renewed Motion for Summary Judgment at 2, Seife v. FDA, No. 1:17-cv-03960, 2020 WL 5913525 (S.D.N.Y. Oct. 6, 2020), ECF No. 157 (revealing the FDA alleging that such weighing of the public interest "has never been articulated by any court").

169. *See, e.g.*, Goldwater Inst. v. Dep't of Health & Human Servs., 804 Fed. App'x 661, 664 (9th Cir. 2020) (holding that a broad assertion by the FDA that all data and information submitted with IND applications constitutes CCI was "insufficient under FOIA"); Teich v. FDA, 751 F. Supp. 243, 253 (D.D.C. 1990) (holding that preclinical data on breast implants did not qualify as CCI because the public interest in the relevance of the data outweighs defendant's financial concerns); Pub. Citizen Health Rsch. Grp. v. FDA, 964 F. Supp. 413, 415 (D.D.C. 1997) (suggesting that a clinical trial protocol was not CCI); Order re: Defendant's Motion for Summary Judgment at 21, AIDS Healthcare Found. v. FDA, No. 11-cv-07925-MMM (JEMx), 2014 WL 10983763 (C.D. Cal. Aug. 6, 2013), ECF No. 60 (holding that the "FDA has not established a likelihood that disclosure of the data summaries and analyses withheld under Exemption 4 would cause substantial competitive injury . . . ."); *cf.* Pub. Citizen Health Rsch. Grp. v. Dep't of Health, Educ. & Welfare, 477 F. Supp. 595, 605 (D.D.C. 1979), *rev'd*, Public Citizen Health Rsch. Grp. v. Dep't of Health, Educ & Welfare, 668 F.2d 537 (D.C. Cir 1981) (holding that medical documents that contained "no data concerning fees, payment schedules, or other commercial arrangements [and] . . . no information about secret formulas or rare treatment methods" were not CCI); *but see* Citizens Comm'n on Hum. Rts. v. FDA, No. 92-cv-5313, 1993 WL 1610471, at *9 (C.D. Cal. May 10, 1993), *aff'd in part, remanded in part sub nom.* Citizens Comm'n on Hum. Rts. v. FDA, 45 F.3d 1325 (9th Cir. 1995) (holding that "research data and results [in an NDA for an FDA-approved drug] were properly withheld from plaintiff pursuant to Exemption 4 of the FOIA"); Judicial Watch, Inc. v. FDA, 449 F.3d 141, 148–49 (D.C. Cir. 2006) (holding that "Exemption 4 extends to at least some information contained in INDs and NDAs," but "Exemption 4 does not categorically exempt all information in INDs and NDAs . . . ").

in 2016.[170] Before *FMI*, submitters generally had to show that the disclosure would cause "substantial" competitive harm to the submitter in order to support withholding as CCI.[171] This definition was narrow enough to permit some determined FOIA requesters to obtain some (incomplete) safety and efficacy data on FDA-approved drugs.[172] *FMI* held instead that information could be withheld as "confidential" if it "[was] both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy . . . ."[173]

The *FMI* decision thus raises a troubling prospect: drug companies and the agency have more latitude than ever before to subjectively determine whether material remains secret from FOIA requesters.[174] Both drug companies and the FDA face many temptations to secrecy.[175] However, the FDA still possesses authority to *proactively* disclose safety and efficacy data that qualifies as a trade secret or CCI. *FMI* confirmed, not undermined, this authority.[176]

A brief example drawn from our own experience may illuminate how these four problems together make it difficult for researchers to understand FOIA. In December 2016, investigative journalist Charles Seife filed a targeted FOIA request for safety and efficacy data, agency records, and correspondence concerning the drug eteplirsen (Exondys 51), which is marketed by Sarepta

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170. Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2366 (2019). In order for an agency to justify withholding data, new statutory language introduced in the FOIA Improvement Act of 2016 requires the agency to prove that it "reasonably foresees that disclosure would harm an interest protected by" the FOIA exemption. 5 U.S.C. § 552(a)(8)(A)(i)(I). The Supreme Court did not decide if this language heightens the standard for withholding for FOIA requests filed after 2016. This statutory text, not yet construed by any court cases in connection with Exemption 4, provides an alternative basis for FOIA requesters to argue that FOIA Exemption 4 cannot possibly cover anything and everything that regulated entities subjectively deem secret upon submission to a regulator. *See, e.g.*, Memorandum of Law in Support of Plaintiff's Combined Cross-Motion for Summary Judgment and in Opposition to Defendants' Motions for Summary Judgment at 11, Seife v. FDA, No. 1:17-cv-03960, 2020 WL 5913525 (S.D.N.Y. Oct. 6, 2020), ECF No. 148 (proposing that the FDA must "demonstrate a high likelihood of harm to an interest protected by Exemption 4 sufficient to outweigh FOIA's core objective of informing the public about 'what the government is up to'").

171. *See* Nat'l Parks & Conservation Assn. v. Morton, 498 F.2d 765 (D.C. Cir. 1974) *abrogated in part by Food Mktg. Inst.*, 129 S. Ct. 2356 (requiring disclosure to a FOIA requester unless the agency can show that disclosure poses the likelihood of substantial harm to the competitive positions of the parties from whom it has to be obtained).

172. *See supra* note 164 and accompanying text.

173. *Food Mktg. Inst.*, 139 S. Ct. at 2366.

174. *See id.* at 2363. The Supreme Court left open whether information or data that is merely "customarily kept private, or at least closely held, by the person imparting it" constitutes CCI, or whether the information or data must also be subject to "some assurance" from the agency that receives the submission "that it will remain secret" to the submitter. *Id.* But while this open question may provide FOIA requesters with a glimmer of hope, the FDA's long-standing regulations, ones that promise the secrecy of much of the safety and efficacy data in drug applications, may render this potential second element of the *FMI* test moot.

175. *Id.* at 2368 (Breyer, J., dissenting) (noting the "temptation, common across the private and public sectors, to regard as secret all information that need not be disclosed, . . . for reasons no better than convenience, skittishness, or bureaucratic inertia").

176. *See supra* Part II.A.

Therapeutics and was approved by the FDA for treatment of Duchenne muscular dystrophy earlier in 2016. Seife became interested in eteplirsen because of the controversial circumstances of its approval; in his words, the FDA "overruled its own scientific advisers, rejected the recommendations of its review panel, triggered a formal internal dispute process, and apparently sparked the resignation of one senior official and the retirement of another."[177] Sarepta now charges close to $1,000,000 per patient per year for eteplirsen[178] despite the fact that, even as of mid-2020, it had yet to generate any persuasive evidence that the drug actually works.[179]

Seife's 2016 FOIA request was narrowly targeted and sought a specific subset of safety and efficacy data—Clinical Study Reports, protocols and protocol amendments, statistical analysis plans and plan amendments, and regulatory communications—from two specific clinical trials of eteplirsen.[180] The FDA denied Seife expedited processing, placed his request in the "complex processing queue," and declined to provide an estimate of when his request would be fulfilled.[181] With legal help from Yale's Collaboration for Research Integrity and Transparency and Media Freedom and Information Access Clinic, with which both of us are affiliated, Seife filed a FOIA suit against the FDA in May 2017.[182] As of writing in summer 2020, more than three years later, most of the data Seife seeks remains secret,[183] despite eteplirsen's use by patients with Duchenne muscular dystrophy, projected annual sales of over $400,000,000,[184] and hundreds of hours of pro bono legal assistance. Sarepta has intervened in the suit as a co-defendant, and Seife continues to litigate. Sarepta and the FDA continue to argue that, under the Supreme Court's new *FMI* test, the clinical data Seife seeks can be withheld from Seife and other members of the public.[185]

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177. Charles Seife, *FDA Documents Reveal Depths of Internal Rancor over Drug's Approval Process*, UNDARK (Aug. 2, 2017), https://undark.org/2017/08/02/fda-eteplirsen-janet-woodcock/ [https://perma.cc/8UWJ-8BF2].

178. *See* Thomas & Abelson, *supra* note 61.

179. *ICER Publishes Evidence Report on Treatments for Duchenne Muscular Dystrophy*, INST. FOR CLINICAL & ECON. REV. (July 11, 2019), https://icer-review.org/announcements/dmd_evidence_report/ [https://perma.cc/NU6G-UU98].

180. Complaint for Injunctive and Declaratory Relief at ¶ 37, Seife v. FDA, No. 1:17-cv-03960, 2020 WL 5913525 (S.D.N.Y. Oct. 6, 2020), ECF No. 2.

181. *See id.* at Ex. D (letter from the FDA stating that Seife's request had been placed in the complex processing queue and that the "FDA needs additional time to respond to your request because of exceptional circumstances").

182. *Id*.

183. The parties negotiated a document production from 2017 to 2018, with over 35,000 pages of data and discussion that Seife and counsel painstakingly reviewed, but Seife is unable to use much of the data due to extensive redactions. *See* Seife, *supra* note 124.

184. *Sarepta Therapeutics (SRPT) Q4 2019 Earnings Call Transcript*, MOTLEY FOOL, https://www.fool.com/earnings/call-transcripts/2020/02/27/sarepta-therapeutics-srpt-q4-2019-earnings-call-tr.aspx [https://perma.cc/N8TE-ZHL3] (Sarepta's CEO projecting 2020 sales for eteplirsen (Exondys 51) at $420 million to $430 million).

185. Sarepta Therapeutics, Inc.'s Memorandum of Law in Opposition to Plaintiff's Combined Cross-Motion for Summary Judgment and Reply in Further Support of its Supplemental Motion for Summary Judgment, Seife v. FDA, No. 1:17-cv-03960, 2020 WL 5913525 (S.D.N.Y. Oct. 6, 2020),

The flaws we have identified in FOIA are not unique to the FDA, though they are perhaps particularly severe there. Margaret Kwoka,[186] David Pozen,[187] and other scholars[188] have analyzed the law and practice of FOIA across the entire federal government, exploring its limitations, pitfalls, values, and political economy. Pozen has criticized FOIA as "a distinctively 'reactionary' form of transparency."[189] We share these concerns for evident reasons.

Moreover, FOIA is not only bad for researchers; it is bad for the agency itself. FOIA impedes the core work of the FDA, as it consumes resources and employee time that could be used to other ends.[190] The costs are high: between 2008 and 2017, the FDA spent $305 million on FOIA at $2,653 per request.[191] User fees recover only a trivial fraction of these costs.[192] Shifting to an alternative disclosure system that reduces the number and complexity of the FOIA requests that the FDA processes could plausibly save tens of millions of dollars. This money could be used to create and sustain that alternative disclosure system.

C. The Role of the FDA in Proactive Data Publicity

Proactive disclosure by the FDA is the best way to break the logjam and make public the safety and efficacy data currently withheld by the FDA. Although this view aligns with more general critiques of FOIA,[193] the problem

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ECF No. 154; Defendants' Memorandum of Law in Opposition to Plaintiff's Renewed Cross-Motion for Summary Judgment and Reply Brief in Further Support of Defendants' Renewed Motion for Summary Judgment, Seife v. FDA, No. 1:17-cv-03960, 2020 WL 5913525 (S.D.N.Y. Oct. 6, 2020), ECF No. 157.

186. *See* Kwoka, *FOIA, Inc.*, *supra* note 23; Margaret B. Kwoka, *Inside FOIA, Inc.*, 126 YALE L.J. F. 265 (2016); Margaret B. Kwoka, *First-Person FOIA*, 127 YALE L.J. 2204 (2018).

187. Pozen, *Transparency's Ideological Drift*, *supra* note 22; Pozen, *Freedom of Information*, *supra* note 152; David E. Pozen, *The Leaky Leviathan: Why the Government Condemns and Condones Unlawful Disclosures of Information*, 127 HARV. L. REV. 512 (2013); David E. Pozen, *Deep Secrecy*, 62 STAN. L. REV. 257 (2010).

188. For other important recent work, see David C. Vladeck, *Information Access—Surveying the Current Legal Landscape of Federal Right-to-Know Laws*, 86 TEX. L. REV. 1787 (2008); Michael Herz, *Law Lags Behind: FOIA and Affirmative Disclosure of Information*, 7 CARDOZO PUB. L. POL'Y & ETHICS J. 577 (2009); TROUBLING TRANSPARENCY: THE HISTORY AND FUTURE OF FREEDOM OF INFORMATION (David E. Pozen & Michael Schudson eds., 2018); MARK FENSTER, THE TRANSPARENCY FIX: SECRETS, LEAKS, AND UNCONTROLLABLE GOVERNMENT INFORMATION (2017); Laurence Tai, *Fast Fixes for FOIA*, 52 HARV. J. ON LEGIS. 455 (2015); Jennifer Shkabatur, *Transparency With(out) Accountability: Open Government in the United States*, 31 YALE L. & POL'Y REV. 79 (2012); Kreimer, *supra* note 152.

189. Pozen, *Freedom of Information*, *supra* note 152, at 1097.

190. *Id.* at 1123–31.

191. Egilman et al., *supra* note 142, at 4.

192. *Id.* (showing that HHS as a whole spent $446.4 million on FOIA and recovered just $8.5 million in fees between 2008 and 2017).

193. *See* Kwoka, *FOIA, Inc.*, *supra* note 23, at 1429 ("Targeted, strategic affirmative disclosure . . . provides one of the most promising avenues for alleviating the privatization of FOIA and returning public information to its anticipated democratic use."); Pozen, *Freedom of Information*, *supra* note 152, at 1149 ("The most scalable approach . . . to transparency policy, and the most plausible substitute for the traditional FOIA model, is affirmative disclosure.").

at the FDA is still more acute because, when the industry and data sets are the targets, confidential commercial information and patient privacy arguments compound the general problems with FOIA.

The FDA has historically lacked the will to try proactive disclosure.[194] In 2006, Lurie and Zieve remarked that the FDA's tradition of disclosure lagged behind the rest of the Department of Health and Human Services (HHS).[195] What is different now? For one, there is growing enthusiasm among both academics and policy makers to examine and challenge corporate influence over regulatory agencies and to bolster those agencies' power, integrity, and accountability.[196] Political will for real reform may be building as well. President-elect Joe Biden has called for safety and efficacy data on any FDA-approved COVID-19 vaccine to "be made available to the public for independent expert review," as part of a "dedication to science, coordination, transparency, truth, and fairness to all . . . ."[197]

Moreover, the legal case for proactive disclosure has become both stronger and more urgent since June 2019 because of the Supreme Court's decision in *FMI*.[198] As noted above, *FMI* dealt further damage to the already broken FOIA system, making it harder than ever for researchers to use FOIA to get safety and efficacy data from the FDA. At the same time, the decision contained a little-noticed silver lining: it confirmed that agencies have authority to disclose information to the public even when that information is protected by FOIA Exemption 4. We propose creating a separate, functional proactive disclosure regime alongside FOIA that embraces this authority.

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194. O'Reilly and Fisher have explained how then-FDA Commissioner Frank Young and other FDA officials intervened during the negotiation and passage of the Hatch-Waxman Act in 1984 to express the view that the Act did and does not expand the agency's obligation to disclose safety and efficacy data, despite statutory language mandating that "[s]afety and efficacy data" "be made available to the public, upon request," under various circumstances. Pub. L. No. 98-417, 98 Stat. 1585, 1597 (1984) (codified at 21 U.S.C. § 355(l)); James T. O'Reilly, *Knowledge Is Power: Legislative Control of Drug Industry Trade Secrets*, 54 U. CIN. L. REV. 1, 20–21 (1985); Jane A. Fisher, *Disclosure of Safely and Effectiveness Data Under the Drug Price Competition and Patent Term Restoration Act*, 41 FOOD DRUG COSM. L.J. 268, 270–71, 280–81, 284 (1986).

195. Lurie & Zieve, *supra* note 98, at 96; *see also* Tai, *supra* note 142, at 429 (discussing FDA's self-imposed obstacles to proactive disclosure).

196. *See, e.g.*, Pozen, *Transparency's Ideological Drift*, *supra* note 22; Amy Kapczynski, *The Lochnerized First Amendment and the FDA: Toward a More Democratic Political Economy*, 118 COLUM. L. REV. ONLINE 179 (2018); K. Sabeel Rahman, *The New Utilities: Private Power, Social Infrastructure, and the Revival of the Public Utility Concept*, 39 CARDOZO L. REV. 1621, 1669 (2018).

197. *Statement from Joe Biden on COVID-19 Vaccines*, BIDEN/HARRIS, https://joebiden.com/2020/07/27/statement-from-vp-joe-biden-on-covid-19-vaccines/ [https://perma.cc/CM5K-GRL8].

198. Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356 (2019).

II.
REBOOTING THE BIG DATA REGULATOR

A. The FDA's Authority to Disclose Safety and Efficacy Data

Proactive disclosure of clinical trial data and other evidence of the risks and benefits of prescription drugs and vaccines is legal. Some commentators, especially in the pharmaceutical industry, have suggested that release of this information is simply illegal, whether because of the absence of authority to disclose or because of actual prohibition by statute.[199] The FDA itself has sometimes,[200] but inconsistently,[201] adopted this view. This view is mistaken. Proactive disclosure is permitted under existing law because agencies have the right to release data in their possession unless specifically prohibited by law. The Supreme Court[202] and members of the executive branch, including President Obama and the Solicitor General of the United States under President Trump, have repeatedly recognized this principle.[203] Congress formally recognized

199. *See, e.g.*, Francer & Turner, *supra* note 20, at 92 ("Federal law consistently has protected the confidentiality of companies' non-public clinical trial information provided to FDA as part of the new drug approval process, including study reports, protocols, and raw safety and effectiveness data."); Joseph G. Milner, *Sunlight and Other Disinfectants: Disclosure Obligations Under the Federal Securities and Drug Regulatory Regimes*, 72 FOOD & DRUG L.J. 141, 141 (2017) ("[A] trio of federal statutes requires FDA to keep sensitive information submitted by drug companies confidential."); Biotechnology Industry Organization (BIO), Comment Letter on FDA Proposed Rule "Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation" (Jan. 18, 2001), https://www.bio.org/advocacy/letters/disclosure-information [https://perma.cc/BVB6-DLCJ] (current FDA regulations and the United States Code prohibit the release of such information) [hereinafter BIO Comment Letter]; Pharmaceutical Research and Manufacturers of America (PhRMA), Comment Letter on FDA Draft Proposals for Public Comment Regarding Disclosure Policies (July 20, 2010), https://www.regulations.gov/contentStreamer?documentId=FDA-2009-N-0247-0252&attachmentNumber=1&contentType=pdf [https://perma.cc/C3D7-XFQS] [hereinafter PhRMA Comment Letter]. Lietzan has argued that prospective disclosure of safety and efficacy data by the FDA is not prohibited outright but should require compensation under the Takings Clause. *See* Lietzan, *A New Framework*, *supra* note 21. As we explain, *infra* Part II.C, this is incorrect.

200. Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1792 n.122 (1996) ("FDA has consistently taken the legal position that unpublished safety and effectiveness data submitted as part of an NDA are confidential and cannot be released to the public or used to support another manufacturer's NDA" (quoting Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 275 (1985))); *see* Lietzan, *A New Framework*, *supra* note 21, at 51–53 (collecting examples of the FDA expressing the view that it has no discretion to release safety and efficacy data).

201. *See, e.g.*, Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation, 66 Fed. Reg. 4688 (proposed Jan. 18, 2001) (expressing the view that the FDA has authority to disclose proactively, *inter alia*, certain safety and efficacy information); Robert Temple & Gordon W. Pledger, *The FDA's Critique of the Anturane Reinfarction Trial*, 303 NEW ENG. J. MED. 1488, 1488 (1980) (FDA publication criticizing a drug company's safety and efficacy claims and apparently disclosing to the public previously secret details of one of the drug company's clinical trials).

202. *See* Chrysler Corp. v. Brown, 441 U.S. 281, 309 n.39 (1979) and *infra* note 206.

203. *See* Brief for the United States as Amicus Curiae Supporting Petitioner at 32, *Food Mktg. Inst.*, 139 S. Ct. 2356 (2019) (No. 18-481) (Because "[FOIA] does 'not limit an agency's discretion to

agencies' proactive disclosure power in the federal "housekeeping statute,"[204] codified at 5 U.S.C. § 301, which grants all federal agencies general authority to disclose information in their possession.[205] In fact, the FDA already has statutory authority to release many varieties of data about pharmaceuticals, including metadata, summary data (aggregate data), and executable (analyzable) data from clinical trials, as well as certain real-world evidence gathered by the FDA. And FOIA is not itself a limit to disclosure, because while certain exemptions *permit* agencies to withhold information from requesters, no FOIA exemption standing alone requires agencies to withhold.[206]

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disclose information,'" "even if a district court's order *requiring* disclosure under FOIA is stayed pending appeal, the government could simply release the records itself, rendering any appeal moot," and "nothing in an appeal by a nongovernment person could prevent the agency's disclosure of its own records." (quoting *Chrysler*, 441 U.S. at 294)); Freedom of Information Act: Memorandum from Barack Obama, of the United States, for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 4683 (Jan. 21, 2009) ("The presumption of disclosure should be applied to all decisions involving FOIA. The presumption of disclosure also means that agencies should take affirmative steps to make information public."); Memorandum from the Attorney General for Heads of Executive Departments and Agencies Concerning the Freedom of Information Act (FOIA), 74 Fed. Reg. 51,879 (Oct. 8, 2009) ("I strongly encourage agencies to make discretionary disclosures of information. An agency should not withhold records merely because it can demonstrate, as a technical matter, that the records fall within the scope of a FOIA exemption."). At one point, the FDA itself recognized this principle. Public Information, 42 Fed. Reg. 3094, 3103 (Jan. 14, 1977) ("Agencies and departments subject to the FOIA may decide not to disclose exempt material; they are not required to withhold it.").

204. *Chrysler*, 441 U.S. at 309 n.39.

205. "The head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." 5 U.S.C. § 301. In *Chrysler*, the Supreme Court named § 301 as a source of authority for agencies to create proactive disclosure regulations. *Chrysler*, 441 U.S. at 309 n.40 ("This does not mean, of course, that disclosure regulations promulgated on the basis of § 301 are 'in excess of statutory jurisdiction, authority, or limitations' for purposes of § 10(e)(B)(3) of the APA, 5 U.S.C. § 706(2)(C)."). Certain circuit court decisions can be read to suggest that 5 U.S.C. § 301, as a "housekeeping" statute, does not provide agencies with "substantive" authority to craft regulations and policies concerning disclosure. *See, e.g.*, *In re* Bankers Trust Co., 61 F.3d 465, 470 (6th Cir. 1995); Exxon Shipping Co. v. U.S. Dep't of Interior, 34 F.3d 774, 777 (9th Cir. 1994). However, these decisions uniformly address and criticize agency efforts to *withhold* information from discovery under the alleged authority of § 301, in contravention of the statute's explicit command that "[t]his section does not authorize withholding information from the public or limiting the availability of records to the public." 5 U.S.C. § 301. These decisions do not hold that an agency cannot promulgate rules for proactive *disclosure* under the authority of § 301. *See* Gen. Eng'g, Inc. v. NLRB, 341 F.2d 367, 374 n.10 (9th Cir. 1965) (holding that the housekeeping statute is not "a convenient blanket to hide anything Congress may have neglected or refused to include under specific secrecy laws"). Agencies promulgated proactive disclosure regulations under the authority of § 301 at least as recently as the 1960s and '70s—*see, e.g.*, Sears, Roebuck & Co. v. Eckerd, 575 F.2d 1197 (7th Cir. 1978) *vacated by* Sears, Roebuck & Co. v. Eckerd, 441 U.S. 918 (1979); Chrysler Corp. v. Schlesinger, 565 F.2d 1172 (3d Cir. 1977), *vacated by* Chrysler Corp. v. Schlesinger, 441 U.S. 281 (1979)—and there is nothing in *Chrysler* or subsequent cases to prevent agencies from doing so in the future.

206. The Supreme Court has explained repeatedly that agencies' proactive disclosure authority extends not just to information *outside* the scope of the FOIA exemptions but to information *within* these exemptions, including FOIA Exemption 4. FOIA Exemption 4 merely *permits* agencies to withhold "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). In *Chrysler v. Brown*, the Court squarely held that FOIA Exemption 4 is an "exception to the disclosure mandate of the FOIA and not a limitation on agency discretion."

Existing limits on the FDA's disclosure of safety and efficacy data on prescription drugs primarily arise from two concerns: patient privacy and trade secrecy.[207] Patient privacy is a widely accepted value[208] and one we share. Privacy is a vital concern any time clinical data is shared, and the risk of violation of patient privacy is particularly critical when individual patient data is released. Privacy concerns are even more pronounced when the patient population is stigmatized, as in trials of medical abortion drugs or treatments for sexually transmitted infections. Privacy is harder to protect where the clinical study size is small or the disease is rare. The FDA currently, and properly, exempts from disclosure any data that "constitutes a clearly unwarranted invasion of personal privacy,"[209] and the agency discloses safety and efficacy data only after the data has been "deidentified" to remove information that readily identifies individual patients to protect patient privacy.[210] As explained in Part II.B, the FDA's rules and practices on deidentification appear reasonable and should be incorporated into the "rebooted" data publicity regime we propose. Existing protocols for deidentification make the practice a viable one for the agency and for researchers.[211] As we discuss below, reidentification is a potential concern, and data use agreements can and should be used to forbid it.[212]

However, we disagree with the FDA's stance on trade secrecy and the related concept of CCI. That stance is currently the central obstacle to

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Chrysler, 441 U.S. at 291 n.11. "[T]he FOIA by itself protects the submitters' interest in confidentiality only to the extent that this interest is endorsed by the agency collecting the information." *Id.* at 293. "Congress did not limit an agency's discretion to disclose information when it enacted the FOIA." *Id.* at 294. In *Ruckelshaus v. Monsanto Co.*, the Court concluded that even if certain health, safety, and environmental data about pesticides submitted to the EPA were trade secrets, the Federal Government had the authority to disclose that data as long as it did not provide assurances to the company that it would not do so. 467 U.S. 986, 1004–05 (1984). The Supreme Court's recent decision in *FMI* again confirms, albeit with little fanfare, that federal agencies possess discretion to proactively disclose material that falls within the scope of FOIA Exemption 4. *Food Mktg. Inst.*, 139 S. Ct. at 2362. In *FMI*, respondent Argus Leader argued that the petitioner's "injury is not redressable because a favorable ruling would merely restore the government's *discretion* to withhold the requested data under Exemption 4, and it might just as easily choose to provide the data anyway." *Id.* The Court dismissed this argument not by questioning the agency's (USDA) discretionary authority to disclose the requested data but instead by relying on the agency's assurances that it would not exercise that authority unless compelled to do so by court order. *Id.* As such, *FMI* implicitly acknowledged the agency's discretion to disclose information eligible for withholding under FOIA Exemption 4.

207. *See, e.g.*, *FDA's Clinical Data Summary Pilot Program: Questions Frequently Asked by Industry*, FDA (May 2, 2018), https://www.fda.gov/drugs/development-approval-process-drugs/fdas-clinical-data-summary-pilot-program-questions-frequently-asked-industry [https://perma.cc/38ZL-CEGJ] ("FDA will redact selected portions of the CSRs for trade secrets, confidential commercial information, and personal privacy information."). FOIA formally reflects both of these concerns in 5 U.S.C. § 552(b)(4) (trade secrets and CCI) and § 552(b)(6) (personal privacy).

208. *The Value and Importance of Health Information Privacy*, *in* BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH (Sharyl J. Nass, Laura A. Levit & Lawrence O. Gostin eds., 2009).

209. 21 C.F.R. § 20.63 (2019). *See also id.* § 20.82(b)(2).

210. *See infra* Part II.B.

211. *See id.*

212. *See id.*

meaningful public access to safety and efficacy data on prescription drugs.[213] The FDA's professed concern over trade secrecy arises from two distinct federal trade secrecy statutes that govern the FDA: section 301(j) of the Food, Drug, and Cosmetic Act (FDCA), codified at 21 U.S.C. § 331(j), and the Trade Secrets Act (TSA), codified at 18 U.S.C. §§ 1905-1909—but the FDA's concern also implicates other sources of trade secrecy law, including FOIA, the Uniform Trade Secrets Act (UTSA), and other state-level trade secrecy laws.[214] We consider each and show that none of these sources of law creates an impassable barrier to data publicity.

1. Section 301(j) of the Food, Drug, and Cosmetic Act (FDCA)

The first statute—section 301(j) of the FDCA—is no barrier to safety and efficacy data publicity at all. Section 301(j) only prohibits "revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired . . . concerning any method or process which as a trade secret is entitled to protection . . . ."[215] Contrary to the FDA's prevailing view that this section covers some safety and efficacy data,[216] the statutory language is limited to manufacturing information—information "concerning any method or process"—and no court has ever construed § 301(j) to cover safety or efficacy data. The Tenth Circuit has held that § 301(j) "is arguably narrower than [the already narrowly construed trade secret provision of FOIA] Exemption 4 in that

213. *See supra* notes 199–200 and accompanying text.

214. The FDA has, at times, improperly conflated these sources. *See, e.g.*, Trade Secrets and Commercial or Financial Information that Is Privileged or Confidential, 39 Fed. Reg. 44,612 (Dec. 24, 1974) ("[I]t is not feasible or practical to determine the differences, if any, between the confidentiality provisions in 18 U.S.C. 1905 and 21 U.S.C. 331(j), and in the Freedom of Information Act. If there are any differences, they are extremely subtle and small. Accordingly, the Commissioner intends, for practical reasons of daily administration of the law, to regard the coverage of these provisions as identical.").

215. 21 U.S.C. § 331(j). Yaniv Heled has observed that FDCA § 301(j) poses an obstacle to the FDA's disclosure of biologics manufacturing information and has argued that Congress should consider amending it. Yaniv Heled, The Case for Disclosure of Biologics Manufacturing Information, 47 J.L. MED. & ETHICS 54, 63 (2019).

216. *See, e.g.*, Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports, 65 Fed. Reg. 64,607, 64,612 (Oct. 30, 2000) ("FDA will not disclose any information from postmarketing study reports that is considered a trade secret as defined in § 20.61(a) and section 301(j) of the act (21 U.S.C. 331(j)) . . . ."); 39 Fed. Reg. 44,602, 44,612, 44,633 (1974) (stating that "[u]nder the Federal Food, Drug, and Cosmetic Act, . . . the safety and effectiveness data for new drugs and new animal drugs, including antibiotic drugs for veterinary use, fall within the trade secrets exemption" and that "[e]ven if [disclosure of trade secrets and CCI] would be in the public interest, in order to protect the public health, and even if the Commissioner wishes as a matter of discretion to release such material, such disclosure cannot lawfully be undertaken"); *see also* Francer & Turner, *supra* note 20, at 92; Milner, *supra* note 199; BIO Comment Letter, *supra* note 199; PhRMA Comment Letter, *supra* note 199. *But see* Lietzan, A New Framework, *supra* note 21.

it is limited to information relating to methods or processes whereas Exemption 4 applies to all trade secret information."[217]

2. The Trade Secrets Act (TSA)

The second statute, the TSA,[218] requires somewhat more extensive analysis, but ultimately it, too, creates no legitimate barrier to disclosure of the safety and efficacy data we describe above.[219] The TSA is a criminal statute that prohibits federal employees from disclosing certain confidential information when not "authorized by law":

> Whoever, being an officer or employee of the United States or of any department or agency thereof, . . . publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; . . . shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.[220]

Under the plain text of the Act, disclosure of trade secrets is permissible whenever "authorized by law." The FDA, as we explain below, has the statutory authority to disclose safety and efficacy data, making such disclosure "authorized by law" and within the power of the FDA.[221] The agency need not even evaluate whether the data in question is a trade secret, but as we explain below,[222] can simply promulgate a rule that explicitly authorizes disclosure "by law" and thus avoid conflict with the TSA. The data use agreements we advise below[223] would also permit the agency to contractually prohibit behavior that would violate trade secrecy law, and further insulate regulators from any sanction under the TSA.

However, agencies are undoubtedly more likely to release information that they believe does not rise to the level of trade secret protection, so we first

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217. Anderson v. Dep't of Health & Human Servs., 907 F.2d 936, 951 (10th Cir. 1990). Cf. Pub. Citizen Health Rsch. Grp. v. FDA, 704 F.2d 1280, 1287 n.19 (D.C. Cir. 1983) (proffering, in dicta, a narrow interpretation of § 301(j)). *See also* Richard S. Fortunato, FDA Disclosure of Safety and Efficacy Data: The Scope of Section 301(j), 52 FORDHAM L. REV. 1280, 1283 (1984) (explaining why section 301(j) should be construed narrowly); McGarity & Shapiro, *supra* note 19, at 886–87 (same).

218. 18 U.S.C. §§ 1905–1909.

219. *See supra* Part I.A.

220. 18 U.S.C. § 1905.

221. We identify two statutory sources of this authority: 21 U.S.C. § 355(r) and § 371(a). *See infra* Part II.A.

222. *See infra* Part II.A.

223. *See infra* Part II.B.4.

explain why clinical trial data will not generally be protected by trade secrecy law generally. Two questions arise when assessing whether the TSA even covers safety and efficacy data. The first is whether clinical trial data can ever be considered trade secrets, even under the most expansive understanding of that term. The second is whether the TSA incorporates a narrow or broad definition of "trade secret."

As to the first question, safety and efficacy data generally will not meet the definition of a trade secret under current law. State trade secrecy laws are grounded in the UTSA and common law. These laws generally sweep broadly to protect any information that is secret, is subject to reasonable efforts to maintain its secrecy, and that "derives independent economic value" from being secret from competitors who can "obtain economic value from its disclosure or use."[224] The data we seek would rarely meet even this broad definition, contrary to the industry's assertions.[225] First, by its nature, safety and efficacy data has little or no direct value to brand-name competitors developing alternative compounds and thus will confer minimal or no competitive advantage to the company on whose behalf the FDA is currently maintaining secrecy. While PhRMA, one of the two largest pharmaceutical industry trade organizations in the world, has contended that safety and efficacy data "would provide competitors with relevant insight into how to develop other, competitive products,"[226] courts have held that most safety and efficacy data from clinical trials have no demonstrable competitive value.[227] Regarding individual patient-level data, competitors generally cannot use "subject-specific data to demonstrate the safety or effectiveness of other products," because "[t]he slightest change in the pharmaceutical formulation or dosage" from an existing drug to a new one can

224. *See* UNIF. TRADE SECRETS ACT § 1(4) (UNIF. L. COMM'N 1985) ("'Trade secret' means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use."); *see also* Restatement (Third) of Unfair Competition at § 39 (Am. L. Inst. 1995).

225. *See, e.g.*, PhRMA Comment Letter, *supra* note 199 (asserting that disclosure of safety and efficacy data "could cause grave competitive harm to the research-based biopharmaceutical industry—and subsequently damage incentives to take new products through the costly drug approval process").

226. *Id.*

227. *See, e.g.*, Pub. Citizen Health Rsch. Grp. v. FDA, 704 F.2d 1280, 1290, 1290 n.28 (D.C. Cir. 1983) ("[N]ot every bit of information submitted to the government by a commercial entity qualifies for protection under Exemption 4."); Pub. Citizen Health Rsch. Grp. v. Dep't of Health, Educ. & Welfare, 477 F. Supp 595, 605 (D.D.C. 1979), reversed by Public Citizen Health Rsch. Grp. v. Dep't of Health, Educ. & Welfare, 668 F.2d 537 (D.C. Cir. 1981) (holding medical documents that contained "no data concerning fees, payment schedules, or other commercial arrangements [and] . . . no information about secret formulas or rare treatment methods" did not constitute "commercial information"); AIDS Healthcare Found. v. FDA, No. 11-cv-07925-MMM (JEMx) (C.D. Cal. Aug. 6, 2013) at 21 ("FDA has not established a likelihood that disclosure of the data summaries and analyses withheld under Exemption 4 would cause substantial competitive injury."); *see also* Teich v. FDA, 751 F. Supp. 243, 253–54 (D.D.C. 1990) (holding that preclinical data on breast implants did not qualify as CCI); Pub. Citizen Health Rsch. Grp. v. FDA, 964 F. Supp. 413, 415–16 (D.D.C. 1997) (suggesting that a clinical trial protocol was not CCI).

render the data unacceptable for approval of the new drug.[228] Incomplete but nonetheless informative summaries of much of the same safety and efficacy data must already be disclosed via ClinicalTrials.gov and the FDA's Drugs@FDA website,[229] blunting whatever adverse competitive impact disclosure of the complete set of safety and efficacy data could have. Courts have ruled that clinical trial protocols can in general be released by the FDA, concluding that they do not meet the definition of CCI (more capacious even than trade secrets) under FOIA Exemption 4. By the time a drug is approved, years have likely passed since the clinical trials relied on for approval were designed. This increases the likelihood that details of those trials' designs have been disclosed through other means, thus decreasing their competitive value.

Some worry that releasing safety and efficacy data would undermine periods of data exclusivity.[230] "Data exclusivity" law forbids a generic competitor from relying on originator data when seeking an abbreviated application for a follow-on generic or biosimilar drug. But a generic company that could obtain a full data set from the originator might theoretically instead seek to have its product approved as an original rather than a generic or biosimilar drug, evading data exclusivity.[231] As we explain below, the FDA can and should impose data use agreements on data users, which would prohibit competitors from making this kind of use of the data.[232] Data sharing in this fashion will not undermine data exclusivity in the United States. PhRMA has also contended that disclosure of safety and efficacy data would cause competitive harm overseas, because "these data could be used to support approval in virtually every other country in the world, even after redaction of trade secret information."[233] An analysis of drug regulatory processes in leading

228. Pub. Citizen Health Rsch. Grp. v. FDA, No. Civ.A. 99–0177(JR), 2000 WL 34262802, at *1, *3 (D.D.C. Jan. 19, 2000).

229. *See supra* Part I.B. Some courts have held, in the FOIA context, that when federal law requires publication of certain information (e.g., publication of clinical trial results on ClinicalTrials.gov), that information should be deemed public by operation of law, even if not actually published in practice. *See, e.g.*, Inner City Press/Cmty. on the Move v. Bd. of Governors of the Fed. Rsrv., 463 F.3d 239, 249 (2d Cir. 2006).

230. *See* Francer & Turner, *supra* note 20, at 76 ("Patent and data exclusivity protections may prove insufficient if safety and effectiveness data at the patient-level are disclosed."); *see also* Frequently Asked Questions on Patents and Exclusivity, FDA (Feb. 2, 2020), https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity [https://perma.cc/B9VB-Y2GW]. For helpful overviews of different FDA-granted exclusivities, including distinctions between "data exclusivity" and "market exclusivity," see Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299, 314–17 (2015); Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 103 (2016).

231. PhRMA Comment Letter, *supra* note 199, at 30 (describing PhRMA's concern that "no aspect of United States law would prevent a competitor from re-submitting [safety and efficacy data] to support approval of a subsequent NDA for its own drug").

232. *See infra* Parts II.B.4, II.C.1.

233. *Id.*

foreign jurisdictions shows that these concerns are exaggerated.[234] Foreign jurisdictions make their own decisions about how much data to require and how to enforce data exclusivity where it exists, as is appropriate given the general principle of territorial application of U.S. intellectual property law.[235]

Could *any* safety and efficacy data have legitimate competitive value and thus qualify as a trade secret under a broad state law definition? The EMA offers helpful guidance here: it has explained that, for purposes of EU law, only data that bears "innovative features" qualifies for secrecy.[236] An EMA advisory committee enumerated examples of the relatively few subcategories of safety and efficacy data likely to bear such features, which include new assay methodologies for biomarkers, methods to pursue newly validated endpoints, and novel trial designs that streamline and make more economical proof of efficacy.[237] Public Citizen's Health Research Group has endorsed the EMA advisory committee's list as illustrative of the rare circumstances under which safety and efficacy data might qualify for protection as a trade secret or CCI.[238] We agree with the EMA and with Public Citizen that the safety and efficacy data in routine drug applications generated via established clinical protocols will

234. *See* AMY KAPCZYNSKI, THE INTERACTION BETWEEN OPEN TRIAL DATA AND DRUG REGULATION IN SELECTED DEVELOPING COUNTRIES 3 (2014), available at https://law.yale.edu/sites/default/files/area/center/ghjp/documents/kapczynski_interaction_between_open_data_report_for_nam_.pdf [https://perma.cc/P235-TRRT]. In 2013, industry critics of the EMA's safety and efficacy data publicity plan (Policy 0070) warned of "the potential for inappropriate use of such data by third parties either to circumvent existing regulatory data protection (RDP) rules, or take advantage of the absence of such rules in the many countries which do not have robust systems of RDP equivalent to that in the EU," such as Australia, China, and Mexico. *See* ADVICE TO THE EUROPEAN MEDICINES AGENCY ON RULES OF ENGAGEMENT FOR ACCESSING CLINICAL TRIAL DATA, CLINICAL TRIAL ADVISORY GRP. ON RULES OF ENGAGEMENT (CTAG3) 2 (Apr. 4, 2013), http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142859.pdf [https://perma.cc/7599-MPSN]. In the several years since EMA's Policy 0070 has made safety and efficacy data available, we are aware of no such inappropriate use and no serious competitive harm to the original submitters of that data.

235. *See* Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 531 (1972).

236. EUR. MEDS. AGENCY, *supra* note 136, at 54–59.

237. *Advice to the European Medicines Agency on Rules of Engagement for Accessing Clinical Trial Data*, *supra* note 234, at 1. The Court of Justice of the European Union (CJEU) apparently approved this understanding in the *PTC Therapeutics* decision issued in early 2020, where the court endorsed the EMA's proactive release of safety and efficacy data contained in a clinical study report. Judgment in Case C-175/18 P, PTC Therapeutics Int'l Ltd. v. Eur. Meds. Agency, ECLI:EU:C:2020:23 (Jan. 22, 2020). The CJEU noted, approvingly, that the EMA had redacted a relatively narrow set of data from the report because of concern for patient privacy and possible competitive harm: "certain passages containing references to protocol design discussions with the US Food and Drug Administration, batch numbers, materials and equipment, exploratory assays, the quantitative and qualitative description of the method for drug concentration measurement, and the start and end dates of treatment and additional dates that could lead to the identification of patients." *Id.* at ¶ 64. The CJEU upheld EMA's decision to release of the remainder of the report, concluding that the drug company had not "specifically and precisely identified" how disclosure of any of the remaining information in the clinical study report "could harm its commercial interests." *Id.* at ¶ 82.

238. *See* Sarah Sorscher & Michael Carome, *Submission of Comments on 'Policy 0070 on Publication and Access to Clinical-Trial Data,'* PUB. CITIZEN 6 (2013), https://www.citizen.org/wp-content/uploads/migration/2163.pdf [https://perma.cc/FK7H-FCXQ].

likely contain no "innovative features" whatsoever and thus not qualify for secrecy, whatever the definition of trade secret or CCI applied.[239] However, these rare circumstances cannot be *a fortiori* ruled out, making redactions and data use agreements sometimes important to effective data publicity.

All of the foregoing analysis considered a first question of whether safety and efficacy data constitute a trade secret under the broad definition of trade secrecy that prevails at the state level. Also pertinent is a second question regarding the scope of the TSA's definition of "trade secrets" as it is the TSA, not state law, that directly applies to FDA officials. We believe that definition should be narrowly construed, lest it encompass a great deal of information that is important to the public, but of minimal importance to business. The TSA was adopted, notably, in 1948, an era when trade secret law was less capacious.[240] The Seventh Circuit has suggested that Congress likely intended that the TSA—a "rather obscure criminal statute"—to at most prevent agencies from releasing "that narrower category of trade secrets—secret formulas and the like—whose disclosure could be devastating to the owners and not just harmful."[241] In

239. *See supra* notes 235–237.

240. The most influential statement of trade secrecy protection was then the First Restatement of Torts, which is commonly understood to have defined a narrower scope for trade secrecy law than did the UTSA or the Restatement (Third) of Unfair Competition, both elaborated in the 1980s. *See generally* Edmund W. Kitch, *The Expansion of Trade Secrecy Protection and the Mobility of Management Employees: A New Problem for the Law*, 47 S.C. L. REV. 659 (1996) (cataloguing the differences between various formulations of trade secrets). The TSA also codifies a handful of older federal anti-disclosure statutes, each narrowly focused on protecting closely held manufacturing and financial information shared with government employees. *See* Chrysler Corp. v. Brown, 441 U.S. 281, 296–98 (1979) (tracing history of TSA); Mark Q. Connelly, *Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosures of Business Data*, 1981 WIS. L. REV. 207, 230 (trade secrets).

241. *See* Gen. Elec. Co. v. U.S. Nuclear Regulatory Comm'n, 750 F.2d 1394, 1402 (7th Cir. 1984). In 1983 the D.C. Circuit also endorsed a narrow construction of the TSA in dicta. Pub. Citizen Health Rsch. Grp. v. FDA, 704 F.2d 1280, 1287 (D.C. Cir. 1983) (reasoning that "health and safety data submitted to the FDA" would not meet the definition of "trade secrets under the federal TSA . . . "). Oddly, the D.C. Circuit has elsewhere held that the TSA is broad in scope, possibly even broader than FOIA Exemption 4. *See, e.g.*, CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1151–52 (D.C. Cir. 1987) ("[T]he scope of the [Trade Secrets] Act is at least co-extensive with that of Exemption 4 of FOIA, and . . . in the absence of a regulation effective to authorize disclosure, the Act prohibits [the Office of Federal Contract Compliance Programs] from releasing any information . . . that falls within Exemption 4." (citations omitted)). However, the D.C. Circuit subsequently suggested the view, later affirmed by the Supreme Court in *FMI*, that the TSA must be narrower than FOIA Exemption 4, such that some material covered by Exemption 4 can be released at the agency's discretion. *See* Pub. Citizen Health Rsch. Grp. v. FDA, 185 F.3d 898, 903 (D.C. Cir. 1999) (certain information in IND applications "*may* be withheld if the agency carries its burden under Exemption 4 of the FOIA" (emphasis added)). Commentators have also argued that "trade secrets" and other purportedly confidential information should receive narrow and thin protection in public law contexts, as when information is submitted to government agencies or created by private industry with public money. *See* David S. Levine, *Secrecy and Unaccountability: Trade Secrets in Our Public Infrastructure*, 59 FLA. L. REV. 135, 191–92 (2007) [hereinafter Levine, *Secrecy and Unaccountability: Trade Secrets in Our Public Infrastructure*]; Mary L. Lyndon, *Secrecy and Access in an Innovation Intensive Economy: Reordering Information Privileges in Environmental, Health, and Safety Law*, 78 U. COLO. L. REV. 465, 498 (2007)*; see also* David S. Levine, *The People's Trade Secrets?*, 18 MICH. TELECOMM. & TECH. L. REV. 61 (2011) [hereinafter Levine, *The People's Trade Secrets*]; Levine, *The Impact of Trade Secrecy*, *supra* note 20, at 438; Peter

Ruckelshaus v. Monsanto, the Supreme Court also gave the TSA little weight in a case about agencies' power to release "health and safety data" under the Takings Clause.[242] Moreover, on two occasions, it appears the FDA has proactively disclosed discrete non-public safety and efficacy data on FDA-approved drugs when doing so served the public interest.[243] To our knowledge, the FDA faced no litigation or other negative consequences after these actions.

a. Statutory Authority to Promulgate Regulations: the FDCA and the Food and Drug Administration Amendments Act of 2007 (FDAAA)

Finally, the TSA prohibits disclosure of trade secret information only when that disclosure is "not authorized by law."[244] This means that the FDA can legally disclose safety and efficacy data *even if* that data is deemed a trade secret, so long as the FDA makes the disclosure pursuant to an authorizing regulation with proper "force of law."[245] An agency disclosure regulation has the "force of law" when promulgated under a grant of Congressional authority via statute.[246] Data

S. Menell, *Tailoring a Public Policy Exception to Trade Secret Protection*, 105 CALIF. L. REV. 1 (2017); *cf.* Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 YALE J.L. & TECH. 61 (2020) (arguing that the true prices paid for pharmaceuticals should not be protected from disclosure by regulators as a trade secret or CCI).

242. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1001–02, 1008–09 (1984) (concluding that the Trade Secrets Act was "not a guarantee of confidentiality to submitters of data," even in a case where it assumed the information was a trade secret under state law).

243. In 1980, the FDA published a letter in the New England Journal of Medicine criticizing an article a drug company had published in the same journal. The drug company's article suggested that a clinical trial proved that an already-approved drug (Anturane) was safe and effective for an as-yet unapproved (off label) method of use. The FDA's letter provided a detailed critique of the trial and the drug company's claims and apparently disclosed to the public previously secret data from the trial—data that could have qualified as CCI under the FDA's definition. *See* Temple & Pledger, *supra* note 201. In *Pub. Citizen Health Rsch. Grp. v. FDA*, No. 04-304 (D.D.C. Feb. 26, 2004), the FDA settled a FOIA litigation and released NDA documents concerning unapproved uses of the FDA-approved drug valdecoxib (Bextra) that may have been deemed CCI, at least at the time of the litigation. This case is described in Lurie & Zieve, *supra* note 98.

244. 18 U.S.C. § 1905.

245. *See* Memorandum from William B. Schultz to Allan Coukell, Director, Pew Prescription Project 4 (Aug. 5, 2009), https://www.regulations.gov/document?D=FDA-2009-N-0247-0097 [https://perma.cc/E6QS-DLMF] ("[I]t is not necessary to address [the question of whether clinical data is protected by the TSA] because the Trade Secret bar does not apply where disclosure is authorized by law."); *see also* INST. OF MED. OF THE NAT'L ACADS., *supra* note 18 at 71 ("One important open question is the extent to which the FDA may have the authority to issue regulations that override the ordinary constraints of the TSA.").

246. Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979) ("The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes."); *see also* Qwest Commc'ns Int'l Inc. v. FCC, 229 F.3d 1172, 1177 (D.C. Cir. 2000) (interpreting *Chrysler* and holding that the relevant question is "whether [a] reviewing court could reasonably conclude that the statutory grant of authority contemplated the regulations providing for release of information"). According to the Supreme Court, an "authoriz[ing]" pro-disclosure regulation, for purposes of the TSA, must have "force and effect of law." *Chrysler*, 441 U.S. at 298, 301. Assuming it is promulgated with proper process, a disclosure regulation has the requisite force and effect of law so long as there is "a nexus between the regulations and some delegation of the requisite legislative authority by Congress." *Id.* at 304. The nexus standard is permissive: "[t]he

use agreements that limit who uses data and how those users use that data will further shield the FDA, as we describe below.[247]

Two distinct statutes empower the FDA to promulgate an authorizing regulation, with force of law, to permit or require disclosure of safety and efficacy data without risk of criminal liability under the TSA. One is the general purpose rulemaking provision of the Food, Drug, and Cosmetics Act (FDCA).[248] Section 701(a) of the FDCA grants the FDA blanket "authority to promulgate regulations for the efficient enforcement of" the FDCA, including the FDCA's mandate to "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective."[249]

The other statute is a more recent provision of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which expanded the FDA's already broad mandate to disclose information on drug safety.[250] Subsection (r)(1) compels the Secretary of HHS to "improve the transparency of information about drugs and allow patients and health care providers better access to

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pertinent inquiry is whether under any of the arguable *statutory* grants of authority the . . . disclosure regulations . . . are reasonably within the contemplation of that grant of authority." *Id.* at 306; *see also id.* at 308 ("This is not to say that any grant of legislative authority to a federal agency by Congress must be specific before regulations promulgated pursuant to it can be binding on courts in a manner akin to statutes. What is important is that the reviewing court reasonably be able to conclude that the grant of authority contemplates the regulations issued."); Parkridge Hosp. v. Califano, 625 F.2d 719, 724 (6th Cir. 1980) (holding that a statute that provided, generally, that "no disclosure . . . shall be made except as the Secretary may by regulations prescribe" met the *Chrysler* nexus standard (citing 42 U.S.C. § 1306(a))).

247. *See infra* Part II.B.4.

248. 21 U.S.C. § 371(a) (corresponds to the Food, Drug, & Cosmetic Act, § 701(a), 52 Stat. 1040).

249. 21 U.S.C. § 393(b)(1)–(2). The FDA has expressed a justifiably expansive view of its powers under § 371(a), stating that it "gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the [FDCA]." Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation, 66 Fed. Reg. 4688, 4694 (proposed Jan. 18, 2001). The FDA explicitly recognized that § 371 authorizes it to disclose even information protected by the TSA. "FDA's issuance of this proposed rule is authorized even if the information to be disclosed could be considered confidential commercial information covered by Exemption 4 and within the scope of protection of the Trade Secrets Act (18 U.S.C. 1905)." *Id.* The FDA ultimately withdrew the proposed rule but did not repudiate its interpretation of FDCA § 371(a). *See* 67 Fed. Reg. 33040, 33045 (withdrawing the proposed rule without comment). Courts endorse a broad interpretation of the FDA's power to regulate under § 371(a). *See* Nat'l Ass'n of Pharm. Mfrs. v. FDA, 637 F.2d 877, 889 (2d Cir. 1981) (holding that 21 U.S.C. § 371(a) confers power to make substantive regulations that are binding); Pharm. Mfrs. Ass'n v. FDA, 484 F. Supp. 1179, 1183 (D. Del. 1980) (holding that § 371(a) "has been broadly construed to uphold a wide variety of assertions of regulatory power," so long as regulations promulgated under § 371(a) "effectuate a Congressional objective expressed elsewhere in the [FDCA]"); *see also* United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 246 (2d Cir. 1977) (holding generally that "[w]hen agency rulemaking serves the purposes of the statute, courts should refuse to adopt a narrow construction of the enabling legislation which would undercut the agency's authority to promulgate such rules").

250. 21 U.S.C. § 355(r). On the mandate, see *supra* Part I.B (explaining, *inter alia*, FDAAA's mandate to disclose safety and efficacy data through ClinicalTrials.gov and approval packages); *see also* Andrew C. von Eschenbach, *The FDA Amendments Act: Reauthorization of the FDA*, 63 FOOD & DRUG L.J. 579, 581 (2008) (describing FDAAA as "massive legislation" informed by a "spirit of transparency").

information about drugs by developing and maintaining an Internet Web site" that "improves communication of drug safety information to patients and providers."[251] Disclosure of safety and efficacy data by the FDA pursuant to a regulation promulgated under either of these statutes would constitute disclosure "authorized by law."

Below we outline the data publicity regime that the FDA should create through regulation.[252] We close this subpart by observing that when the FDA creates regulations authorizing and implementing disclosure of safety and efficacy data, it can and should concomitantly revise its set of existing disclosure regulations, which insufficiently define and support the agency's proactive disclosure power.[253] The FDA should embrace its proactive disclosure authority and provide stakeholders with notice and certainty. The FDA should revise its rather vague definition of CCI[254] to match the EMA's definition[255] and clarify that only safety and efficacy data that has a genuine "commercial or financial" character qualifies as CCI. This revision should set out in advance clear examples of what may qualify and what likely will not. The FDA should also rescind 21 CFR § 20.61(c), which unnecessarily surrenders the agency's discretionary disclosure authority by promising that "[d]ata and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure." Short of rescission, the FDA should at least specify in a new, superseding rule that § 20.61(c) does not apply to safety and efficacy data.[256] The FDA should also revise scattered rules that promise, or can

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251. 21 U.S.C. § 355(r), (r)(1). Congress did not cabin the proper scope of HHS's authority (or that of its delegee, FDA) to disclose of drug safety information but instead explicitly extended its discretion to define and disclose "other material determined appropriate by the Secretary." 21 U.S.C. § 355(r)(2)(B)(vii). While the phrase "other material determined appropriate by the Secretary" has not, at time of writing, been interpreted by any court, it seems clear that Congress intended to authorize FDA to disclose information protected as a "trade secret" or as "confidential commercial information." In another subsection of the same section of FDAAA (§ 355(l)(2)), written at the same time, Congress explicitly withheld authorization to disclose information that qualifies as a trade secret or CCI, but Congress did not withhold this authorization in subsection (r). *Compare* 21 U.S.C. § 355(r) (which places no limits on disclosure) *with id.* § 355(l)(2) (the provision of FDAAA that requires "[p]ublic disclosure of safety and effectiveness data and action package[s]" but which explicitly "does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5."). As explained above, *supra* Part I.A, drug safety and drug efficacy are inexorably linked, and the mandate of § 355(r) to publicize "information about drugs" and "drug safety information" should be understood to encompass safety in the context of a particular use—that is, safety in the context of efficacy.

252. *See infra* Part II.B.

253. *See supra* note 158; *see also* Schultz, *supra* note 245, at 4 ("The only bar to releasing clinical information submitted in connection with NDAs and INDs is FDA's own regulation.").

254. *See* 21 C.F.R. § 20.61(b) (2019).

255. *See supra* text accompanying note 236.

256. The FDA should also rescind 21 C.F.R. § 20.82(b)(1), which declares that any information that meets the FDA's definition of CCI or a trade secret will not be disclosed. Once these regulations have been duly rescinded, the FDA will have no legal obligation to provide the companies that submit safety and efficacy data with notice or an opportunity to be heard before the FDA proactively discloses

be construed to promise, secrecy for specific submissions of safety and efficacy data.[257]

B. Rebooting the FDA's Disclosure Rules: A Roadmap to Data Publicity

We have explained that the FDA has all the statutory authority it needs to proactively disclose safety and efficacy data on pharmaceuticals. The only step required to reboot the FDA's data disclosure is for the agency to promulgate and implement, pursuant to that statutory authority, a relatively simple set of authorizing rules that establish procedures for effective data publicity oriented around non-commercial uses and public health. Here we provide a high-level roadmap to those rules, including what we believe are four key features:

(1) Prospectively disclosing data on all newly approved drugs;

(2) Retrospectively disclosing historical data on a limited number of important drugs;

(3) Requiring the industry to submit its clinical data in redacted, publicly disclosable form to minimize burden on the FDA; and

(4) Requiring users to make data requests and enter into data use agreements to prevent misuse of sensitive data.

These four features are intended to ensure effective clinical trial publicity while assuaging the two chief concerns that have historically limited the FDA's data disclosure: patient privacy and trade secrecy. The fourth feature will be particularly valuable because data use agreements will not only help to protect patient privacy and relieve any lingering concerns over trade secrecy, but will also increase flexibility, reduce administrative costs, and limit the agency's potential legal liability.

1. Prospective Disclosure of Data on All Newly Approved Drugs

Going forward, the FDA should disclose the safety and efficacy data we described above[258]—metadata, summary data (including FDA analyses), and individual participant data—for all the drugs it approves. Disclosure should occur on the day of, or immediately after, approval because it is in the months following approval that safety and efficacy data is most useful. [259] Of course, the FDA should also disclose later-collected safety and efficacy data from studies of

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that data. *See* Pharm. Mfrs Ass'n v. Weinberger, 401 F. Supp. 444, 447–49 (D.D.C. 1975) (denying request for preliminary injunction to provide notice and an opportunity to be heard). Executive Order 12600 requires the FDA and other agencies to notify submitters when agencies receive FOIA requests that implicate FOIA Exemption 4, but the Order does not require notification in the event that the same information is disclosed through other legal avenues. Exec. Order No. 12,600, 52 C.F.R. 23,781 (June 23, 1987).

257. *See* Sharfstein et al., *supra* note 19, at 8 n.7 (listing specific anti-disclosure rules that govern different types of applications submitted to the FDA). An important example is 21 C.F.R. § 314.430. *See supra* note 158.

258. *See supra* Part I.A.

259. *See supra* Part I.A.

already-approved products, including Phase 4 studies submitted to the FDA (e.g., under postmarketing requirements and commitments)[260] and Phase 2 and 3 studies submitted to support approval of new indications.

Disclosing data for all FDA-approved drugs will ensure that all patients have access to information about the drugs they are putting in their bodies, regardless of whether the drug is a blockbuster taken by millions of patients or an orphan drug used by only a handful. Given that the costs of preparing data for disclosure will be borne by the pharmaceutical industry, not the FDA,[261] we see no reason for the FDA to limit data disclosure to only a subset of approved drugs, such as those that are controversial or best-selling. Access to broad data sets that incorporate data from many different drugs will also allow some of the promised benefits of big data to emerge, including applications of artificial intelligence.[262]

2. Retrospective Disclosure of Historical Data on a Limited Number of Highly Important Drugs

What to do with the enormous trove of data that the FDA currently possesses on already-approved drugs? We believe that at least some of this historical data should be disclosed. Retrospective disclosure of this sort involves practical and legal obstacles that prospective disclosure does not. Our analysis of the primary potential legal hurdle—the Takings Clause—is presented below.[263] As we explain below, takings claims will be surmountable. The bigger hurdle to retrospective disclosure will likely be practical, not legal; locating, formatting, and redacting data for public disclosure would be expensive and time-consuming for the agency. We propose the FDA could begin by retroactively disclosing data from a relatively small number of drugs—perhaps ten to twenty per year. These drugs could be selected based on their aggregate public health significance (e.g., by number of prescriptions or by the impact on overall disease burden), economic importance (e.g., top drugs by revenue), specific concerns over safety or efficacy, or other factors the FDA deems appropriate. The drugs could be selected by experts within the FDA or by an expert advisory committee.

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260. *Postmarketing Requirements and Commitments: Introduction*, FDA (Jan. 12, 2016), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments [https://perma.cc/B42N-ZG7A].

261. *See infra* Part II.B (arguing that the FDA should require industry to submit data in appropriate, redacted form).

262. Jennifer Bresnick, *FDA: Real-World Data, Machine Learning Critical for Clinical Trials*, HEALTH IT ANALYTICS (Jan. 31, 2019), https://healthitanalytics.com/news/fda-real-world-data-machine-learning-critical-for-clinical-trials [https://perma.cc/TS4A-SSFW]; Pratik Shah et al., *Artificial Intelligence and Machine Learning in Clinical Development: A Translational Perspective*, NPJ DIGIT. MED. (2019), https://www.nature.com/articles/s41746-019-0148-3 [https://perma.cc/C6WH-AJLZ].

263. *See infra* Part II.C.2.

3. *Industry Submission of Clinical Data in Redacted, Publicly Disclosable Form*

In explaining the need for clinical trial publicity, we traced some of the enormous costs that data secrecy currently imposes on patients, payers, and the public at large. Shifting from secrecy to data publicity would produce correspondingly large cost savings, as well as benefits to human health and to medical science. Yet we acknowledge that creating and maintaining a data publicity program could impose costs on the FDA. To minimize these costs, the FDA can and should place the burden of preparing data for public disclosure on the pharmaceutical industry,[264] as do the EMA and Health Canada.[265] The FDA can, by regulation, require the industry to submit redacted versions of all submissions of clinical trial data, with (genuine) trade secrets, confidential commercial information, and sensitive individual patient data redacted.[266]

Requiring the industry to do the redaction, and then requiring the FDA to ensure it has been done correctly, is consistent with the FDA's primary function in regulating medicines: specifying and validating the information that drug companies generate and disclose about their products.[267] The FDA could give the redaction requirement real teeth by rejecting submissions wherein data is

264. Federal statute authorizes the FDA to dictate the specific format in which drug companies submit clinical data, see 21 U.S.C. §§ 355(k), 379k-1. The FDA has issued detailed guidance that does just that. FDA, PROVIDING REGULATORY SUBMISSIONS IN ELECTRONIC FORMAT – STANDARDIZED STUDY DATA: GUIDANCE FOR INDUSTRY (2014), https://www.fda.gov/media/82716/download [https://perma.cc/6SXN-FQTE] (guidance document establishing requirements for electronic submission of standardized clinical and nonclinical study data under § 745A(a) of the FDCA (21 U.S.C. § 379k-1)); FDA, PROVIDING REGULATORY SUBMISSIONS IN ELECTRONIC FORMAT – SUBMISSIONS UNDER SECTION 745A(a) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: GUIDANCE FOR INDUSTRY (2014), https://www.fda.gov/media/88120/download [https://perma.cc/B9UJ-6F5B] (same). The FDA already asks drug companies to help prepare clinical trial data sets in redacted form, in case they become subject to disclosure through FOIA. 21 C.F.R. § 20.63(b) (2019). In 2001, the FDA proposed regulations to require sponsors of trials to "submit information . . . in redacted version for public disclosure, removing all information that would be defined as trade secret or personal information whose disclosure would constitute a clearly unwarranted invasion of privacy, and certain confidential commercial information. Each submission for public disclosure would be accompanied by a statement, signed by a responsible person, that the information has been suitably redacted." Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation, 66 Fed. Reg. 4688, 4703 (proposed Jan. 18, 2001). The FDA currently requires all submissions adhere to a data standard (format) developed in collaboration with the nonprofit Clinical Data Interchange Standards Consortium (CDISC). *See* FDA, STUDY DATA STANDARDS: WHAT YOU NEED TO KNOW (2017), https://www.fda.gov/media/98907/download [https://perma.cc/PNU6-FY7P]. This standard is useful to outside researchers, so no further manipulation of the data is required.

265. *See, e.g.*, EUR. MEDS. AGENCY, *supra* note 136, at 15, 29, 30 (describing a multi-stage procedure in which a drug company first submits proposed redactions to the EMA, the EMA then reviews and accepts or rejects each proposed redaction in a "consultation process," and the drug company then submits to the EMA a final redacted document package for publication); *Public Release of Clinical Information: Guidance Document*, *supra* note 137, at 4.4: Submission of Annotated Documents with Proposed CBI Redaction(s) and Anonymization.

266. *See supra* note 264 and accompanying text.

267. *See* Kapczynski, *Dangerous Times*, *supra* note 10, at 2359.

incompletely or incorrectly redacted, whether over- or under-redacted, and by threatening to place ongoing trials on clinical hold if sponsors do not comply.[268]

The costs imposed on the industry to prepare these redactions would be non-zero but reasonable. As one admittedly inexact point of comparison, in 2001, the FDA estimated the cost of redacting safety and efficacy data in one investigational new drug (IND) application to prepare it for public disclosure at approximately $124,000[269] (in 2001 dollars, equivalent to about $185,000 today[270]). As another point of comparison, a 2020 National Academies report on clinical trial data sharing suggests the costs of redacting and otherwise preparing individual patient data for publication are only a few thousand dollars per trial.[271] And, as noted above, the EMA and Health Canada already require the industry to prepare redactions in line with what we propose.[272]

The FDA should also follow the lead of the EMA in another respect and revise its regulatory definitions of trade secrecy and CCI to define the many specific forms of clinical data that will generally qualify as neither, to clarify its policies to the industry and prevent overbroad redactions.[273] Indeed, there are good reasons for the FDA to adopt rules for redaction that closely resemble the EMA's and Health Canada's. As noted above, the EMA currently maintains the world's most extensive data publicity regime for clinical trial data on prescription drugs (though it is stalled as of writing),[274] and the EMA has propounded a properly narrow definition of redactable CCI.[275] Health Canada has modeled its nascent data publicity regime after the EMA's.[276] Harmonizing the FDA's redaction rules with those of the EMA and Health Canada would minimize burdens on the drug companies that perform the redaction, allow these regulatory agencies to double check each other's work, and improve overall compliance.[277]

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268. In its 2001 proposal to disclose safety and efficacy data from human gene therapy and xenotransplantation trials, the FDA proposed to place pending INDs on clinical hold if sponsors failed to submit data in the correct, redacted form for public disclosure. *See* Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation, 66 Fed. Reg. 4688, 4692, 4697 (proposed Jan. 18, 2001).

269. *Id.* at 4701.

270. *CPI inflation Calculator*, U.S. BUREAU LAB. STAT., https://www.bls.gov/data/inflation_calculator.htm [https://perma.cc/BC2W-BQY4] (indicating that $124,000 in January 2001 has the same buying power as $184,321.64 in September 2020).

271. NAT'L ACADS. OF SCIS., ENG'G & MED., REFLECTIONS ON SHARING CLINICAL TRIAL DATA: CHALLENGES AND A WAY FORWARD 65 (2020) (indicating the costs of preparing individual patient data for publication at "more than £3,000 ($3,900)" and "about £2,500 ($3,250).").

272. *See* EUR. MEDS. AGENCY, *supra* note 136, at 15, 29, 30; *Public Release of Clinical Information: Guidance Document*, *supra* note 137, at 4.4: Submission of Annotated Documents with Proposed CBI Redaction(s) and Anonymization.

273. *See supra* notes 236–237.

274. *See supra* Part I.B.3.

275. *See supra* Part II.A.

276. *See supra* Part I.B.3.

277. When the FDA announced the termination of its Clinical Data Summary Pilot Program, it acknowledged "significant inefficiencies in having multiregional disclosure requirements relating to

Because of its potential privacy implications for patients, individual patient data provides the most significant logistical challenge.[278] While not purporting to detail here how such data can be deidentified most effectively, we do note that protocols, though perhaps imperfect, are already in place,[279] and that the FDA has long experience with redacting individual patient information before disclosing clinical data.[280] The FDA's 2018 clinical data summary pilot program provides a helpful template for deidentification,[281] as do Health Canada's[282] and the EMA's[283] guidance on deidentification of clinical data.

Deidentification is not a panacea. As artificial intelligence grows more powerful and as more data on each of us is collected, aggregated, and traded by corporations, reidentification becomes more likely and more deeply problematic.[284] We might reasonably fear, for example, insurers reidentifying individual people from a clinical trial in patients with chronic disease to deny coverage to those whose treatment costs are likely to be highest,[285] or residential landlords using reidentification to discriminate against potential renters with certain health conditions, such as HIV.[286] Where certain forms of individual patient data are particularly susceptible to reidentification, such as individual

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often identical clinical data summaries," which "multipl[ied] the transactional, administrative and redaction (because there are differing regional disclosure standards) costs, whether the costs are incurred by industry or a regional regulatory authority." Press Release, *supra* note 94. The FDA expressed a desire to achieve a "centralized or regional approach." *Id.*

278. *See generally* I. Glenn Cohen & Michelle M. Mello, *Big Data, Big Tech, and Protecting Patient Privacy*, 322 JAMA 1141 (2019); W. Nicholson Price & I. Glenn Cohen, *Privacy in the Age of Medical Big Data*, NATURE MED., Jan 2019, at 37; Efthimios Parasidis, Elizabeth Pike & Deven McGraw, *A Belmont Report for Health Data*, 380 NEW ENG. J. MED. 1493 (2019); BIG DATA, HEALTH LAW, AND BIOETHICS, (I. Glenn Cohen et al. eds., 2018).

279. For a detailed analysis of deidentification in practice, see Khaled El Emam & Bradley Malin, *Concepts and Methods for De-Identifying Clinical Trial Data*, *in* INST. OF MED. OF THE NAT'L ACADS., SHARING CLINICAL TRIAL DATA app. B 203, 231–32 (2015). *See also*, ADAM TANNER, CENTURY FOUND., STRENGTHENING PROTECTION OF PATIENT MEDICAL DATA 11–12 (2017), https://production-tcf.imgix.net/app/uploads/2017/01/11165252/strengthening-protection-of-patient-medical-data-1.pdf [https://perma.cc/6SP4-V7CB].

280. For an overview, see *§ 22:51. The FDA and Personal Privacy Information*, *in* 2 FOOD & DRUG ADMIN. (James T. O'Reilly & Katherine A. van Tassel eds., 4th ed. 2019).

281. *See FDA's Clinical Data Summary Pilot Program: Questions Frequently Asked by Industry*, *supra* note 207 (noting personal privacy information (PPI) to be redacted before disclosure).

282. *Public Release of Clinical Information: Guidance Document*, *supra* note 137.

283. *See* EUR. MEDS. AGENCY, *supra* note 136.

284. *See generally* SHOSHANA ZUBOFF, THE AGE OF SURVEILLANCE CAPITALISM (2019); *see also* Sharona Hoffman, *Citizen Science: The Law and Ethics of Public Access to Medical Big Data*, 30 BERKELEY TECH. L.J. 1741 (2015) (describing a growing risk of reidentification of health data specifically); Ira S. Rubinstein & Woodrow Hartzog, *Anonymization and Risk*, 91 WASH. L. REV. 703, 710 (2016).

285. Specialty credit rating agencies already create and sell health reports on individual people. Ann Carrns, *Consumers Can Check on Data Beyond Their Credit Reports*, N.Y. TIMES (Jan. 15, 2014), https://www.nytimes.com/2014/01/15/your-money/consumers-can-check-on-data-beyond-their-credit-reports.html [https://perma.cc/DQ3C-49CL].

286. Noah Remnick, *Suit Accuses Landlord of Discriminating Against Tenant with AIDS*, N.Y. TIMES (June 23, 2015), https://www.nytimes.com/2015/06/24/nyregion/suit-accuses-landlord-of-discriminating-against-tenant-with-aids.html [https://perma.cc/3MPN-T44G].

adverse event reports for drugs that treat rare diseases,[287] the risk might be so great that the data should not be disclosed at all. But past experience with clinical data disclosure shows that reidentification can be discouraged—and its harms reduced—through imposition of data use agreements, which contractually prohibit reidentification and other unauthorized use.[288] These agreements form the fourth key feature of data publicity that we describe here, and we turn to them now.

4. Data Requests and Data Use Agreements

Some safety and efficacy data can be disclosed to the public without restriction, as it does not implicate patient privacy or other protected interests. This is particularly true for certain high-level metadata and summary data, like clinical study reports (with minimal redactions to excise manufacturing information or individual information about patients) and internal assessments prepared by the FDA.[289] The same data can and should be released to FOIA requesters in the same way. But open access is the wrong solution for more sensitive data.

The FDA should limit access to more sensitive data that implicates patient privacy, risks competitors' misuse, or concerns another legitimate interest. First, the FDA should disclose sensitive data only upon receipt of a "data request" from the prospective user. Each request should be reviewed by the FDA. In this review, the FDA could confirm that a given requester is credible and intends to use the data for a legitimate purpose, such as meta-analysis of clinical trials to be published in the medical literature.[290] Requiring data requesters to complete data requests should minimize frivolous requests and thereby reduce the

287. Katherine Tucker, Janice Branson, Maria Dilleen, Sally Hollis, Paul Loughlin, Mark J. Nixon & Zoë Williams, *Protecting Patient Privacy When Sharing Patient-Level Data from Clinical Trials*, BMC MED. RSCH. METHODOLOGY, July 8, 2016 (Supp. 1), at 5, 10 (2016).

288. El Emam & Malin, *supra* note 279.

289. These materials are unlikely to raise concerns about evading data exclusivity since they are less than the full package required by the most rigorous regulators.

290. The FDA could require data requesters to submit analysis plans that detail how requesters intend to access, store, and analyze the data, and how requesters intend to disseminate their findings. The FDA does not currently review data use requests, but it does have expertise in assessing whether researchers are legitimate, established, non-commercial, and so on, in the context of evaluating whether researchers who file FOIA requests are entitled to expedited processing and/or a fee waiver. *See* 21 C.F.R. §§ 20.44, 20.46 (2019). In addition, certain offices within the FDA currently evaluate researchers for eligibility for FDA-administered grants, such as Orphan Product Grants for clinical trials and natural history studies. *See About Orphan Products Grants*, FDA, https://www.fda.gov/industry/developing-products-rare-diseases-conditions/about-orphan-products-grants [https://perma.cc/C44G-E6B5]. In our view, the FDA could quickly develop expertise in evaluating data use requests, as NIH's Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC) database has. *See generally* Sean A. Coady, George A. Mensah, Elizabeth L. Wagner, Miriam E. Goldfarb, Denise M. Hitchcock & Carol A. Giffen, *Use of the National Heart, Lung, and Blood Institute Data Repository*, NEW ENG. J. MED. (May 11, 2017), https://www.nejm.org/doi/full/10.1056/NEJMsa1603542 [https://perma.cc/SM98-VPDL]; *see also BioLINCC FAQ*, NAT'L HEART, LUNG, AND BLOOD INST., https://biolincc.nhlbi.nih.gov/faq/#dataset-requirements [https://perma.cc/DX4D-Y8EZ].

administrative burden on the agency. The FDA can and should prioritize requests from noncommercial requesters, which would both conserve agency resources and advance policy goals like prompt communication of drug risks to patients and prescribers.[291]

Second, whenever the FDA grants a data use request, the agency should require the requester to sign a legally binding data use agreement that would prohibit, *inter alia*, unauthorized dissemination of the data, commercial use (including resubmission to the FDA), and reidentification of individual patients.[292] These agreements are common in the world of clinical data sharing and have been used successfully by the EMA (under Policy 0070),[293] the NIH (for access to the Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC)),[294] and the Yale Open Data Access (YODA) Project, among others.[295] The precise language of the data use agreement and the specific terms and conditions imposed are left to the agency. For example, YODA's data use agreement identifies possible conditions including a prohibition on using the data "in pursuit of litigation or for commercial interests," a prohibition on distribution of the data to third parties, a prohibition on reidentification of individuals, an obligation to disseminate findings through the

291. If the FDA promulgates its proactive disclosure regulations under the authority Congress delegated in 21 U.S.C. § 355(r), there is textual support for privileging access by patients and doctors over other users of the data, such as commercial users. "[T]he Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that . . . improves communication of drug safety information to patients and providers." 21 U.S.C. § 355(r)(1).

292. *See, e.g.*, *How Can Covered Entities Use and Disclose Protected Health Information for Research and Comply with the Privacy Rule?*, NAT'L INSTS. HEALTH, https://privacyruleandresearch.nih.gov/pr_08.asp [https://perma.cc/78XC-WF9L] (describing a data use and protection agreement that may include "[s]tipulations that the recipient will [n]ot use or disclose the information other than permitted by the agreement or otherwise required by law[,] [u]se appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered entity any uses or disclosures in violation of the agreement of which the recipient becomes aware[,] [h]old any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information[,] [and] [n]ot identify the information or contact the individuals"). In endorsing proactive sharing of safety and efficacy data subject to some restrictions on the use of that data, we align with Lietzan's conclusion that "[t]he public policy arguments together point to controlled sharing with non-profit researchers to advance general scientific knowledge, including our understanding of approved medicines." Lietzan, *A New Framework*, *supra* note 21, at 39.

293. EUR. MEDS. AGENCY, *supra* note 136, at 10 (setting out in Annex 1 the "terms of use" agreement for data shared by the EMA, which only allows non-commercial uses and forbids re-identification of trial subjects).

294. Coady et al., *supra* note 291. *See also Agreement Templates*, NAT'L HEART, LUNG, AND BLOOD INST., https://biolincc.nhlbi.nih.gov/website_templates/ [https://perma.cc/DLA7-ZKM3] (providing template data use agreements for BioLINCC).

295. *See* Ross et al., *supra* note 105. YODA's template data use agreement is available at http://yoda.yale.edu/data-use-agreement [https://perma.cc/LTK8-GZNM].

peer-reviewed medical literature, and an obligation to immediately report "any unexpected or serious safety findings" to health and regulatory authorities.[296]

Data use agreements would offer legal and affirmative protections. First, they would be legally binding and enforceable as contracts, which should provide significant assurances to patients and the pharmaceutical industry, particularly given experience with such agreements to date.[297] Data use agreements could also impose affirmative obligations such as completing data analysis promptly and sharing findings with the public. These affirmative obligations would ensure that data publicity provides real benefits to the public and, in fact, promotes accountability, democracy, and public health.

That said, no legal restriction—whether a data use agreement with stiff penalties or any other legal governance regime—can provide a perfect guarantee against harmful uses of safety and efficacy data. The FDA might decide to implement technical restrictions as an additional layer of protection. For example, the FDA could decide to house the data it shares through its data publicity plan on a secure server administered by the agency; data users could then "visit" and query the data to conduct their analyses but would not be able to obtain the complete data set.[298] The FDA could also apply "differential privacy,"

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296. YALE UNIVERSITY OPEN DATA ACCESS (YODA) PROJECT PROCEDURES TO GUIDE EXTERNAL INVESTIGATOR ACCESS TO CLINICAL TRIAL DATA 7 (2019), https://yoda.yale.edu/sites/default/files/files/YODA%20Project%20Data%20Release%20Procedures%20February%202019.pdf [https://perma.cc/XBU7-KAVL] [hereinafter YODA PROJECT PROCEDURES].

297. In practice, data requests and data use agreements do seem to work. The YODA Project's collaboration with Johnson & Johnson employs both data use agreements, see *supra* note 295, and a simple technical safeguard—a secure private server that permits users to conduct online statistical analysis but denies users unfettered access to the data (preventing them from downloading and distributing the data sets). *See* Joseph S. Ross, Joanne Waldstreicher & Harlan Krumholz, *Sharing Clinical Trial Data: Lessons from the YODA Project*, STAT NEWS (Nov. 18, 2019), https://www.statnews.com/2019/11/18/data-sharing-clinical-trials-lessons-yoda-project/ [https://perma.cc/5ELQ-HUWK]; YODA PROJECT PROCEDURES, *supra* note 296; Ross et al., *supra* note 105. The collaboration has been a success thus far: between 2014 and 2018, Johnson & Johnson voluntarily shared the results of over 200 clinical trials of prescription drugs through the YODA Project, generating at least a dozen new scientific publications without any evidence of harmful use of that data by Johnson & Johnson's competitors. *See* Ross et al., *supra* note 105. As of writing, Johnson & Johnson had increased its voluntary sharing of clinical trial data to cover nearly 400 different trials. YODA PROJECT PROCEDURES, *supra* note 296. The NIH's BioLINCC database allows data users wide access to its safety and efficacy (and other) data. NAT'L HEART, LUNG, AND BLOOD INST., THE BIOLINCC HANDBOOK 19–20, https://biolincc.nhlbi.nih.gov/media/guidelines/handbook.pdf [https://perma.cc/TG29-2W3G] (explaining that BioLINCC data sets "may be accessed and downloaded via a secure link" and must be destroyed when the project is completed or the data use agreement is otherwise terminated); *see also BioLINCC FAQ*, *supra* note 290; Coady et al., *supra* note 291. It relies on data use agreements to prohibit unauthorized use. *See* Coady et al., *supra* note 291, at 1850. Data sharing through the BioLINCC database has likewise been a success—over 250 articles were published based on BioLINCC data accessed between January 2000 and May 2016, *id.* at 1849, and no misuse has been reported, to our knowledge.

298. *See, e.g.*, Nicholson Price & Cohen, *supra* note 278, at 41–42 (2019) ("[P]erhaps data sharing should be limited to the minimal amount necessary in all contexts, data should be retained only for limited time, or data should be intentionally obfuscated, if consequential harms are difficult to limit.").

a technical trick derived from cryptography that adds mathematical "noise" to data sets to effectively obscure information about individuals within a data set while still permitting analysis of wider patterns in the data.[299] In this Article we raise but do not attempt to settle the debate over the optimal technical restrictions for clinical trial and other medical data.[300] Rather, the data publicity regime we sketch in this Article can adapt to different technical and legal controls that FDA and outside experts ultimately deem appropriate.

C. Defending Data Publicity

If the FDA adopts the proactive data publicity regime we propose, it will undoubtedly be met with industry resistance. The FDA's past proposals for even modest proactive disclosure of safety and efficacy data provoked a barrage of criticism and threats of legal challenges.[301] We have already addressed one of the most important criticisms of data publicity above[302]—the notion that disclosure of clinical data will threaten patient privacy. The pharmaceutical industry's two main remaining arguments are a policy argument—disclosure will erode incentives to innovate—and a legal one—disclosure will violate the Takings Clause of the Fifth Amendment. Neither withstands scrutiny.

1. Incentives to Innovate

The pharmaceutical industry has repeatedly protested that disclosure of safety and efficacy data would be bad public policy. The industry argues that, whatever the benefits, disclosure would permit later market entrants to "free ride" on an innovator company's clinical techniques and clinical data, thereby

299. *See* Alexandra Wood et al., *Differential Privacy: A Primer for a Non-Technical Audience*, 21 VAND. J. ENT. & TECH. 209 (2018). *See also* Rubinstein & Hartzog, *supra* note 284 (explaining differential privacy and its possible use as a complement to traditional deidentification). Differential privacy is being used by the 2020 Census. *See* John M. Abowd & Victoria A. Velkoff, *Balancing Privacy and Accuracy: New Opportunity for Disclosure Avoidance Analysis*, U.S. CENSUS BUREAU (Oct. 29, 2019), https://www.census.gov/newsroom/blogs/research-matters/2019/10/balancing_privacyan.html [https://perma.cc/QJ7R-ZDP7].

300. *See, e.g.*, Michelle M. Mello, Jeffrey K. Francer, Marc Wilenzick, Patricia Teden, Barbara E. Bierer & Mark Barnes, *Preparing for Responsible Sharing of Clinical Trial Data*, NEW ENG. J. MED. (Oct. 24, 2013), https://www.nejm.org/doi/full/10.1056/NEJMhle1309073 [https://perma.cc/E6VB-VVTN]; Brent Daniel Mittelstadt & Luciano Floridi, *The Ethics of Big Data: Current and Foreseeable Issues in Biomedical Contexts*. SCI. & ENG'G ETHICS, April 2016, at 303; Parasidis et al., *supra* note 278; Nicholson Price & Cohen, *supra* note 278.

301. *See, e.g.*, Pharmaceutical Research and Manufacturers of America (PhRMA), Comment Letter on FDA Transparency Task Force Initiative at 10–18 (Aug. 7, 2009), https://www.fdanews.com/ext/resources/files/archives/f/FDA-2009-N-0247-0107.1.pdf [https://perma.cc/JJU2-R7JE] (alleging, *inter alia*, that disclosure by FDA of safety and efficacy data could undermine industry's incentives to innovate and would violate the TSA, § 301(j) of the FDCA, and the Takings Clause); PhRMA Comment Letter, *supra* note 199 (same). *See generally*, John Castellani, *Are Clinical Trial Data Shared Sufficiently Today? Yes*, 347 BRIT. MED. J. 16 (2013) (opinion piece by the President and CEO of PhRMA).

302. *See supra* Part II.B.

undermining incentives to develop new drugs.[303] For example, in 2010, PhRMA submitted comments to the FDA alleging that "[i]mplementation of [an FDA proposal to consider release of non-summary (raw) safety and effectiveness data within INDs, BLAs, and NDAs] could cause grave competitive harm to the research-based biopharmaceutical industry—and subsequently damage incentives to take new products through the costly drug approval process."[304]

The pharmaceutical industry makes these arguments despite the absence of any study showing conclusively that clinical data secrecy provides significant incentives to innovate. Nonetheless, the incentives-to-innovate argument against data publicity is widespread[305] and worth examining carefully.

One foundational observation is that drug companies will continue to generate and submit clinical trial data to the FDA for as long as they continue to develop drugs, whatever the FDA's disclosure policy. This is because statute[306] and FDA rules[307] continue to require that data in order to approve new drugs and new indications of existing drugs. Generation and submission of clinical trial data is thus a non-negotiable condition of participation in the marketplace.

The pharmaceutical industry argument that companies will choose to abandon drug discovery and development altogether for fear of free riders undercutting returns on investment, or even that it would necessarily diminish incentives to innovate at all is unfounded. We have shown above[308] that disclosure of safety and efficacy data will cause no genuine competitive harm to the submitter of that data, whether from competition by brand-name competitors or generic free riders in the United States. To recap, this is because the safety and efficacy data we propose disclosing has little direct competitive value and

303. *See* PhRMA, Comment Letter on FDA Transparency Task Force Initiative, *supra* note 301; PhRMA Comment Letter, *supra* note 199; Castellani, *supra* note 301; *see also* Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93 (2004).

304. PhRMA Comment Letter, *supra* note 199, at 30.

305. *See, e.g.*, Lietzan, *A New Framework*, *supra* note 21, at 37 (noting the pharmaceutical industry's argument that disclosure of safety and efficacy data will "reduc[e] incentives for medical innovation"); Francer & Turner, *supra* note 20, at 68 ("Because of the potential impacts on patient privacy and incentives for long term investment in costly biomedical research, any proposals to expand data sharing must be thoroughly assessed before they are implemented."); Eisenberg, *Data Secrecy*, *supra* note 19, at 489–90 (considering arguments that disclosure of clinical trial data reduces incentives to innovate); W Nicholson Price II & Timo Minssen, *Will Clinical Trial Data Disclosure Reduce Incentives to Develop New Uses of Drugs?*, 33 NATURE BIOTECHNOLOGY 685 (2015) (considering whether disclosure of safety and efficacy data may disincentivize the development of new uses for already approved drugs).

306. *See* 21 U.S.C. § 355(b)(1) (requiring that NDAs include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use . . . ."); 42 U.S.C. § 262(a)(2)(C) (instructing that the FDA shall approve BLAs "on the basis of a demonstration that . . . the biological product that is the subject of the application is safe, pure, and potent . . . .").

307. *See* 21 C.F.R. § 314.50(d)(5) (2019) (requiring NDAs to include a "[c]linical data section"); *id.* § 601.2(a) (requiring BLAs to include "data derived from . . . clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency . . . .").

308. *See supra* Part II.A.

because the FDA can prevent any genuinely competitive uses of safety and efficacy data through imposition of data use agreements.[309]

Competitive harm may not actually be the industry's main objection to safety and efficacy data publicity. Drug companies may simply wish to avoid the release of data showing that their products are ineffective or unsafe. As the D.C. Circuit has observed, drug companies' reluctance to allow the FDA to disclose clinical data on prescription drugs sometimes arises not from a legitimate fear of competitors making use of that data but instead "the embarrassing publicity attendant upon public revelations concerning, for example," violations of safety laws.[310] This is all the more reason to demand disclosure.

Contrary to the industry's assertions, data publicity can improve innovation incentives. Data publicity can direct companies toward investments in genuinely efficacious medicines. It can discourage wasteful spending on treatments that provide no meaningful therapeutic advantage over older, cheaper alternatives.[311] And, were the United States to develop a centralized or decentralized system for effective drug pricing based upon efficacy, data publicity would help to inform that system. Even absent a formal system of efficacy-based drug pricing, data publicity will discourage the use and purchase of drugs that are entirely unsafe and ineffective and thereby disincentivize their development—a socially useful result.

A final observation implicates not just incentives but basic concepts of fairness in our system of laws and policies that promote development and distribution of drugs and vaccines. Conceptually, the data that drug companies generate on prescription drugs arguably emerges from a kind of public-private partnership between the industry and the FDA; to deprive the American public of access to data that the public pays to create would be unreasonable.[312] The public often pays directly for the clinical trial data that the pharmaceutical industry generates through public-private partnerships with the NIH and other biomedical research agencies[313] and indirectly through tax credits for clinical trials conducted by the industry.[314] Even without public financing, disclosure of

309. *See supra* Part II.A.

310. Pub. Citizen Health Rsch. Grp. v. FDA, 704 F.2d 1280, 1291 n.30 (D.C. Cir. 1983).

311. *See supra* Part I.A.

312. *See* Kapczynski, *Dangerous Times*, *supra* note 10. Others have explained that information submitted to regulatory agencies by private industry or generated with public dollars may not deserve protection as a trade secret. *See* Levine, *The People's Trade Secrets*, *supra* note 241; Levine, *Secrecy and Unaccountability: Trade Secrets in Our Public Infrastructure*, *supra* note 241; Lyndon, *Secrecy and Access*, *supra* note 241, at 498.

313. *See, e.g.*, *NIH-Industry Partnerships Frequently Asked Questions*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCI., https://ncats.nih.gov/ntu/about/partnerships-faq [https://perma.cc/84GU-EFXJ] (describing NIH's support of clinical trials through its Discovering New Therapeutic Uses for Existing Molecules program).

314. Aaron S. Kesselheim, Michael S. Sinha, Jerry Avorn & Ameet Sarpatwari, *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape & Avenues for Improvement*, 30 STAN. L. & POL'Y REV. 421, 428 (2019) (summarizing tax credits and other tax benefits used by the pharmaceutical industry).

safety and efficacy data might be a reasonable quid pro quo: if drug companies want to sell their products in the enormously profitable U.S. market[315] and benefit from the widespread (though fragile) trust in the safety of drugs that decades of mostly conscientious FDA regulation has cultivated, they must consent to disclosure of clinical data on those products.[316] The pharmaceutical industry's enthusiastic exploitation of the patent system—including so-called "method of use" patents on clinical methods[317]—is another choice that requires (or arguably should require) disclosure of clinical data as a quid pro quo. The publicity of safety and efficacy data that we recommend would expand on and complement the often paltry disclosure of drug patents[318] without disturbing innovators' patent incentives.[319]

2. Takings

Drug companies that submit safety and efficacy data from clinical trials of prescription drugs to the FDA have often argued that this data contains trade secrets protected by the Takings Clause of the Fifth Amendment. They contend that disclosure of the data without the submitter's consent constitutes a regulatory taking and requires payment of "just compensation."[320] However, the

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315. In 2018, over a third of global pharmaceutical revenues were generated in the United States. *Global Pharma Spending Will Hit $1.5 Trillion in 2023, Says IQVIA*, PHARM. COM. (Jan. 29, 2019), https://pharmaceuticalcommerce.com/business-and-finance/global-pharma-spending-will-hit-1-5-trillion-in-2023-says-iqvia/ [https://perma.cc/B9H7-GNSE].

316. FDA does already disclose some clinical data upon approval of a drug. *See supra* Part I.B.

317. Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOSONE (Dec. 5, 2012), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470 [https://perma.cc/KX6D-PUB8].

318. Many commentators have questioned the practical quality and value of patent disclosure, pharmaceutical patents very much included. *See generally*, *e.g.*, Colleen V. Chien, *Contextualizing Patent Disclosure*, 69 VAND. L. REV. 1849, 1850–51 (2016) (providing an overview of the justification for the patent system as an incentive to encourage innovators to disclose technical information to public); Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715, 1721 (2016); Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 531, 560 (2012); Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 626 (2010); Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 560 (2009). For more detailed analysis of pharmaceutical patents, see Gregory N. Mandel, *The Generic Biologics Debate: Industry's Unintended Admission that Biotech Patents Fail Enablement*, 11 VA. J.L. & TECH. 1 (2006); Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663 (2019); Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419 (2012); Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845 (2017).

319. Method-of-use patents are typically filed at the preclinical or early clinical stage, before much or any clinical data has been generated and long before FDA approval of the method of use in question. "Typically, patent applications claiming new methods of treatment are supported by test results. . . . [But] human trials are not required for a therapeutic invention to be patentable." *In re* '318 Patent Infringement Litigation, 583 F.3d 1317, 1324 (Fed. Cir. 2009). As such, the data publicity we propose will not create prior art that invalidates these patents or prevents them from issuing in the first place.

320. For example, in 2010, the FDA's Transparency Task Force proposed disclosing some metadata and summary data on safety and efficacy of prescription drugs. FDA, FDA TRANSPARENCY INITIATIVE: DRAFT PROPOSALS FOR PUBLIC COMMENT REGARDING DISCLOSURE POLICIES OF THE

FDA will owe little or no compensation under the Takings Clause if it begins proactive disclosure of safety and efficacy data.

For prospective disclosure of any safety and efficacy data submitted to the FDA *after* the agency implements new data publicity rules, the analysis is simple: the Takings Clause does not apply. In *Ruckelshaus v. Monsanto*, the leading Supreme Court case on the application of the Takings Clause to data submitted to federal regulatory agencies, the Court held that agency disclosure of industry-submitted information can constitute a taking if and only if the agency first provided an assurance of secrecy.[321] As soon as the FDA ceases assuring the industry that future submissions of safety and efficacy data will be kept secret, all future takings claims will be foreclosed.[322]

The takings analysis for *retrospective* disclosure of safety and efficacy data submitted to the FDA before the agency implements new data publicity rules is more complex but still favors the agency. Under *Monsanto*, safety and efficacy data could constitute "property" eligible for protection under the Takings Clause if the data is "property" under state law and the agency has promised to keep that data secret. But, as we have argued above,[323] only a relative few subcategories of safety and efficacy data should qualify for protection as trade secrets under

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U.S. FOOD AND DRUG ADMINISTRATION (2010), http://www.lb7.uscourts.gov/documents/02c51292.pdf [https://perma.cc/7RPY-SAPL]. PhRMA subsequently submitted comments alleging that "[e]ven if statutory and regulatory changes were made to allow FDA to implement the Task Force's recommendations, disclosure of trade secrets and confidential commercial information currently in FDA's hands or developed in reliance on the current statutory and regulatory scheme would constitute an unconstitutional taking requiring payment of just compensation." PhRMA Comment Letter, *supra* note 199, at 40.

321. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1011 (1984). ("[T]he statute also gave Monsanto explicit assurance that EPA was prohibited from disclosing publicly, or considering in connection with the application of another, any data submitted by an applicant if both the applicant and EPA determined the data to constitute trade secrets. Thus, with respect to trade secrets submitted under the statutory regime in force between the time of the adoption of the 1972 amendments and the adoption of the 1978 amendments, the Federal Government had explicitly guaranteed to Monsanto and other registration applicants an extensive measure of confidentiality and exclusive use. This explicit governmental guarantee formed the basis of a reasonable investment-backed expectation." (citation omitted)); *see also id.* at 1008 ("[A]s long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking."); *id.* at 1013 ("[W]e hold that EPA's consideration or disclosure of data submitted by Monsanto to the agency prior to October 22, 1972, or after September 30, 1978, does not effect a taking."); Thomas v. Union Carbide Agr. Prods. Co., 473 U.S. 568, 584 (1985) ("As a matter of state law, property rights in a trade secret are extinguished when a company discloses its trade secret to persons not obligated to protect the confidentiality of the information.").

322. *See* Amy Kapczynski, *The Public's Trade Secrets*, (forthcoming) (manuscript on file with authors); *see also* Pamela Samuelson, *Principles for Resolving Conflicts between Trade Secrets and the First Amendment*, 58 HASTINGS L.J. 777, 809 (2006) ("While proponents of the trade-secrets-as-property conception tend to invoke *Ruckelshaus* as supporting the property concept, a fuller review of the Court's ruling demonstrates that trade secret interests are balanced against other societal interests, and sometimes the larger societal interests override trade secret interests. The strong property right theory that Monsanto propounded was soundly trounced in *Ruckelshaus*." (footnote omitted)).

323. *See supra* Part II.A.

state law: data that has a genuine "commercial or financial" character and some innovative quality, such as new assay methodologies for biomarkers,[324] and data that the FDA formally and unequivocally promises to keep secret after approval, such as where extraordinary circumstances exist for biologic drugs.[325]

To the extent that safety and efficacy data *does* qualify as "property" eligible for protection under the Takings Clause, disclosure of this data will be very unlikely to be construed a taking for two reasons. First, *Monsanto* held that if an agency does disclose a trade secret against the submitter's wishes, the disclosure does not amount to a compensable taking unless there was interference with "reasonable investment-backed expectations."[326] The Court has elsewhere held that a crucial aspect of the character of the governmental action is the "nature of the State's interest" and that a strong, legitimate public interest tips in favor of finding no taking.[327] As explained above, the public

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324. Scholars have argued that under the Restatement and state law definitions of a trade secret, information that private industry submits to regulatory agencies will not always qualify for protection as a trade secret. *See* Levine, *The People's Trade Secrets*, *supra* note 241; Levine, *Secrecy and Unaccountability: Trade Secrets in Our Public Infrastructure*, *supra* note 241; Lyndon, *Secrecy and Access*, *supra* note 241. In Part II.A, *supra*, we explained that a few subcategories of clinical data that have genuine "commercial or financial" character and some innovative quality, such as new assay methodologies for biomarkers, properly qualify as confidential commercial information (CCI). In our view, it is, at most, these subcategories of clinical data that meet the definition of a trade secret found in the Restatement (First) of Torts, under which a trade secret must "differ[] from other secret information in a business . . . in that it is not simply information as to single or ephemeral events in the conduct of the business" and must instead be "a process or device for continuous use in the operation of the business." RESTATEMENT (FIRST) OF TORTS § 757, cmt. b. Moreover, the Supreme Court might revisit or refine *Monsanto*—which relied on a stipulation of all parties, not an actual finding, that trade secrets were property under the relevant state law. *See* Samuelson, *supra* note 322; *Monsanto*, 467 U.S. at 1001–02. The Court might conclude that trade secrets are not property in the relevant sense. *Cf.* Golden v. United States, 955 F.3d 981, 989 n.7 (Fed. Cir. 2020) (suggesting that patents may not be property for the purposes of the Takings Clause (citing Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1373, 1379 (2018))).

325. *See supra* note 158.

326. *Monsanto*, 467 U.S. at 1005 (citations omitted). The court observed that there is no "set formula" for determining when regulatory action constitutes a taking but focused on investment-backed expectations, noting two other relevant factors too: "the character of the governmental action, [and] its economic impact." *Id.* (citing PruneYard Shopping Ctr. V. Robins, 447 U.S. 74, 83 (1980)).

327. Keystone Bituminous Coal Ass'n v. DeBenedictis, 480 U.S. 470, 488 (1987) ("In *Pennsylvania Coal* the Court recognized that the nature of the State's interest in the regulation is a critical factor in determining whether a taking has occurred, and thus whether compensation is required." (citing Pennsylvania Coal Co. v. Mahon, 260 U. S. 393, 415 (1922))). *But see* Philip Morris, Inc. v. Reilly, 312 F.3d 24, 44, 45–46 (1st Cir. 2002) (holding that a Massachusetts state law requiring disclosure the ingredient lists in cigarettes was a taking because "[t]he Disclosure Act causes the tobacco companies to lose their trade secrets, entirely, and appellants advance no convincing public policy rationale to justify the taking itself"). Setting aside whether *Philip Morris* was correctly decided, the facts of *Philip Morris* are readily distinguishable insofar as the FDA can articulate a convincing public policy rationale to justify disclosure of safety and efficacy data on prescription drugs—*see supra* Part I.A—and, indeed, already has in some instances. *See* Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation, 66 Fed. Reg. 4688, 4692 (proposed Jan. 18, 2001) ("The agency believes that there is great benefit in having human gene therapy and xenotransplantation products scrutinized, as they are being developed, by individuals with a wide variety of perspectives . . . because of the unique blend of proposed benefit

interest in disclosure of safety and efficacy data on prescription drugs is strong. Second, the economic impact of disclosure would be minor, given the weakness of trade secrecy arguments and the impact of data use agreements that prevent competitor drug companies from relying on the data in their own drug applications or otherwise making harmful competitive use of the data.[328] As such, courts should conclude that disclosures of the kind we describe do not "take" company property at all.[329]

CONCLUSION AND EXTRAPOLATION

Comprehensive access to clinical trial data is important to protect public health and the integrity of the FDA. Today, researchers and clinicians can only rarely access all of the data they need to validate the efficacy and safety of medicines and guide clinical practice. The current data secrecy regime has already contributed to the deaths of tens of thousands of people and will continue to put the public at risk until steps are taken to proactively disclose data. Regulators in Canada and the EU have taken halting steps in this direction, showing that it can be done, but gaps remain that only the FDA can fill. Here, we show how an administration committed to health care reform and corporate accountability could reboot the FDA and establish an effective proactive clinical trial data publicity regime.

The data publicity regime we propose will also help the FDA protect its staff and resources. The FDA has been described in recent years as an under resourced agency squeezed by political, industry, and patient pressures.[330] Switching from reactive disclosure through FOIA to data publicity will shift much of the burden of redaction from the agency to the industry and may therefore produce substantial cost savings. The FDA currently spends about $300

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as well as potential risk to society that these products possess."). For arguments that *Phillip Morris* is wrongly decided, and that *Monsanto* applied differently when the state seeks to shape competition (as it did in that case), and when it seeks to inform the public (as here), see Kapczynski, *The Public's Trade Secrets*, *supra* note 322.

328. *See supra* Part II.B & C.1.

329. *See* Fan, *supra* note 22, at 200 (arguing that limiting disclosure of confidential data to researchers subject to strict limits on data use "renders disclosure nonpublic, averting Fifth Amendment takings concerns"); *cf.* Exxon Corp. v. FTC, 589 F.2d 582, 589 (D.C. Cir. 1978) (holding that limited disclosure of alleged trade secrets to a Congressional committee did not constitute public disclosure, did not "impair the value of the trade secrets involved," and did not implicate the due process clause).

330. Editorial, *The F.D.A. in Crisis: It Needs More Money and Talent*, N.Y. TIMES (Feb. 3, 2008), https://www.nytimes.com/2008/02/03/opinion/03sun1.html [https://perma.cc/TJ5L-BT6Y]; Matthew Herder, *Pharmaceutical Drugs of Uncertain Value, Lifecycle Regulation at the US Food and Drug Administration, and Institutional Incumbency*, 97 MILBANK Q. 820 (2019). Past transparency initiatives at the FDA have failed, at least in part, for lack of resources and enthusiasm on the part of agency personnel. *See* Tai, *supra* note 142, at 443; Sarah Karlin-Smith & Sarah Owermohle, *Up This Week: Breast Implant Safety* (Mar. 25, 2019), https://www.politico.com/newsletters/prescription-pulse/2019/03/25/up-this-week-breast-implant-safety-414932 [https://perma.cc/NR7H-3T9Y] (quoting the former head of the FDA, Scott Gottlieb, as asking "[i]s trying to increase transparency around complete response letters the best use of the finite public resource i [sic] have?").

million per year fulfilling FOIA requests, at about $3,000 per request.[331] A significant portion of the FOIA requests fielded by the FDA are for clinical data on approved products.[332] Making this data available through alternative means should reduce the volume of FOIA requests and the costs incurred by processing them. The FDA could then reallocate the money and employee time saved on FOIA to implementing and maintaining the data publicity system. Second, and perhaps more important, data publicity will permit independent researchers to double-check and otherwise support the work of the agency, reducing its error rate and increasing its overall efficiency and credibility. And, of course, from the wider public's perspective, data publicity is an excellent bargain even if it requires increasing the FDA's budget and staff, as it is likely to save hundreds of millions, even billions, of dollars in spending on unsafe and ineffective drugs.[333]

We conceived our data publicity regime and wrote this Article before the COVID-19 pandemic began. Now, as we finish our Article in the summer of 2020, the novel coronavirus has cost hundreds of thousands of lives and devastated our country and the world. This catastrophe has exposed and exacerbated innumerable longstanding and systemic problems in our society, our economy, and our politics—problems beyond the scope of this Article. But the virus has also raised issues of data secrecy in a new and unusually vital way. The benefits that would flow from data publicity[334] are desperately needed vis-à-vis COVID-19, including improvements in clinical care; better coordination of clinical research, including avoidance of redundant or unproductive clinical trials; acceleration of the development of new therapies; and validation of the work of the FDA.

This last benefit—double-checking the FDA's work—may be particularly crucial at a moment when the FDA finds itself under enormous pressure to shepherd new medical technologies to market as quickly as possible. For example, HHS's "Operation Warp Speed" and President Trump called on the FDA to approve COVID-19 vaccines and therapeutics on an unprecedentedly short timetable, and raised concerns that decisions would be made on the basis of incomplete or less than convincing evidence of safety and efficacy.[335] The FDA has already been criticized for hurrying to grant an emergency use authorization for the COVID-19 treatment remdesivir before anything more than preliminary analysis had been published on the clinical trial data that supported

331. Egilman et al., *supra* note 142, at 4.

332. For example, Kwoka has documented that the FDA's single highest-volume FOIA request is a for-profit company called FOI Services, Inc., which files hundreds of requests per year, and that a focus of these requests is data from NDAs. Kwoka, *FOIA, Inc.*, *supra* note 23, at 1388–89.

333. *See supra* Part I.A.

334. *See supra* Part I.A.

335. Adam Cancryn, *Is Trump on Track for an October Vaccine Surprise?*, POLITICO (July 22, 2020), https://www.politico.com/news/2020/07/22/trump-october-vaccine-surprise-coronavirus-379278 [https://perma.cc/6XFW-574V].

the authorization.[336] Our proposed data publicity regime would insulate and support the agency in this challenging time.

Our ultimate goal, through the COVID-19 pandemic and beyond, is to supplement and strengthen the FDA's capacity, credibility, and authority. The features we propose, like shifting the burden of redaction to the pharmaceutical industry and creating data use agreements that prohibit commercial use, are intended to serve that goal.

There is, of course, a risk that the agency will not act.[337] If the FDA does not act, Congress can and should. Congress has already acted recently to expand access to certain health data by mandating that the FDA publish approval packages[338] and postmarket drug safety information (including adverse event data at the individual patient level, in anonymized form)[339] on its website. Congress could do the same with the safety and efficacy data we describe. If Congress decides to legislate in this arena, it could helpfully clear up any lingering uncertainty about the boundaries of 18 U.S.C. § 1905 (the TSA) and 21 U.S.C. § 331(j) (§ 301(j) of the FDCA) by mandating release of the specific types of safety and efficacy data we have defined—see *supra* Part I.A —notwithstanding these statutes.[340]

Our analysis also points to a broader problem that is woven through the regulatory state in our information age. Commerce and industry are increasingly informational, making access to data essential to understand the implications of a wide range of products, from self-driving cars to environmental chemicals to complex financial instruments. The same dynamics we trace here—the incentives the industry has to hide data *even as it relies on this data to claim that its products will benefit the public*—are pervasive. Whether it is Boeing, touting

336. Ed Silverman, *Where's the Data? In a Pandemic, Now Is No Time to Sit on Covid-19 Trial Results*, STAT NEWS (May 13, 2020), https://www.statnews.com/2020/05/13/wheres-the-data-in-a-pandemic-now-is-no-time-to-sit-on-covid-19-trial-results/ [https://perma.cc/2Q95-PTP9].

337. As Justice Breyer observed in his dissent in *FMI v. Argus Leader*, there is a "temptation, common across the private and public sectors, to regard as secret all information that need not be disclosed . . . for reasons no better than convenience, skittishness, or bureaucratic inertia." Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2368 (Breyer, J., dissenting). *See also* Kreimer, *The Ecology of Transparency*, *supra* note 152; Seth F. Kreimer, *The Ecology of Transparency Reloaded*, *in* TROUBLING TRANSPARENCY: THE HISTORY & FUTURE OF FREEDOM OF INFORMATION 135 (David E. Pozen & Michael Schudson eds., 2018).

338. Food and Drug Administration Amendments Act of 2007 (FDAAA) tit. IX, § 916, 21 U.S.C. § 355(l).

339. FDAAA § 915, 21 U.S.C. § 355(r).

340. Congress could also ensure that both the FDA and drug companies cooperate with a mandatory data publicity regime by amending the provisions that concern approval of new drugs, 21 U.S.C. § 355 (NDAs) and 42 U.S.C. § 262 (BLAs), to make submission of redacted, publicly disclosable data a precondition of approval and to require FDA disclosure within some defined time period, such as within 30 days of approval. Congress could also legislate to expand disclosure of Phase 4 clinical trial data by making post-approval extensions to patents and other exclusivities that cover prescription drugs conditional on disclosure of that data. For example, the statutes governing patent term extension (35 U.S.C. § 156) and pediatric extensions (21 U.S.C. § 355a) could be amended to require that the drug application holder submit (in appropriately redacted form), and the FDA disclose, all relevant Phase 4 data before the FDA grants the extension.

the safety of its planes while hiding their inner workings from regulators and the public,[341] or Monsanto, urging the safety of its pesticides but suing the EPA to prevent public release of safety data,[342] companies have perverse incentives to claim virtue for their products but obscure the data that would enable third parties to validate their claims. Regulators will often possess relevant data but have limits—resources, person power, and conflicts of their own—that prevent the real benefits of this data from being leveraged unless outside parties have access. But those seeking access to corporate data in other areas are likely to face the same obstacles we address here: the cost and complexity of FOIA and the problems of the new *FMI* standard; the tendency of agencies to overprotect corporate data and treat as confidential or trade secrets data that may not meet that definition;[343] the inability to overcome corporate opposition and privacy concerns without proactive disclosure; and the need to create some limits on disclosure and access to protect values like personal privacy.

The model we offer of data publicity subject to data use agreements will be informative for other agencies. Our analyses of the TSA and takings law are generalizable and can help support data publicity beyond the pharmaceutical context. There will be, of course, fact-specific questions about where and when disclosure is warranted, and even circumstances where calls for transparency will be disingenuously mobilized to harm the public.[344] It is important to appreciate, as we have stressed, that data publicity at the FDA can inform the public, because it occurs within a particular political economy that includes publicly funded scientists with the skills and desire to analyze that data. These elements will be important to the success of other data publicity regimes too. We leave to future work exploration of the need for and avenues to data publicity elsewhere in the regulatory state.

341. Chokshi, *supra* note 30.

342. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 998 (1984).

343. For examples of widespread regulatory and non-regulatory agency rules that extend broad deference to submitters' purported trade secrets and CCI, see 12 C.F.R. § 404.2 (Export-Import Bank); 20 C.F.R. § 402.90 (Social Security Administration); 47 C.F.R. § 0.457(d) (Federal Communications Commission).

344. *See, e.g.*, Letter from Harvard Leaders to Andrew Wheeler, Acting Administrator, Env't Prot. Agency, on Proposed Rule, Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,786 (Apr. 30, 2018) (Aug. 7, 2018), https://www.scribd.com/document/385677020/Letter-from-Harvard-leaders-to-EPA-s-Andrew-Wheeler-on-proposed-science-policy [https://perma.cc/RZN7-5VNS] (describing the problems with an EPA "transparency" proposal that would have undermined access to reliable climate science).