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A NEW FRAMEWORK FOR ASSESSING CLINICAL DATA TRANSPARENCY INITIATIVES

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* Associate Professor of Law, University of Missouri School of Law. I am grateful to Sandy Baggett, Michael Carrier, Lewis Grossman, Heather Hughes, and David Lange for helpful comments on drafts of this paper. I am also grateful to Kathleen Boozang for arranging an informal audience for a draft at the Seton Hall University School of Law and to Lewis Grossman for arranging an informal audience for a draft at the American University Washington College of Law, and to the faculty who participated in those sessions. All errors and shortcomings in the article are, of course, my own. At the time this article was prepared, I was an Adjunct Professor at the George Mason University School of Law and a Partner at Covington & Burling LLP, where I specialized in the regulation of drugs and biological products, with a particular focus on aspects that have an intellectual property component. The views in this article of course should not be attributed to any client of that firm.

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INTRODUCTION

Biopharmaceutical companies submit vast amounts of clinical data and analysis to support approval of their medicines, expecting the information to be kept confidential, as has been the practice of regulators around the world for decades. Over the last ten years, however, pressure has been mounting for regulators or industry to release this data. Indeed, European authorities are moving swiftly now towards full release over industry objections and despite several lawsuits. Industry generally argues that the material is intellectual property—specifically trade secret or confidential commercial information—and that its release will help a company's competitors, devaluing the property and reducing incentives for medical innovation. To the limited extent that they have addressed the issue, however, legal scholars have generally taken the view that no relevant doctrines or bodies of law preclude the release of this material and that public policy considerations compel its release. And the tide is turning, with incremental changes in the law in the United States, coercive pressure from medical journals to release data as a condition of publication, European regulators pressing forward, and industry volunteerism to stave off the most aggressive forced disclosure proposals.

This Article provides a new framework for assessing disclosure of the contents of drug applications, by filling several major gaps in the legal scholarship. The key gaps are as follows. First, scholars in the intellectual property field devote very little attention to this sort of information good—both the actual content and the context in which it is generated and used. Application of the trade secret label, in particular, has not been subjected to close scrutiny. Second, very few have explored the special issues presented by operation in an environment where data and analyses are generated and submitted to government in order to gain market access—i.e., where the content has both an informational value and a regulatory value. Third, very few have explored the implications of operation in a multi-national environment where the decision of one regulatory authority to release the material could have profound implications on legal outcomes in other jurisdictions.

My primary thesis is that this content should be understood as *property* rather than *trade secret* and that the right to exclude includes severable sub-strands. The right to prevent disclosure can be severed from the right to prevent use, including use by regulators to assist one's competitors. This approach blunts the impact in the United States of potential disclosure by European authorities. Although this Article focuses on information submitted by biopharmaceutical companies for approval to market their medicines, my analysis has broader implications. Participants in many other industry sectors submit testing analyses to regulatory authorities around the world to satisfy a barrier to entry and with an expectation of confidentiality.

Section I of this Article explains the relevant features of the safety and effectiveness information in drug applications. Specifically, this content includes raw data (including manipulated and synthesized data) and strategic and interpretive writing. Scholars have not fully identified the potential regulatory uses of the former if released, nor have they fully appreciated the policy implications of releasing the latter. Section I also explains the salient features of the barrier to market entry, including the difference in scope, cost, and risk between innovative applications and follow-on (generic or biosimilar) applications, and the fact that essentially the same content is submitted to regulators around the world.

Section II provides a framework for assessing government disclosure of the content. It argues, first, that labeling this content as trade secret is analytically problematic. Both historically and doctrinally trade secret law is private law—mostly about actions taken in connection with relationships between private parties, not a person and the government. Moreover, the enduring debate in trade secret law, whether this law's origins lie in principles of property or principles of unfair competition, arguably collapses in the regulatory context. It makes no sense to consider whether the doctrine is property-based or liability-based, because the government may in fact "take and pay" with respect to property. All roads lead to the property question. For both reasons, I propose that we ignore the trade secret label when considering the disclosure issue. I consider instead whether the contents of marketing applications are *property*. This Section of the Article works primarily from Lockean principles, but considers also utilitarian norms.

After concluding that the contents are property, I turn to characterizing the sticks in the bundle of rights. This is where a deeper understanding of the content and its context are most relevant. This content has both informational uses and regulatory uses, to its owner and to potential third parties. These qualitatively different uses for the content lead to a broader right to exclude than scholars and courts have previously asserted, including *severable* rights to prevent disclosure and to prevent use. Thus, disclosure need not deprive the owner of the right to disallow direct use—including, for instance, reliance on a company's information by regulators for the benefit of the company's competitors. This conclusion represents a significant departure from conventional wisdom about trade secrets (that disclosure eviscerates the property right) and helps to demonstrate why the trade secret label is wrong. A robust reading of the right to exclude, combined with an understanding of the full regulatory context, also helps to explain why this content should not be viewed as a true public good. Among other things, released clinical modules might be excludable, insofar as a regulator can decline (or be forbidden) to use them in support of third party products.

Understanding this content as property leads to the conclusion that in the United States, takings law applies. The leading case with respect to data submitted for regulatory purposes, *Ruckelshaus v. Monsanto*, suggests that disclosure is a taking, but it suffers from a serious analytical flaw; Justice Blackmun commented that disclosure of the data eviscerated the property interest.[1] The balance of the Court's property takings jurisprudence would lead to a similar conclusion, although *Kaiser Aetna* and *Mahon* remain the most compelling precedents, particularly because disclosure to the public at large would eliminate the information owner's ability to profit from the fruits of its labor.[2] But, because the right to exclude can be understood more broadly than Justice Blackmun asserted, disclosure should not be understood to have eviscerated all property right in the material. This could have profound implications in the United States, where, for instance, an argument has been made that biologic applications filed prior to the enactment of the new biosimilars law contain property that cannot be *used* over the owner's objection to support biosimilars. The framework presented in this Article should lead to the conclusion that disclosure of the content by European authorities has no bearing on that use-related takings claim.

I also argue in Section II that public policy considerations should shape the taking and ancillary legal reforms. The most compelling argument for disclosure of the contents of applications is that the information could be used by others in ways that would advance the public health (for instance, aggregation and meta-analyses) and that industry either cannot do this work or lacks the incentive to do it. The most compelling argument against broad disclosure, however, is that the information can be used by competitors to support their own commercial programs, immediately harming the application holder. The public policy arguments together point to controlled sharing with non-profit researchers to advance general scientific knowledge, including our understanding of approved medicines. In view of the takings issue, however, the government should consider incentivizing or rewarding volunteerism. If instead a taking is considered, then compensation must be provided, though it could perhaps be accomplished through statutory "in kind" mechanisms. The risk that another regulator will move first, eliminating a takings claim, may also call for consideration of reforms that will blunt the impact of disclosure on incentives to innovate.

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1. 467 U.S. 986 (1984).

2. Kaiser Aetna v. United States, 444 U.S. 164 (1979); Pennsylvania Co. v. Mahon, 260 U.S. 393 (1922).

I. BACKGROUND

This Article provides a legal framework for assessing whether medicine regulators should release to the public the safety and effectiveness information generated and submitted by private companies in applications for permission to market their medicines. Proponents of release generally characterize release as furthering "transparency" with respect to the evidentiary basis for government decisions, and they invoke a general policy preference for government "in the sunshine"—as embodied, for example, in the U.S. Freedom of Information Act (FOIA).[3] This Article refers instead to "disclosure" and "release" of the information in question, in large part because the term "transparency" conveys judgment about the appropriate public policy. The term is also overbroad, covering everything from disclosure of internal agency procedures to disclosure of government employee addresses.

Under most modern regulatory schemes, a company wishing to market a new medicine must obtain approval to do so, from the government, prior to launch. In the United States, new drugs require new drug applications (NDAs) approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA). Biological products require licenses issued under section 351 of the Public Health Service Act (PHSA). FDA may approve an NDA only if the application demonstrates that the drug is safe and effective for use under the conditions described in the proposed labeling and, in particular, that there is "substantial evidence" of efficacy.[4] Substantial evidence means "evidence consisting of adequate and well-controlled investigations, including clinical investigations . . . ."[5] The traditional approach involves three sequential, sometimes overlapping, phases of trials in human subjects.[6] The third phase

3. 5 U.S.C. § 552.

4. 21 U.S.C. § 355(d). The original FDCA required only that new drugs be safe and imposed a premarket notification requirement on new drug sponsors. Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (1938). Congress added the effectiveness standard and premarket approval requirements in 1962. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962). The 1962 amendments are generally understood as having launched the modern and increasingly expensive and lengthy drug research and approval process. *See* Anna B. Laakmann, *Collapsing the Distinction Between Experimentation and Treatment in the Regulation of New Drugs*, 62 ALA. L. REV. 305, 308 (2011) ("The modern U.S. drug regulatory system was born in 1962 with passage of the Kefauver-Harris Amendments [to the FDCA]."); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1790 (1996) ("The 1962 requirements for proof of effectiveness and affirmative FDA approval were destined to increase the cost and time required to introduce new drugs. More extensive clinical testing would be required, and the interest on development expenses would rise with the additional time required to convince the agency to approve an NDA.").

5. 21 U.S.C. § 355(d) (2006).

6. 21 C.F.R. § 312.21 (2013). Generally speaking, in Phase I trials, a drug is given to a small number of test subjects, normally healthy volunteers, in order to determine the metabolism and

provides the substantial evidence of effectiveness. Section 351 of the PHSA requires proof of safety, purity, and potency, and it does not mention "substantial evidence." Nevertheless, since obtaining jurisdiction over biologics in 1972, FDA has interpreted "potent" to require proof of efficacy.[7] The agency also requires biologics applicants to submit substantial evidence of effectiveness.[8]

An original application for a new molecular entity today typically includes the results of dozens of non-clinical studies and clinical trials.[9] Raw data from clinical trials consist in the purest form of subject-specific case report forms (CRFs), on which all information relevant to the clinical trial is recorded—including demographic information and all relevant measurements (laboratory results relevant to outcome measures, for instance). Demographic information and measurements reflect the clinical trial protocol, itself the subject of discussion and negotiation with regulators, and through that protocol, the company's business strategy. Original CRFs are, however, not usually submitted to regulatory agencies. Under FDA regulations, for example, CRFs are required only where the subject dropped out or died during the study. Data tabulations are required for the remaining subjects.[10] These datasets are submitted electronically, conforming to FDA specifications for submission of clinical study datasets in electronic format.[11] The agency expects that the

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pharmacologic actions of the drug in humans, to learn the side effects associated with increasing doses, and to gain early evidence of effectiveness. Phase II investigations involve up to several hundred patients with the disease or condition being studied. They are designed to begin to assess the drug's effectiveness. They are typically well-controlled and well-monitored. They are also intended to determine short-term side effects and to confirm and refine early data on optimal dosage. Phase III trials collect the pivotal safety and effectiveness data necessary for regulatory approval of the drug. They can involve several thousand patients and frequently take place in multiple locations throughout the country and abroad.

7. *See, e.g.*, 46 Fed. Reg. 4634, 4637 (proposed Jan. 16, 1981) (to be codified at 21 C.F.R. pt.601); 37 Fed. Reg. 16679, 16679 (proposed Aug. 18, 1972) (to be codified at 21 C.F.R. pt. 273).

8. *See, e.g.*, 21 C.F.R. § 201.57(c)(2)(iii) (2013). FDA notes that applying the substantial evidence standard to biologics presents "unique problems" in some cases. 37 Fed. Reg. at 16679. Thus, the requirement for data from adequate and well-controlled investigations (or one such investigation with confirmatory evidence) is a default, but not an absolute requirement. 21 C.F.R. § 601.25(d)(2) (2013). An applicant may obtain a waiver by showing that: (1) the standard is "not reasonably applicable" to the product or "essential to the validity of the investigation" and (2) an "alternative method" for substantiating effectiveness is available and adequate. *Id.*

9. According to one report, the average number of clinical studies submitted in an NDA between 1977 and 1980 was thirty. By 1994 and 1995, that figure had more than doubled to sixty-eight studies. Barbara Ann Binzak, *How Pharmacogenomics Will Impact the Federal Regulation of Clinical Trials and the New Drug Approval Process*, 58 FOOD & DRUG L.J. 103, 112 n.57 (2003) ("The average number of clinical trials per new drug application has increased dramatically, from 30 during the period of 1977–1980 to 68 during 1994–1995.").

10. 50 Fed. Reg. 7452, 7453 (Feb. 22, 1985).

11. FDA, STUDY DATA SPECIFICATIONS (1.5 ver., 2009), *available at* http://www.fda.gov/

applicant will discuss with the review division the datasets that will be provided. Thus, even the tabulated datasets reflect discussions between the applicant and the regulator and could signal the applicant's business strategy.

The applicant includes a clinical study report (CSR) for each study. In this, the data is excerpted, organized, manipulated, and presented in tables, graphs, and other forms that are helpful to explaining or presenting the trial or some aspect of the trial. This document also presents the company's conclusions and addresses possible follow-ups. In essence, it explains the study: how it was designed and why it was designed that way; how it was performed, including changes and surprises along the way (such as protocol deviations and amendments and patients dropping out); the results as to every endpoint; and statistical analysis and interpretation of the results pursuant to the data analysis plan. A CSR is interpretive and nuanced, and it reflects the company's judgments as to the information the regulator will consider most important and which data are key. The study report inherently conveys information about how the company manages its clinical development programs, such as its relationship with clinical research organizations and monitors. There may be extensive information about the company's meetings with and commitments to regulators, as well as conclusions based on those meetings. There may be descriptions of the status of ongoing or planned studies and the dates of protocols, amendments, and other regulatory submissions.

The cost to the average company of generating this content is difficult to quantify, and there is disagreement regarding what one should measure in the first instance and how one should quantify time, lost opportunities, and failed molecules. Estimates vary, but no one doubts that the cost is substantial.[12] Notwithstanding the enormous investment that first entrants must make to bring their new medicines to market, second entrants are permitted to piggy-back on this investment, so as to climb over the barrier to entry with their copycat products without making a similar investment of their own.[13] Statutory exclusivity periods prevent—for a time—submission or approval of these

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downloads/ForIndustry/DataStandards/StudyDataStandards/UCM199599.pdf.

12. *See generally* Christopher P. Adams & Van V. Brantner, *Estimating The Cost Of New Drug Development: Is It Really $802 Million?*, 25 HEALTH AFFAIRS 420 (2006). Adams and Brantner review a widely cited figure of $802 million per new drug (in 2000 dollars) for drugs entering human clinical trials for the first time between 1989 and 2002 and provide their own estimates, which vary from around $500 million to more than $2 billion, depending on the drug and the company. The $802 million figure appears in Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003).

13. There are three possibilities: an abbreviated new drug application (ANDA), 21 U.S.C. § 355(j), a 505(b)(2) application, *id.* at § 355(b)(2), and a biosimilar biological product application, 42 U.S.C. § 262(k) (Supp. IV 2010).

abbreviated applications.[14] These exclusivity periods are known as data exclusivity, because when they expire, the second entrants rely indirectly on the data in the pioneer application demonstrating that the molecule and product were safe and effective.[15]

FDA regulations prevent the release of non-public safety and effectiveness data and information submitted in an approved NDA unless and until one of six events has occurred; and even in those cases, regulations preclude release if extraordinary circumstances are shown.[16] FDA applies the extraordinary circumstances exception where the data and information retain competitive value, including overseas, so as a practical matter it does not release the content in question.[17] The agency's regulation with respect to biologics license applications (BLAs) is drafted differently but achieves the same result.[18] The current regulations date to the 1970s, but the agency's non-disclosure policy

14. If no active moiety in a product subject to an NDA has previously been approved, an ANDA or 505(b)(2) application may ordinarily not be submitted for five years. 21 U.S.C. § 355(j)(5)(F)(ii). This period is shortened to four years if the follow-on applicant challenges a patent claiming the drug or a method of using the drug, but then there is a 30-month stay of approval if the NDA holder or patent owner brings timely suit. *Id.* at § 355(j)(5)(B)(ii). If the pioneer product contains a previously approved active moiety, there is no bar on submission of a follow-on application, but FDA may not approve the application for three years (assuming the pioneer application included clinical data essential to its approval). *See id.* § 355(j)(5)(F)(iii); 21 C.F.R. § 314.108. A biosimilar application may not be submitted until four years after first licensure of a pioneer product, and it may not be approved until twelve years after first licensure. 42 U.S.C. § 262(k)(7).

15. *See* Letter from Janet Woodcock, M.D., Director, CDER, to Katherine M. Sanzo, Esq. and Lawrence S. Ganslaw, Esq., Morgan, Lewis & Bockius, LLP; Jeffrey B. Chasnow, Esq., Pfizer; Stephan E. Lawton, Esq. and Gillian R. Woollett, Ph.D., BIO; and William R. Rakoczy, Esq., Lord, Bissell & Brook LLP, 10 n. 14 (Oct. 14, 2003) (on file with author) ("[R]eliance on an FDA finding of safety and effectiveness for an NDA is certainly indirect reliance on the data submitted in the original NDA . . . ."); Valley Drug Co. v. Geneva Pharm. Inc., 344 F.3d 1294, 1296 (11th Cir. 2003) (indicating that the ANDA allows the applicant "to piggyback on the safety and efficacy studies conducted for the pioneer drug . . . .").

16. These events include that the application was found not approvable (and all legal appeals exhausted), and that an abbreviated application under the generic drug provisions has been (or could be, as a legal matter) approved. 21 C.F.R. § 314.430(f) (2013).

17. 39 Fed. Reg. 44602, 44613 (Dec. 24, 1974) (clarifying that "extraordinary circumstances" include situations in which the information in question retained competitive value); *see also* 130 Cong. Rec. 24977 (Sept. 12, 1984) (statement of Sen. Hatch) ("Under current practice . . . extraordinary circumstances are present for example when the information is trade secret or confidential commercial or financial information."); *id.* at 24978 (statement of Sen. DeConcini) (quoting Commissioner of Food and Drugs that this approach "reflects FDA's current interpretation of the term 'extraordinary circumstances' as it now appears in the regulations.").

18. 21 C.F.R. § 601.51(e) provides that, after FDA approves a BLA, all safety and effectiveness data and information in the file "are immediately available for public disclosure unless extraordinary circumstances are shown." The agency does not, in fact, release the premarket safety and effectiveness information, because the information retains competitive value. *See generally* FEDERAL DRUG ADMINISTRATION, 2004P-1071 C7, LETTER OF ROBERT A. LONG, JR. (July 13, 2005).

dates to enactment of the FDCA in 1938.[19]

In response to President Obama's government-wide initiative to promote greater transparency in federal agencies, however, FDA convened a Transparency Task Force that ultimately suggested convening a panel to consider disclosure of safety and effectiveness data in applications.[20] The report focused on regulatory policy, however, and eschewed legal issues. After Deputy Commissioner Sharfstein left the agency in early 2011, the work of the task force was laid aside. More recently, the agency has solicited comment on possibly releasing safety and effectiveness data that have been masked as to product identity.[21]

The Europeans, however, have taken concrete steps towards release of the safety and efficacy information. In early 2012, the European Medicines Agency (EMA) published a guidance document on implementation of the Transparency Regulation (the equivalent of our FOIA) with respect to marketing authorization applications.[22] This guidance states that, following product approval, the EMA may release the full non-clinical and clinical data package in an application. This guidance represented the culmination of a process that had begun in 2010, when—following an Ombudsman recommendation relating to release of data to scientific researchers—the EMA

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19. *See Drug Listing Act, 1971: Hearing on S. 2167 and H.R. 9936 Before the Comm. on Labor & Pub. Welfare*, 92d Cong. 46 (1971) (letter submitted by Peter Barton Hutt, Assistant Gen. Counsel, Food, Drugs & Envtl. Health Div.) ("Since 1938, the Food and Drug Administration has interpreted [various applicable laws] to protect from public disclosure, as confidential, . . . safety and effectiveness data, and other similar information submitted to the FDA by the regulated industries. This has broadly been the practice of other Government agencies."). From time to time, agency officials have supported federal legislation permitting a different approach. *E.g.*, *Business Record Exemption of the Freedom of Information Act: Hearings Before the Gov't Info. & Individual Rights Subcomm. of the H. Comm. on Gov't Operations*, 95th Cong. 87 (1977) (statement of Dr. Donald Kennedy, Comm'r, FDA) ("We are on record for such a long time and so consistency as regarding safety and efficacy data as being in that zone and the industry has come to rely on it. There is such a long list of precedents that we really think we need statutory help with changing that."); *see also Freedom of Information Act: Hearings before the Subcomm. on Admin. Practice & Procedure of the S. Comm. on the Judiciary,* 95th Cong. 6 (1977) (statement of Sherwin Gardner, Deputy Comm'r, Food and Drug Admin.) ("Legal constraints rather than agency policy choice has largely dictated FDA's policies and practices with respect to release of safety and efficacy data.").

20. FDA TRANSPARENCY INITIATIVE: DRAFT PROPOSALS FOR PUBLIC COMMENT REGARDING DISCLOSURE POLICIES OF THE U.S. FOOD AND DRUG ADMINISTRATION 48–49 (May 2010), *available at* http://www.fda.gov/downloads/AboutFDA/Transparency/PublicDisclosure/GlossaryofAcronymsandAbbreviations/UCM212110.pdf.

21. 78 Fed. Reg. 33421 (Jun. 4, 2013).

22. EUROPEAN MEDICINES AGENCY & HEADS OF MEDICINES AGENCIES, HMA/EMA GUIDANCE DOCUMENT ON THE IDENTIFICATION OF COMMERCIALLY CONFIDENTIAL INFORMATION AND PERSONAL DATA WITHIN THE STRUCTURE OF THE MARKETING AUTHORISATION (MA) APPLICATION—RELEASE OF INFORMATION AFTER THE GRANTING OF A MARKETING AUTHORISATION (Mar. 2012), *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf.

changed its own long-standing view that the clinical modules of applications were confidential.[23] Several lawsuits were brought in early 2012 challenging application of the EMA's policy,[24] and interim measures had been granted at the time of this Article's drafting. In June 2013, consistent with its new position, the EMA released a draft policy on *proactive* release of clinical trial data.[25] The fate of the EMA policy remains unclear, but the issue is likely to end up in the European Commission and Parliament if not preempted by some sort of voluntary arrangement.

Others have joined the discussion, including medical journal editors,[26] various public figures,[27] and industry.[28] With the exception of the research-based biopharmaceutical industry, writers in this space almost uniformly support release of the safety and effectiveness information in applications. The health policy arguments cited in favor of disclosure, discussed in Section II, include the argument that industry may not have the incentive or ability to perform some socially beneficial research with the information in question. Some who support release also believe that the publicly available information is biased in favor of newer and more expensive medicines, driving up utilization and healthcare costs. The academic literature directly on point is scant,

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23. DECISION OF THE EUROPEAN OMBUDSMAN CLOSING HIS INQUIRY INTO COMPLAINT 2560/2007/BEH AGAINST THE EUROPEAN MEDICINES AGENCY, EUROPEAN OMBUDSMAN, *available at* http://www.ombudsman.europa.eu/en/cases/decision.faces/en/5459/html. The Cochrane Institute had requested clinical study reports and trial protocols for certain anti-obesity drugs, so that they could perform their own analysis. The Ombudsman rejected the EMA's view that disclosure to the Cochrane Institute would harm the marketing authorization holder's commercial interests. *Id.*

24. Case T 29/13, AbbVie e.a. v. EMA, 2013 O.J. (C 079) 26; Case T 44/13, AbbVie e.a. v. EMA, 2013 O.J. (C 079) 53; Case T 73/13, InterMune v. EMA, 2013 O.J. (C 114) 38.

25. DRAFT POLICY, EMA, PUBLICATION AND ACCESS TO CLINICAL-TRIAL DATA (June 24, 2013), *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf. This document generally takes the position that clinical trial data "cannot be considered" confidential commercial information. *Id.* at line 50.

26. *See, e.g.*, Katie Thomas, *Medical Journal to Require More Details on Drug Trials*, N.Y. TIMES, Oct. 31, 2012, *available at* http://www.nytimes.com/2012/11/01/business/british-medical-journal-to-require-detailed-clinical-trial-data.html?_r=0 ("The British Medical Journal has announced that, beginning in January, it will no longer publish the results of clinical trials unless drug companies and researchers agree to provide detailed study data on request.").

27. *See, e.g.*, BEN GOLDACRE, BAD PHARMA: HOW DRUG COMPANIES MISLEAD DOCTORS AND HARM PATIENTS (2012).

28. *See, e.g.*, European Fed'n of Pharm. Indus. and Ass'ns [EFPIA], *EFPIA Position Transparency of Information on Clinical Trials Included in the Proposed EU Database* (Article 78 of the Proposal for a Regulation on Clinical Trials) (Dec. 10, 2012); Letter from Steve Miller, Executive Vice President of Regulatory Affairs, NPAF, to FDA, Div. of Dockets Mgmt. (HFA-305) (July 20, 2010). At least in part in response to the threat of disclosure in Europe, industry has recently committed to sharing patient-level and study-level data, and protocols, for medicines and uses approved in the United States and Europe, with qualified scientific and medical researchers for research purposes. *Principles for Responsible Clinical Trial Data Sharing*, PHRMA, (July 18, 2013), http://www.phrma.org/print/1277.

although important contributions have been made by Professors Lemmens and Telfer (who argue for disclosure primarily from a right to health), Professor Reichman (who argues for disclosure partially on the ground that clinical trials are a public good), and Professor Cahoy (who argues for tort reform linked to disclosure).[29] As discussed later, it is possible to shape a narrow approach to data release that responds in large part to Professors Lemmens and Telfer. Professor Reichman ultimately argues for more profound changes to the way we test and approve new medicines, which are beyond the scope of this Article, but the "public good" concept may not be fully on point. Professor Cahoy's points are well taken. Others whose work might have implications for the issue—including scholars writing in the trade secret field—have generally not considered this type of information good or the unique context in which it is created and shared.

II. PLACING DISCLOSURE WITHIN THE LEGAL LANDSCAPE

The clinical module of an application is generally considered to be trade secret. Labeling it as trade secret is, however, analytically problematic; the label fits awkwardly, trade secret law itself concerns private relationships and not relationships with the government, and the doctrinal debate about the nature of trade secret law collapses in a regulatory context. This Article therefore proposes to consider the property question from first principles. Application of Lockean labor theory leads to the conclusion that this content is property, and this conclusion can also be justified on utilitarian grounds. Labeling this content as property in turn leads to application of the Fifth Amendment. The special context in which this content is generated and functions allows us to frame the right to exclude more carefully, however, and leads to an important distinction between preventing disclosure and preventing use. Thus, depending on additional factors—some within the control of the disclosing regulator and some not—disclosure may or may not obliterate all of the right to exclude. This, then, is another reason to reject the trade secret label: it has prompted courts and scholars to assume erroneously that disclosure of premarket testing information eliminates its status as property. I agree that public policy

29. *See* Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency*, 38 AM. J.L. & MED. 63, 66 (2012); Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 9 (2009); Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 626–27 (2007). Others have written about the issue or subsidiary issues while tackling broader or ancillary topics. *See, e.g.*, Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477 (2003); Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005).

considerations point towards carefully controlled disclosure to, or sharing with, certain third parties for general medical research. I conclude that policymakers should consider measures that would blunt any taking they effect, for instance by protecting some of the right to exclude. But once private property is taken, the right to just compensation applies. In-kind compensation is a possibility, but policymakers may want to incentivize volunteerism instead.

A. Classification as Trade Secret

Broadly speaking, trade secret law relates to and in some fashion protects ideas, inventions, or knowledge (or other analogous intangibles) that are kept mostly secret by a business and are valuable to the business because of that secrecy. The definitions of "trade secret" to which most scholars and courts refer can be found in the Restatement (First) of Torts, published by the American Law Institute (ALI) in 1939, and the Uniform Trade Secrets Act (UTSA), adopted forty years later. Both the Restatement and the UTSA concern themselves with the liability that attaches when one private party commits an act with respect to the trade secret of another private party. This aspect of trade secret law traces its origins to English common law.[30]

Section 757 of the Restatement laid out a general principle of liability for unauthorized disclosure or use of trade secrets. Comment b described a "trade secret" as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it" but explicitly eschewed definition.[31] The Restatement also described factors to consider, including the extent to which the information is known outside the business; the extent to which it is known by employees and others involved in the business; measures taken to guard the secrecy of the information; the value of the information to the company and its competitors; the effort or money expended by the company in developing the information; and the ease or difficulty with which the information could be properly acquired or duplicated by others. None of these factors was meant to be dispositive. Most courts agree that the Restatement concept reaches safety and efficacy information in modern drug applications.[32]

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30. *See infra* note 57.

31. *See* RESTATEMENT (FIRST) OF TORTS § 757 cmt. b (1939) ("An exact definition of a trade secret is not possible.").

32. *See* Pub. Citizen Health Research Grp. v. FDA, 704 F.2d 1280, 1286 (D.C. Cir. 1983) (quoting McGarity & Shapiro, *The Trade Secret Status of Health and Safety Testing Information Reforming Agency Disclosure Policies*, 93 HARV. L.REV. 837, 961 (1980)) ("Strictly applied, 'this definition would classify virtually all undisclosed health and safety testing data as trade secrets.'"); A.L. Labs., Inc. v. Philips Roxane, Inc., 803 F.2d 378, 381 (8th Cir. 1986) (upholding jury decision that "study data" in a new animal drug application constituted trade secrets in accordance with the Restatement (First) of Torts § 757).

Analogously, in the seminal Supreme Court case relating to use and disclosure of testing data submitted to the Environmental Protection Agency, *Ruckelshaus v. Monsanto*, the parties stipulated that "much of the information, research, and test data" that Monsanto had submitted for approval of its pesticide "contain[ed] or relate[d] to trade secrets as defined by the Restatement of Torts."[33]

In 1979, the National Conference of Commissioners of Uniform State Laws (NCCUSL), now known as the Uniform Law Commission (ULC), adopted the Uniform Trade Secrets Act (UTSA). The ULC serves a very different purpose from the American Law Institute. Rather than restating what they believe to be general principles of common law, its members are appointed by state governments to draft model legislation in order to *achieve* "clarity and stability" in areas of state law where "uniformity is desirable and practical."[34] The drafting of uniform laws is a forward-looking exercise, not a retrospective synthesis, although a model law that departs substantially from the common law is unlikely to be favored in the state legislatures. The UTSA, which has now been adopted in forty-seven states, D.C., Puerto Rico, and the U.S. Virgin Islands, defines a trade secret as "information" that: (1) "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" and (2) "is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."[35] This is similar to the Restatement definition, except it does not require that the information be used in business, and it adds a requirement that the information

33. *Ruckelshaus*, 467 U.S. 986, 1001–02 (1984).

34. *About the ULC*, UNIFORM LAW COMMISSION, http://www.uniformlaws.org/Narrative.aspx?title=About%20the%20ULC. Uniformity is desirable with respect to trade secret law for the very reason that the multi-national nature of modern medicines law has become problematic: the action of one rogue state (for instance, abolishing the concept of "trade secrets" altogether) would have profound extraterritorial implications. In the United States, constitutional principles—including the dormant commerce clause—would probably constrain a state in this regard. In the international context, it may ultimately become necessary to bring the issue into treaty negotiations. Whether and to what extent Article 39.3 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) already prohibits signatory countries from releasing data that can be used by competitors in a foreign jurisdiction is beyond the scope of this article but has generated a considerable amount of academic scholarship, generally hostile to the view. *See, e.g.*, Reichman, *supra* note 29, at 8; *see also* CARLOS MARÍA CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT at ix–x, xiii, 14–16, 47–52, 57–58 (2002).

35. U.T.S.A. § 1(4) (amended 1985); *See also* RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 39 (1995) ("A trade secret is any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others.").

be the subject of reasonable efforts to ensure secrecy.[36] Neither distinction matters here. The safety and efficacy information at issue is used by biopharmaceutical manufacturers (to obtain marketing authorization, for instance) and is the subject of extensive efforts to maintain secrecy.[37]

The information at issue, therefore, is clearly protected by state trade secret law. Although various federal statutes also employ the phrase, these statutes are not analogous to this body of law. They do not concern themselves with the liability that attaches when one private party commits an act with respect to the trade secret of another private party.[38] Instead, they relate to release by a regulator. These public laws are FOIA, the federal Trade Secrets Act (TSA), and the FDCA, discussed briefly below. As explained below, these laws do not independently give meaning to the phrase. They incorporate the state law meaning, and the question for the courts has become whether they incorporate the Restatement definition of the phrase or some other definition.

The most important development in this regard was a 1983 decision of the D.C. Circuit relating to Exemption 4 of FOIA.[39] This exemption permits agencies to decline to disclose "'trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential."[40] FDA took the position that undisclosed safety and efficacy information was governed by the phrase "trade secret." At issue were summaries of adverse reaction and complication data, adverse reaction reports, reports of prior experiences, recall and product defect information, and information in export approval letters—all

36. Courts applying the state statutes tend to consider the six factors laid out in comment b of the Restatement. *See* 1 ROGER M. MILGRIM & ERIC E. BENSEN, MILGRIM ON TRADE SECRETS § 1.01 (2013).

37. For instance, there is extensive security at manufacturing facilities and corporate offices to prevent unauthorized access to and release of confidential information. Company employees typically receive training on proper procedures for handling confidential information. Access is limited through password protection and other security measures preventing access by employees who do not need the information to perform their job functions. Internal company documents are frequently marked with trade secret and/or confidential commercial information designations. Contractors engaged to support applications are required to sign confidentiality agreements. Documents ultimately submitted to regulators are often expressly marked as confidential. Companies usually have rigorous publication review procedures to prevent inadvertent disclosure of trade secrets. If the data and information are subject to discovery during litigation, companies will often seek robust protective orders.

38. There is one exception. The Economic Espionage Act of 1996, Pub. L. No. 104–294, 110 Stat. 3488 (EEA), criminalizes misappropriation of trade secrets. The definition of "trade secret" in the EEA is not materially different from the definition in the UTSA. *Id.* § 1839(3). A criminal law does not function like a statute authorizing trade secret owners to pursue injunctive relief or money damages. Its effectiveness in protecting the interests of industry depends entirely on prosecutorial interest.

39. *Pub. Citizen*, 704 F.2d at 1290.

40. *Id.*

submitted to FDA by manufacturers of intraocular lenses.[41] The Court of Appeals conceded that the Restatement would "classify virtually all undisclosed health and safety testing data as trade secrets."[42] It asserted, however, a second strand of common law jurisprudence that defined the phrase more narrowly, incorporating "a direct relationship between the information at issue and the productive process."[43] It further noted that this "restrictive approach" was adopted in the only pre-FOIA case interpreting the phrase "trade secret" in the federal Trade Secrets Act, "a source to which," the court assumed, "Congress surely would have looked."[44] Thus, the court concluded, "the term 'trade secrets' in Exemption 4 of the FOIA should be defined in its narrower common law sense, which incorporates a direct relationship between the information at issue and the productive process."[45]

Whether the *Public Citizen* case controls with respect to safety and effectiveness information in new drug and biologics applications is unclear,[46] but the reasoning of the court is vulnerable. For instance, the invocation of a second significant strand of common law jurisprudence is not borne out by the literature on trade secret law; most scholars take the view that the Restatement faithfully synthesized the common law.[47] Also, the primary legislative history of FOIA does not indicate that Congress considered the Restatement or that it looked to judicial interpretation of the Trade Secrets Act.[48] The reasoning of

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41. Brief of Appellant, Public Citizen Health Research Grp v. FDA, 704 F.2d 1280 (D.C Cir. 1983) (No. 82-1745), 1982 WL 608916 at *10.

42. *Pub. Citizen*, 704 F.2d at 1286.

43. *Id.* at 1288.

44. *Id.*, 704 F.2d. at 1287 (citing United States *ex rel.* Norwegian Nitrogen Prods. Co. v. United States Tariff Comm'n, 6 F.2d 491, 495 (D.C. Cir. 1925), *vacated*, 274 U.S. 106 (1927)).

45. *Pub. Citizen*, 704 F.2d at 1288.

46. Safety and effectiveness information are still protected under Exemption 4. The exemption separately protects commercial information that is privileged or confidential. And this concept has been held to reach, and is viewed by FDA as reaching, safety and effectiveness information. *See, e.g.*, Pub. Citizen Health Research Grp. v. FDA, 185 F.3d 898 (D.C. Cir. 1999) (holding that safety and effectiveness data in investigational new drug applications fall within exemption 4 as confidential commercial information).

47. Some have, however, argued that the narrow *Public Citizen* definition should be extended to other contexts. *See, e.g.*, Richard S. Fortunato, Note, *FDA Disclosure of Safety and Efficacy Data: The Scope of Section 301(j)*, 52 FORDHAM L. REV. 1280, 1283 (1984) (arguing that the narrow definition from *Public Citizen* should be adopted for purposes of section 301(j) of the FDCA). Even prior to the decision, some urged the agency to abandon the Restatement definition for FOIA purposes. *See, e.g.*, 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, 862–63 (1980).

48. The legislative history of Public Law 89-487 does not mention the Restatement. Although there was discussion of 18 U.S.C. § 1905 in the hearings, it was mostly government witnesses speaking of the statute, and the issue appears to have largely been the relationship between the two schemes. *See, e.g.*, *Federal Public Records Law, Pt. 1: Hearings Before the Subcomm. on Foreign Operations & Gov't Info. of the H. Comm. on Gov't Operations,* 89th Cong. 30 (1965) (exchange between Benny

the Court of Appeals is also undermined by the fact that the federal Trade Secrets Act—to which the Court purported to be referring—*is* interpreted to reach testing data. This criminal statute prohibits unauthorized disclosure of trade secrets by federal officials and agencies.[49] Courts have generally agreed with federal agencies that this provision is coextensive with Exemption 4, reaching testing data and analyses, just as the Restatement does.[50]

Section 301(j) of the FDCA contains a prohibition similar to that of the TSA: it prohibits any person from revealing "information acquired under the authority of" the NDA requirement "concerning any method or process which as a trade secret is entitled to protection."[51] FDA views this prohibition as

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L. Kass, counsel, Foreign Operations & Gov't Info. Subcomm. and Norbert A. Schlei, Assistant Att'y Gen., Dep't of Justice); *Federal Public Records Law, Pt. I: Hearings Before the Subcomm. on Foreign Operations & Gov't Info. of the H. Comm. on Gov't Operations*, 89th Cong. 67 (1965) (exchange between Benny L. Kass, counsel, Foreign Operations & Gov't Info. Subcomm. and Fred Burton Smith, Acting Gen. Counsel, Treasury Dep't). The case cited by the D.C. Circuit also does not appear in the key Senate and House hearings and reports from 1966.

49. The current statute was adopted in 1948 when Congress consolidated three prior nondisclosure statutes: a Commerce Department Statute, a revenue statute, and a Tariff Commission Statute. *See* H.R. REP. NO. 80-304, at A127-28 (1947). The latter was the only one of the three to prohibit disclosure of trade secrets. The reference to trade secrets can be traced to the Revenue Act of 1916, but the legislative history of the time sheds no light on its meaning. The revenue statute was originally passed in 1864 and prohibited disclosure of the "operations, style of work, or apparatus of any manufacturer or producer" by revenue officers. Revenue Act of 1864, ch. 173, § 38, 13 Stat. 223, 238 (1864). The legislative history yields no information beyond what the Supreme Court observed in 1979, that "Congress was primarily concerned with unauthorized disclosure of business information by feckless or corrupt revenue agents." Chrysler Corp. v. Brown, 441 U.S. 281, 296 (1979).

50. U.S. DEP'T OF JUSTICE, DEPARTMENT OF JUSTICE GUIDE TO THE FREEDOM OF INFORMATION ACT, at 354 (2009), *available at* http://www.justice.gov/oip/foia_guide09/exemption4.pdf ("Finally, it should be noted that the Trade Secrets Act . . . prohibits the disclosure of much more than simply 'trade secret' information and instead prohibits the unauthorized disclosure of all data protected by Exemption 4. . . . Indeed, the Court of Appeals for the District of Columbia Circuit and nearly every court that has considered the issue has found the Trade Secrets Act and Exemption 4 to be 'coextensive.'"); 76 Fed. Reg. 21432, 21518 (Apr. 15, 2011) (noting in a final rule promulgated by the Centers for Medicare & Medicaid Services that Exemption 4 "is as co-extensive with the Trade Secrets Act"); 61 Fed. Reg. 16424, 16425 (proposed April 15, 1996) (to be codified at 47 C.F.R. Part 0) ("Thus, if information may be withheld under Exemption 4, the [Federal Communications Commission] is barred from disclosing it by the terms of the Trade Secrets Act unless the disclosure is otherwise authorized by law.").

51. 21 U.S.C. § 331(j) (2006). Section 301(j) of the Act does not mention information acquired under the authority of the BLA provision, but there is a strong argument it applies. In 1972, when authority for reviewing biologics was transferred to FDA, the Commissioner of Food and Drugs noted that "all applicable provisions of the [FDCA]" would apply to biologics and that the Division of Biologics Standards would have authority to enforce all aspects of the FDCA "except for sections 302 and 304," thereby implying that section 301 applied. 37 Fed. Reg. 4004, 4004–05 (Feb. 25, 1972). And FDA routinely applies the rest of section 301 to biologics. Congress codified this approach in 1997, when it enacted section 351(j) of the PHSA. This section provides that "[t]he [FDCA] applies to a biological product subject to regulation under [PHSA section 351], except that a product for which a license has been approved under [section 351(a)] shall not be required to have an approved

nondiscretionary[52] and has, since its inception, treated section 301(j) as reaching safety and effectiveness information in applications.[53] No court has directly addressed the issue, although the Tenth Circuit has rejected the argument that the term "concerning" extends the reach of the provision beyond trade secrets (i.e., that information concerning a trade secret method might include information that is not, in itself, trade secret). The case, *Anderson v. Dep't of Health & Human Servs.*,[54] involved an attempt to compel FDA to

application under section 505 of such Act." 42 U.S.C. § 262(j) (2006). Although BLAs are not submitted under section 505, this provision brings them within the protections of section 301(j), which is part of the FDCA. And, indeed, FDA withholds the contents of BLAs from public disclosure. *See* Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 688 (2010) ("[T]o the authors' knowledge the agency never released the full preclinical and clinical package from a BLA."); Richard A. Epstein, *The Constitutional Protection of Trade Secrets and Patents Under the Biologics Price Competition and Innovation Act of 2009*, 66 FOOD & DRUG L.J. 285, 290 (2011) ("I am aware of only one case in which a competitor successfully requested access to a company's safety and effectiveness data" but noting that FDA interpreted its disclosure regulations for BLAs "in a way that allowed it to limit the disclosure it was prepared to authorize.").

52. *See* 39 Fed. Reg. 44602, 44619 (Dec. 24, 1974) ("The Commissioner advises . . . that he has no discretion to release trade secret information. All records subject to the trade secrets exemption from the Freedom of Information Act are prohibited from public disclosure pursuant to 18 U.S.C. 1905 and 21 U.S.C. 331(j)."); Jerome Stevens Pharms. v. FDA, 402 F.3d 1249, 1252 (D.C. Cir. 2005) (stating that "[t]he parties appear to agree that the disclosure of trade secrets is not a discretionary function because federal laws [including 21 U.S.C. § 331(j)] prohibit it"); Anderson v. Dep't of Health & Human Servs., 907 F.2d 936, 950 (10th Cir. 1990) (noting that section 301(j)'s "prohibition against disclosure is absolute").

53. 39 Fed. Reg. at 44634 ("The [FDA] Commissioner advises that, since 1938, it has been the consistent administrative interpretation that [section 301(j)] can encompass animal and human data. . . ."); *Business Record Exemption of the Freedom of Information Act: Hearings Before the Gov't Info. & Individual Rights Subcomm. of the H. Comm. on Gov't Operations*, 95th Cong. 70 (1977) (statement of Dr. Donald Kennedy, Comm'r, FDA) ("We have interpreted, since, 1938, the term 'method of process which as a trade secret is entitled to protection' under section 301(j) of our law as encompassing animal and human testing data."); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1792 n.122 (1996) (noting that "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. This position is based on the FDA's longstanding interpretation of the FD&C Act, the Freedom of Information Act (FOIA), and the Trade Secrets Act." (footnotes omitted) (citing 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)); David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*, 60 FOOD & DRUG L.J. 143, 214 (2005) ("FDA's long standing interpretation is that information submitted to demonstrate safety and effectiveness is proprietary, nonpublic information that is protected from disclosure under 21 U.S.C. § 331(j)."); *see, e.g.*, United States v. Pastor, 419 F. Supp. 1318, 1342 (S.D.N.Y. 1975) (noting that Bureau of Narcotics and Dangerous Drugs' SCID unit did not have access to "raw data regarding drug safety" because "FDA considered this information to be trade secret information" under section 331(j) of the Act).

54. Anderson v. Dep't of Health & Human Servs., 907 F.2d 936 (10th Cir. 1990).

disclose documents in applications relating to an unapproved liquid silicone product. The manufacturer intervened arguing that the documents fell within exemption 4 of FOIA, the TSA, section 301(j), and a confidentiality provision specific to devices.[55] The district court agreed, but the Tenth Circuit reversed. Among other things, it concluded that the term "concerning" in section 301(j) plays a structural, but not substantive, role. The court was guided by the fact that FOIA is broadly construed in favor of disclosure and its exemptions narrowly construed. That is, the court let the policies of FOIA guide its interpretation of the FDCA. Under the Tenth Circuit view, although the court did not address this point, safety and efficacy data in drug applications probably would not be protected under section 301(j). That does not appear to be FDA's view, however.

In brief, various relevant public laws use the phrase "trade secret," and for the most part the protection of these laws reaches safety and effectiveness information. But these laws borrow the phrase and concept from the substantive common law of trade secrets; they do not comprise a meaningful part of the substantive law themselves.

B. Analytical Problems with Trade Secret Classification

While safety and effectiveness information in drug applications is trade secret under conventional trade secret law principles (and most public laws relating to disclosure or release of testing data and analyses), labeling this content as trade secret is analytically problematic. To begin with, historically and doctrinally trade secret law is really mostly private law or, at least, mostly about action taken in connection with relationships between private parties—not between a person and the government. Further, the enduring debate in trade secret law, whether the law's origins lie in principles of property or principles of unfair competition, arguably collapses in the regulatory context. In this context, we care whether this content is trade secret for two reasons: *first*, because applicable public laws like FOIA incorporate the phrase as defined in state law (but do not incorporate trade secret law itself); and *second*, because various constitutional principles attach to property and the Supreme Court has said that, for purposes of these principles, trade secrets are property.[56] But these principles attach to property, not to trade secrets. Getting to property status for constitutional purposes through the trade secret label is unnecessary and, as shown in Part II(D)(1) may lead to an outcome inconsistent with property status

55. *Id.* at 940. After the manufacturer filed its IND for injectable silicone, Congress passed amendments to the FDCA giving FDA authority to regulate medical devices. As a result, injectable silicone was reclassified from a drug to a medical device. *Id.* at 939.

56. *Ruckelshaus*, 467 U.S. at 1003–04.

in the first instance.

1. Trade Secret Law is Not Directly on Point

Trade secret law in the United States is usually traced through an 1868 decision of the Massachusetts Supreme Court, *Peabody v. Norfolk.*[57] Both before and after *Peabody*, trade secret law in the United States has been a matter of common law. The doctrine that evolved in the states was fairly uniform, however, at least in part because of its origin in English common law[58] and probably also because the basic principles (as articulated in *Peabody* for instance) are necessary for the orderly working of an industrial society with increasingly interstate commerce.[59]

Peabody concerned confidential information shared by Joseph Peabody with John Norfolk in connection with Norfolk's employment as an engineer in Peabody's jute (gunny cloth) factory. The information related to the construction and operation of machinery in the factory. Peabody alleged in his initial prayer for injunction that Norfolk had left his employment, made arrangements with others to build a competing factory, and shared with them information about Peabody's manufacturing process and machinery, including drawings. After Norfolk was enjoined, Peabody identified a recipient of the secrets, James Cook, who was pretending to build competing machinery in his own name, using information, models, and drawings obtained from Norfolk, with full notice of the relationship between Peabody and Norfolk. A second injunction, against Cook, was also granted.[60]

The court began by asserting the policy of the law "for the advantage of the public, to encourage and protect invention and commercial enterprise."[61] Before turning to the facts at hand, the court devoted six paragraphs to laying out a theory for protection of business secrets grounded at least in part in the language of private property. "If a man establishes a business and makes it valuable by his skill and attention," the court observed, "the good will of that business is recognized by the law as property."[62] Moreover, "[i]f he invents or

57. 98 Mass. 452 (1868); *see, e.g.*, Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CALIF. L. REV. 241, 252 (1998); James W. Hill, *Trade Secrets, Unjust Enrichment, and the Classification of Obligations*, 4 VA. J.L. & TECH. 2, ¶ 12 (1999); Michael Risch, *Why Do We Have Trade Secrets?*, 11 MARQ. INTELL. PROP. L. REV. 1, 5 (2007) (citing *Peabody*, 95 Mass. 425 at 458).

58. *E.g.*, Bone, *supra* note 57, at 252 & n.55 (discussing various English cases from the 1800s).

59. *See, e.g.,* U.T.S.A. § 8 (amended 1985) ("This [Act] shall be applied and construed to effectuate its general purposes to make uniform the law with respect to the subject of this [Act] among states enacting it.").

60. *Peabody*, 98 Mass. at 461.

61. *Id*. at 457.

62. *Id.*

discovers, and keeps secret, a process of manufacture, whether a proper subject for a patent or not, . . . he has a property in it."[63] Ultimately, "it is settled that a secret art is a legal subject of property."[64] Thus, "a bond for a conveyance of the exclusive right to it is not open to the objection of being in restraint of trade, but may be enforced by action at law, and requires the obligor not to divulge the secret to any other person."[65]

Although *Peabody* does not represent the birth of trade secret law in this country, the decision is seminal because it collected and synthesized earlier cases and laid out a coherent theory for the doctrine. The court left an important gap, however: if a man "invents or discovers, and keeps secret, a process of manufacture, whether a proper subject for patent or not," although he has a property interest, "he has not indeed an exclusive right to it against the public, or against those who in good faith acquire knowledge of it." This sentence signals the notion that information held trade secret can be "reverse engineered"—independently discovered by a third party—with impunity. And it suggests the early doctrine did not consider public law issues. Indeed, as explained in the paragraphs that follow, trade secret law still mostly does not account for the realities of the modern regulatory state. The doctrine emerged within the context of, and academic and judicial writing continues to focus on, private relationships.[66]

Section 757 of the Restatement, which synthesized the common law as of 1939, set out a general principle of liability for unauthorized use or disclosure of trade secrets. Liability attached if:

> (a) [the defendant] discovered the trade secret by improper means . . . (b) his disclosure or use constitute[d] a breach of confidence . . . (c) he learned the secret from a third party with notice of the fact that it was secret and that the third person discovered it by improper means or that the third person's disclosure . . . [was] . . . a breach of his duty . . . or (d) he learned the secret with notice of the facts that it was secret and its disclosure was made to him by mistake.[67]

The model law created in the 1970s took a similar approach: the goal was to provide remedies for misappropriation, defined broadly to mean both: (1) acquisition through improper means, and (2) use or disclosure without consent

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63. *Id.* at 458.

64. *Id.* at 459–60.

65. *Id.* at 460 (citation omitted).

66. One notable exception in the literature is chapter 12 of Milgrim's treatise on trade secrets. *See* MILGRIM, *supra* note 36, at ch. 12.

67. RESTATEMENT (FIRST) OF TORTS § 757 (1939).

and with some degree of culpability (e.g., knowledge that the secret was acquired under circumstances giving rise to a duty of confidentiality).[68]

The Restatement and UTSA theories comprise the basic essence of trade secret law. The theories can, in principle, work in the regulatory setting. That is, an injunction would appear warranted where a regulator discloses trade secrets without consent and with knowledge that the trade secrets were acquired with the expectation that they would be kept confidential. State statutes adopting the UTSA are not, however, typically invoked by plaintiffs in such a manner,[69] and there is no true federal equivalent. The federal statute criminalizing misappropriation of trade secrets does not provide relief against the government.[70]

Further, basic assumptions of trade secret law do not apply to this content. Most notably, the classic hallmarks of reverse engineering and independent discovery do not apply. While it may be true that trade secrets are not good against the rest of the world *because* others may independently discover them,[71] the point is almost nonsensical with respect to safety and effectiveness information. If a third person were to stumble independently into the secret for Coca Cola, for instance, the rule is that person would be free to make and sell its product. If the formula were instead patented, it would be widely known, but federal law would, for a time, preclude its use. Thus, an inventor faces a choice between patent law (which blocks competition even in the event of independent discovery but ends after twenty years) and trade secret status (which provides no protection against independent discovery but is infinite in duration). It is, however, logically impossible for another person to independently discover the results of a clinical trial, which was performed some years earlier, with particular lots of an investigational product, and involved administration to particular individuals on particular days and measurement of specific parameters from those individuals. It is also logically impossible to independently generate the sponsor's judgments about how to describe the product and results, in view of its own business strategy and after particular

68. *See* U.T.S.A. § 1(2) (amended 1985).

69. The Uniform Trade Secrets Act contemplates such a cause of action. A "person" liable for misappropriation of trade secrets is defined to include a "governmental subdivision or agency." UNIFORM TRADE SECRETS ACT § 1 (amended 1985). Injunctions against government officials are available under other state statutes, however, and these laws seems to be more commonly invoked. *See, e.g.*, Lane v. Commonwealth, 517 N.E.2d 1281, 1282 (Mass. 1988) (holding that the plaintiff would be entitled to an injunction against state officials and employees under the Massachusetts Tort Claims Act if she could establish that the defendants were wrongfully using her trade secrets in the form of a computer software package used to compile municipal financial data).

70. The Economic Espionage Act of 1996, Pub. L. No. 104–294, § 1833, 110 Stat. 3488.

71. *E.g.*, Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L.J. 1575, 1582–83 (2002).

conversations with particular persons at the agency. The possibility of independent discovery makes sense with respect to the formula for Coca Cola or the design of an aircraft. But the possibility of independent discovery, which features prominently in trade secret scholarship, and the classic choice between patent protection and trade secret status, makes no sense for the content at issue here. And the possibility that one might be able to reverse engineer the *product* is irrelevant. The information at issue here is not "how to make the product"—it is instead the data, information, and analyses generated and prepared to overcome the regulatory barrier to market entry.

2. The Doctrinal Debate Collapses

A great deal of scholarship has attempted to make sense of trade secret law, categorizing and critiquing its various justifications and objectives and, in at least one instance, also suggesting that at bottom there is no such thing as a coherent and separate body of trade secret law.[72] The story this scholarship tells of the history and black letter content of state trade secret law is consistent. What varies meaningfully, however, is whether and how scholars see an underlying doctrine and how they describe and assess its justifications. In particular, the scholarship is dominated by an enduring doctrinal debate: whether trade secret law is primarily a law of liability (relationship) principles or a law of property (exclusivity and ownership).

The argument that trade secret law in the United States is primarily a law about the liability that attaches when parties in relationships violate social norms rely heavily on a key sentence in Justice Holmes's 1917 decision, *E.I. du Pont de Nemours Powder Co. v. Masland*.[73] *Masland* concerned secrets learned by Walter Masland while employed by DuPont. Masland was establishing a business that would manufacture artificial leather, and some of the secrets at issue were relevant, although Masland himself asserted that much of the information was in fact "well known to the trade." DuPont nevertheless sought an injunction to prevent Masland from using or disclosing those secrets. As part of the litigation, to defend against the injunction, Masland proposed to

72. *See, e.g.*, Risch, *supra* note 57 at 26–37 (discussing economic, philosophical, and populist justifications for trade secret protection); Hill, *supra* note 57 at ¶ 124 (identifying economic and moral justifications for trade secret law; exploring property, contract, quasi-contract, and tort aspects of trade secret law; and ultimately concluding that trade secret law is a "fusion" of tort and unjust enrichment principles); Bone, *supra* note 57 (examining and rejecting arguments from efficiency, arguments from rights and fairness, and arguments from norms about unfair competition); Jonathan R.K. Stroud, *The Tragedy of the Commons: Toward a Hybrid Property/Relationship Understanding of Trade Secrets*, CHI.-KENT J. INTELL. PROP. (forthcoming 2014), *available at* http://ssrn.com/abstract=2216659 (arguing that a hybrid approach will allow for prospective protection of trade secrets that have been disclosed).

73. 244 U.S. 100 (1917).

disclose the secrets in question to experts and witnesses. At issue before the Supreme Court was the appropriateness of an injunction against disclosing the trade secrets to experts, consultants, and defense counsel for purposes of defense. The case was put to the Court as a conflict between the right of property and the right to make a full defense. In a terse three-paragraph opinion, Justice Holmes brushed that proposed conflict aside. Rather than attempting to resolve a fundamental conflict of first principles, he picked a narrower resolution: "Whether the plaintiffs have any valuable secret or not[,] the defendant knows the facts, whatever they are, through a special confidence he accepted. The property may be denied, but the confidence cannot be." Thus, "the starting point for the present matter is not property or due process of law, but that the defendant stood in confidential relations with the plaintiffs, or one of them . . . If there is any disadvantage in the fact that he knew the plaintiffs' secrets, he must take the burden with the good."[74]

Those who favor the view that trade secret law is primarily a law of unfair competition suggest that Justice Holmes effectively rejected the argument that trade secrets were property. They note also that the drafters of the first Restatement in 1939 took pains to distance trade secret liability principles from property doctrine. Indeed, comment a noted that "[t]he suggestion that one has a right to exclude others from the use of his trade secret because he has a right of property in the idea has been frequently advanced and rejected."[75] According to the drafters, "[t]he theory that has prevailed is that the protection is afforded only by a general duty of good faith and that the liability rests upon breach of this duty."[76] In other words, they asserted, the essence of liability lies in breach of contract, abuse of confidence, or improprieties in obtaining the secret.[77] The ALI later moved trade secrets entirely to the Restatement (Third) of Unfair Competition, again reflecting the supposedly predominant view that trade secret law is primarily about enforcing behavioral norms in business relationships.[78] While the language of natural property rights can be found in early trade/business secret jurisprudence, this approach did not survive the emergence of legal realism in the early twentieth century.[79] Thus, this view holds, trade secrets are not really property at all. Rather, trade secrets are

74. *Id.* at 102

75. RESTATEMENT (FIRST) OF TORTS § 757 cmt. a (1939).

76. *Id.*

77. *Id.*

78. RESTATEMENT (THIRD) OF UNFAIR COMPETITION §§ 39–45 (1995).

79. For instance, Professor Bone states that legal realism "stripped away" the property foundation (and therefore the "justifying theory") for trade secret law. Bone, *supra* note 57, at 251, 260 ("Why give legal protection to secret information? As I discuss later, this question had a relatively clear answer in the late nineteenth century, but the answer lost its power to persuade with the ascendancy of legal realism in the 1920s and 1930s."). *Id.* at 251.

merely the subject of undertakings within the context of a relationship between two parties.[80] Some also make policy and normative arguments against the treatment of trade secrets as property, suggesting that this leads to overprotection of the assets in question.[81]

This Article subscribes to the position that trade secret law is instead primarily about protection of property. Under this view, *Masland* must be understood as an exercise in judicial restraint, a refusal to resolve the doctrinal conflict presented by the petitioner. Justice Holmes meant only that the property question—the tension between first principles—did not need to be resolved in order for the case to be decided.[82] Further, it has been established that despite the prompting of the ALI drafters, the cases that followed did not accept the distancing from property concepts.[83] It is possible the ALI reporters were reading the cases selectively or attempting to shape the law prospectively in the first Restatement. To be sure, the ALI continued on its own path, omitting the chapter on trade secrets in the second Restatement of Torts and ultimately placing them in the third Restatement of Competition. But of these Restatements, it is the initial 1939 Restatement of Torts that remains influential in the courts and agencies with respect to trade secrets, comment a—which most aggressively distanced trade secrets from property—generally forgotten.[84]

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80. *See, e.g.*, Pamela Samuelson, *Privacy as Intellectual Property?*, 52 STAN. L. REV. 1125, 1154 n.148 (2000) (arguing in part from the dictum in *Masland*); Pamela Samuelson, *Information as Property: Do* Ruckelshaus *and* Carpenter *Signal a Changing Direction in Intellectual Property Law?*, 38 CATH. U. L. REV. 365 (1989).

81. Vincent Chiappetta, *Myth, Chameleon, or Intellectual Property Olympian? A Normative Framework Supporting Trade Secret Law*, 8 GEO. MASON L. REV. 69, 84 (1999); Samuelson, *Information as Property*, *supra* note 80, at 399. As to over-protection, Professor Risch responds persuasively that real property rights are themselves neither infinite nor impermeable. They are subject to various limitations, including land use regulations and easements. Risch, *supra* note 57, at 24. This is, indeed, the point of subsection 0 of this article, which suggests that although this content is property, it can be taken, subject to Fifth Amendment compensation requirements.

82. *See, e.g.*, DONALD S. CHISUM, ET AL., UNDERSTANDING INTELLECTUAL PROPERTY LAW 199–200 (2d ed. 2011).

83. *See, e.g.*, *Id.* at 206–207 ("The Restatement's authors also sought to purge the property principle from trade secret laws[.] . . . To the contrary, the theory that has prevailed in the post-Restatement era is that a property right in a trade secret, although terminated by public disclosure, will be upheld against misappropriators and protected in a variety of contexts."). *But see* Samuelson, *Information as Property*, *supra* note 80, at 365 ("Trade secret law has long afforded remedies to the possessor of secret information against those who use improper means to obtain the secret and those who disclose it in violation of confidential relationships, but the law has, in general, resisted characterizing the secret itself as property.").

84. *See generally* MILGRIM, *supra* note 36, at § 1.01 (noting "universal reliance on § 757 of the 1939 *Restatement of Torts*" and the fact that the Restatement (Third) of Competition "has not been relied upon by many courts"). There are twenty-four published federal court cases and ten published state court cases citing comment a. Many focus on the relationship between the parties, and some cite *Masland*, but they constitute a minority of cases.

Professor Epstein also points to a fundamental theoretical problem with the view that trade secret protection derives from a relationship between two parties: this would imply a lack of protection where the information is not shared with anyone, which is illogical.[85]

The debate endures, with some questioning why it even matters,[86] and others arguing that the early cases and writings evidence strains from many strands of thought, including contracts, torts, and ethics.[87] Professor Milgrim marries the two strands by arguing that the law of unfair competition applies only because there is some sort of property at issue in the first instance and that a property right is therefore inherently a relational right.[88] The debate is not only about where the origins of trade secret law lie but also, of course, what the appropriate approach should be going forward. This is an essentially positivist debate to be having in the first instance. If assets generated through intellectual labor are "property" in any sort of natural law sense—which most writers today seem to discount—the debate would be beside the point. It is probably also true that in the private law setting it is "unnecessary to call trade secrets 'property' in order to enforce confidences and penalize those who use improper means to obtain . . . [those] secrets."[89]

But the question whether trade secrets are property in any meaningful sense or simply an interest or posture that is protected through liability rules and behavioral norms collapses in a regulatory setting. The content in question is provided to the government in exchange for a license to do business. The relationship between the parties to this transaction is not one of private entities on equal footing. Further, in a regulatory state, concepts like business ethics, commercial morality, and even misappropriation are replaced functionally by due process and other Fifth Amendment principles. Here, property status is dispositive. Moreover, even the distinction between the doctrines collapses. It makes no sense to consider whether the doctrine is property law (under which

85. Richard A. Epstein, *The Constitutional Protection of Trade Secrets under the Takings Clause,* 71 U. CHI. L. REV. 57, 60 (2004).

86. *E.g.*, Kenneth Einar Himma, *Toward a Lockean Moral Justification of Legal Protection of Intellectual Property*, SAN DIEGO L. REV. (forthcoming 2014) (manuscript at 2–3) (on file with author) (arguing that the debate over whether content is property is a "distraction," because "the important issue is whether content creators have a moral interest in the content they create that justifies legal protection that allows them to exclude others.").

87. *See, e.g.*, MILGRIM, *supra* note 36, at § 1.01. One could place Professor Bone in this group, because he takes the view that trade secret law is "mainly just a collection of other legal norms." Bone, *supra* note 57, at 243.

88. 1A ROGER M. MILGRIM & ERIC E. BENSEN, MILGRIM ON TRADE SECRETS § 2.01 at 2–9 (2013).

89. Samuelson, *Information as Property*, *supra* note 80, at 375. Whether state trade secret statutes ultimately enforce commercial ethics or ownership principles, or both, they can be applied by the courts without a view taken on the underlying doctrinal point. *See, e.g.*, *id.* at 375.

reallocation of assets occurs through voluntary negotiation) or liability law (under which reallocation of assets leads through business norms to a payment requirement), because the government may in fact lawfully "take and pay" with respect to property. Thus, all roads lead to the property question.

To be sure, in the regulatory setting, the trade secret label matters because various applicable public laws use the phrase. The Federal Trade Secrets Act, Exemption 4 of FOIA, and section 301(j) of the FDCA use the phrase. But, as noted, these are not part of the substantive law of trade secrets; they simply incorporate the concept by reference. In the core law that limits the actions of the government with respect to the governed—the Constitution, and here the Fifth Amendment—what *really* matters in this context is whether there is "property" at issue. This Article therefore proposes laying aside the trade secret question and working from first principles on the question whether the content at issue is property.

C. The Property Question

1. Defining the Content as Property

In chapter 5 of his Second Treatise of Government, published in 1690, John Locke posited that when one creates something of value through one's labor, one owns the end result of that labor.[90] There is a fundamental difference of opinion as to whether property arises automatically by operation of natural law, in the sense that Locke envisioned, or is instead a creation of law, dependent on the judgment of society that a particular right to use or exclude should be protected. Locke's formulation was enormously influential in early American political thought,[91] however, and, despite the influence of legal realism, continues to echo through U.S. property doctrine.[92] Moreover, the *Peabody*

90. JOHN LOCKE, THE SECOND TREATISE OF GOVERNMENT, ch. 5 (C. B. Macpherson ed., Hackett Publishing Co. 1980) (1690). *See, e.g.*, *id.* at § 27 ("Though the earth, and all inferior creatures, be common to all men, yet every man has a *property* in his own *person*: this no body has any right to but himself. The *labour* of his body, and the *work* of his hands, we may say, are properly his. Whatsoever then he removes out of the state that nature hath provided, and left it in, he hath mixed his *labour* with, and joined to it something that is his own, and thereby makes it his *property*."); *id.* at § 32 ("*As much land* as a man tills, plants, improves, cultivates, and can use the product of, so much is his *property*. He by his labour does, as it were, inclose it from the common.").

91. *See, e.g.*, Stanley N. Katz, *Thomas Jefferson and the Right to Property in Revolutionary America*, 19 J.L. & ECON. 467, 474 (1976) (indicating Jefferson also adopted the Lockean view that a man's "property was whatever he produced by dint of his personal labor . . . ."); 6 JAMES MADISON, *Property*, *in* THE WRITINGS OF JAMES MADISON 101 (Gailard Hunt ed., 1906) (writing after the Fifth Amendment had been adopted that "[i]n its larger and juster meaning, [the term property] embraces every thing to which a man may attach a value and have a right . . . .").

92. *See, e.g.*, *Ruckelshaus* 467 U.S. 1002–03 ("This general perception of trade secrets as property is consonant with a notion of 'property' that extends beyond land and tangible goods and

case itself echoed Locke.[93]

Locke was writing about a resource open for development—non-scarce land in the new world.[94] In the most relevant respects, pharmaceutical research and development is analogous.[95] Properly understood, this research space is not just non-scarce, it is infinite. A second entrant can build (or attempt to build) the same molecule, or a variation of the molecule, and imagine its own research and development program, perhaps to prove the same propositions, perhaps to prove new propositions, can design trials, recruit entirely new subjects in another part of the country, generate new data, package those data, and seek its own approval. A third entrant can build an entirely different molecule. No two research and development programs are identical—if for no other reason, because it is a physical impossibility for trials and results to be identical; they are the particular product of their time and place. Research and development programs, and the resulting data and analyses, are inherently infinite in permutations and in number. This asset is non-scarce in the sense that a property right would not, in any fashion, block another person who *independently* develops analogous information (the neighboring plot). Approaching the question from the natural rights labor-oriented position of Locke leads to the conclusion that the content of these applications is property.[96]

A utilitarian approach leads to the same conclusion. Biopharmaceutical

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includes the products of an individual's 'labour and invention.'") (citing Locke as well as Blackstone's Commentaries); Alaska Dep't of Natural Res. v. Arctic Slope Reg'l Corp., 834 P.2d 134, 137–39 (Alaska 1991) (finding that company's results from oil well drillings were property for state and federal constitutional purposes and citing Locke).

93. *Peabody*, 98 Mass. at 457 ("If a man establishes a business and makes it valuable by his skill and attention, the good will of that business is recognized by the law as property.").

94. *See* LOCKE, *supra* note 90, at § 33 ("Nor was this *appropriation* of any parcel of *land*, by improving it, any prejudice to any other man, since there was still enough, and as good left; and more than the yet unprovided could use. So that, in effect, there was never the less left for others because of his enclosure for himself: for he that leaves as much as another can make use of, does as good as take nothing at all."); *id.* at § 36 ("The *measure of property* nature has well set by the extent of man's *labour and the conveniences of life*: no man's labour could subdue, or appropriate all; nor could his enjoyment consume more than a small part; so that it was impossible for any man, this way, to intrench upon the right of another, or acquire to himself a property, to the prejudice of his neighbour, who would still have room for as good, and as large a possession (after the other had taken out his) as before it was appropriated.").

95. *See also id.* at § 44 ("From all which it is evident, that though the things of nature are given in common, yet man, by being master of himself, and *proprietor of his own person, and the actions or labour of it, had still in himself the great foundation of property*; and that, which made up the great part of what he applied to the support or comfort of his being, when invention and arts had improved the conveniences of life, was perfectly his own, and did not belong in common to others.").

96. *See also* Wendy J. Gordon, *A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property*, 102 YALE L.J. 1533, 1549–64 (1993) (applying Lockean principles to intellectual property).

research and development generates the safety and efficacy information *without which* the actual medicine could not be provided to patients. So long as the regulatory state erects a barrier to entry for medicines, which requires the creation of this intellectual content, society will benefit from the labor in question. Property status, with its attendant right to exclude, allows the content creator to benefit from his labor and provides the incentive for him to perform it, for society's benefit. Indeed, Lockean theory itself has a utilitarian strain, because society as a whole benefits from the labor that is put into creation of the value in question.[97] A time-shifting variation of the "tragedy of the commons" may also play out in the absence of property status: if every competitor could immediately access, learn from, and use the safety and effectiveness information generated by an innovator, many competitors could profit, and perhaps through lower prices patients and government programs (and thereby taxpayers) would benefit. *But*, appropriation of that property immediately for the benefit of all may lead to less enthusiasm for innovative research in the future—essentially killing the "golden goose" to the detriment of future patients.[98] That said, the utilitarian argument for property status, standing alone, invites abrogation of the right once adequate incentive has been provided.[99] In my view, a positivist approach (content is property only because and if the law says it is property) abandons any pretense to moral grounding for basic property doctrine. Taken to an extreme, this approach to defining property results in anarchy. If intellectual content can simply be reclassified as not-property in the first instance, then so too can real property.

Considering the property question *ab initio* shows that commenters are off the mark when they suggest that patent protection for the product renders

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97. LOCKE, *supra* note 90, at § 37 ("To which let me add, that he who appropriates land to himself by his labour, does not lessen, but increase the common stock of mankind: for the provisions serving to the support of human life, produced by one acre of inclosed and cultivated land, are (to speak much within compass) ten times more than those which are yielded by an acre of land of an equal richness lying waste in common.").

98. A "tragedy of the commons" occurs where no one has the right to exclude, and the optimal resource use for each individual (which ensues) leads to despoliation of the resource, to the detriment of all. *See*, *e.g.*, Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243, 1244–45 (1968).

99. For instance, some stakeholders justified twelve-year regulatory exclusivity for biological products by reference to Professor Grabowski's work finding that the break-even point for most biological molecules is between 12.9 and 16.2 years after approval. *See* BIO, *A Follow-On Biologics Regime Without Strong Data Exclusivity Will Stifle the Development of New Medicines* 4 (Sept. 26, 2007), *available at* http://www.bio.org/sites/default/files/FOBSData_exclusivity_20070926_0.pdf (cited in Krista Hessler Carver, Jeffrey Elikan, & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 727 (2010)); Henry Grabowski, *Data Exclusivity for New Biological Entities* 21, 26 (Duke University Dep't. of Econ., Working Paper, 2007). Some of the debate over the appropriate length of the exclusivity period then shifted to whether this empirical assertion was correct, *see id.* at 735–37, with stakeholders unintentionally conceding the shift from a natural rights perspective to a positivist perspective.

protection of this content superfluous.[100] To be sure, they are also off the mark analytically. Anything that might be patented (the compound, the formulation, a manufacturing process, etc.) is different from the content at issue here (both data and writing that reflect creativity, judgment, strategy, and labor and that are intended to overcome a regulatory barrier to market entry).[101] Although some might argue that generating the data is simply a cost of doing business in the regulatory state and that a patent should provide sufficient incentive, there are both policy and doctrinal responses.[102] Some products receive no patent, and for these, protection of the content in the application (through both non-reliance and non-disclosure rules) is all that stands between abandonment of the molecule and a new medicine for patients.[103] And if the state can use its commerce power to erect regulatory barriers that functionally require, as a condition of market access, the creation of (intellectual) property that is then immediately confiscated for the public good, there is no principled way to draw a line and preclude confiscation of patents or, even, real property as a condition of market access.[104] The theoretical point is therefore important. While patents are a creation of positive law, the generation of ideas and data about an item that may or may not be patented is labor that under Lockean principles results in a property right of its own accord.

Concluding that the content at issue is property leads to the question what rights comprise the bundle of property rights. The straightforward approach is to work from first principles in property law, rather than to create a special list

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100. In his work opposing data protection, for instance, Professor Reichman has noted that would-be competitors generally cannot market a generic drug until patents expire. *E.g.*, Reichman, *supra* note 29, at 7. Emily Marden inverts the argument, suggesting that data exclusivity can render patents unnecessary. *See* Emily Marden, *Open Source Drug Development: A Path to More Accessible Drugs and Diagnostics?*, 11 MINN. J.L. SCI. & TECH. 217, 244–45 (2010).

101. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 493 (1974) ("Each has its particular role to play . . . . Trade secret law encourages the development and exploitation of those items of lesser or different invention than might be accorded protection under the patent laws, but which items still have an important part to play in the technological and scientific advancement of the Nation."); *see also* CHISUM, *supra* note 82, at 3 ("To the extent there is a property interest in intellectual creations, it is an intangible interest that must be carefully distinguished from property in tangible objects that either make the creation possible or that the creation makes possible.").

102. There is also a practical response. Even where the product is protected by patent, the safety and effectiveness information in the application could be used by a competitor to partially support approval of a different and non-infringing product.

103. Drugs that have reached the market with no listed patents, but only regulatory exclusivity, include: Mefloquine HCl (mefloquine hydrochloride), Clozaril (clozapine), Hexalen (altretamine), Leustatin (cladribine), Trasylol (aprotinin bovine), Sclerosol (talc), and Ellence (epirubicin hydrochloride). All were important enough to earn priority review at FDA. By the author's count, over 100 NDAs approved since 1984 held exclusivity but had no listed patents. Congress has considered enacting special incentives for medicines that are unlikely to be patentable and might not otherwise be developed. *E.g.*, MODDERN Cures Act of 2011, H.R. 3497, 112th Cong. § 201 (2011).

104. Epstein, *supra* note 51, at 307.

that attaches to intellectual property or trade secrets *per se*.[105] When one owns property, one has the right to use the property (or not), the right to permit (or deny) others the right to use the property (often called the right to exclude, though it is also a right to include, as selectively as one wishes), and the right to dispose of the property (or not).[106] There is no particular reason why an asset has to be tangible for these principles to apply, and the principles readily apply to the assets at issue here.[107]

To begin with, one has the right to use or not use the property in question. A biopharmaceutical manufacturer that generates safety and effectiveness data and information about a new molecule has the right to use this asset as it sees fit. This includes using the information to support approval of the product in the United States, in Europe, and around the world. It includes not seeking approval, for instance, in countries with regulators that are prone to releasing confidential information or in countries where the company judges market opportunities insufficient. The company may use the data and analysis to generate new ideas. And it could use the content as a template for subsequent research on similar molecules or second generation versions of the same molecule. It could even lay the content entirely aside, having made a decision not to seek approval of the product.

One also has the right to permit, or deny, others to use the property in question—the right to exclude. A biopharmaceutical manufacturer that generates a clinical module thus has the right to permit, or deny, others to use the property. This could include permitting a second applicant to refer to the information in its own regulatory filings, without seeing the information, i.e.,

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105. Professor Risch describes a complex list of rights and duties attendant to trade secrets, deriving from the Uniform Trade Secrets Act, Professor Milgrim's treatise, and the Supreme Court's decision in *Monsanto*. *See* Risch, *supra* note 57, at 24–25 ("The right to keep certain information secret and still obtain legal protection . . . [i]ncluding the right to exclude others from disclosing [and] the right to exclude others . . . from using;" "[t]he duty to attempt to keep information secret;" "[t]he right to use certain information as one wishes and still receive protection even if others have the same information;" "[t]he right to not use certain information if one wishes and still obtain legal protection;" "[t]he right to recover damages for harm caused by illicit use or disclosure;" "[t]he right to recover the benefits from others for the illicit use or disclosure;" "[t]he right to transfer, devise, or otherwise make exclusive grants;" and "[t]he right to compensation for a government taking of certain [property]."). Although Professor Risch suggests that these rights and duties are different from those associated with other types of property, they may ultimately boil down to the three basic principles discussed in this article.

106. *See, e.g.*, *Ruckelshaus*, 467 U.S. at 1003 (quoting United States v. General Motors Corp., 323 U.S. 373, 377–378 (1945)) ("the right to possess, use and dispose"); Minnesota Mining & Mfg. v. Pribyl, 259 F.3d 587 (7th Cir. 2001) (citing *Ruckelshaus* and finding the trade secret property elements to be the ability to use, disclose, and transfer).

107. Even those who argue that information should not be treated as property concede that these concepts apply. *See, e.g.*, Samuelson, *Information as Property*, *supra* note 80, at 370.

selling a right of reference to a business partner.[108] It could include sharing the protocols, case report forms, and tabulations with other business partners, subject to confidentiality arrangements, but declining to share any other materials. A company might share the raw data and tabulations, but not the narratives, with an academic institution, so that institution could perform a meta-analysis with similar material provided by other companies. Or the company could decline to do all of these things, submitting the material only to national regulatory authorities and always with the express request and understanding that the material would be treated as confidential. In this case, it would profit, indefinitely, from its ownership of the contents.[109]

Finally, one has the right to transfer or dispose of the property in question. A biopharmaceutical company that generates a clinical module may transfer, sell, or abandon its rights in the module in question. For example, when one company acquires or merges with another, it may acquire the manufacturing facilities, the right to manufacture and market the drugs and biologics in question, the patent rights at issue, and ownership of (and access to) the relevant NDA and BLA files.[110]

2. A Closer Look at the Right to Exclude

The right to exclude bears a closer look. The scope of the right to exclude should derive from the universe of possible uses. To be sure, as Professor Outterson points out, it is harder to exclude third parties from using knowledge than from using physical property.[111] But when the content at issue here is fully described (i.e., as more than just knowledge) and its possible uses by others catalogued, it becomes evident that one can disclose this property, or even share it selectively, and preserve some of the right to exclude. The paragraphs that

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108. *See* 21 C.F.R. § 314.3 (2013) (defining right of reference for purpose of NDAs).

109. That ability to profit from ownership of the contents is subject to the fact that under the laws of every country, a second entrant's drug can at some point be approved pursuant to a comparative application without comparable support. The abbreviated application pathway is an important limitation on the right to exclude and involves indirect reliance on the company's assets, which in principle the company should have the right to exclude. *See* LOCKE, *supra* note 90, at § 34 ("He that had as good left for his improvement, as was already taken up, needed not complain, ought not to meddle with what was already improved by another's labour: if he did, it is plain he desired the benefit of another's pains, which he had no right to, and not the ground which God had given him in common with others to labor on, and whereof there was as good left, as that already possessed, and more than he knew what to do with, or his industry could reach to.").

110. *See* 21 C.F.R. §§ 314.72, 314.99(a) (governing change in ownership of an NDA); FOOD AND DRUG ADMINISTRATION, SOPP 8403: ISSUANCE AND REISSUANCE OF LICENSES FOR BIOLOGICAL PRODUCTS (2010), http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073468.htm (governing change in ownership of a BLA).

111. Outterson, *supra* note 29, at 199.

follow describe how the information can be used.

A competitor could use the content directly in its own regulatory filings to support approval of its competing products.[112] Professor Eisenberg has argued that the concern about second entrants using released data to obtain approvals of their own was effectively mooted by enactment of the Hatch-Waxman amendments which effectively permit reliance on that data after statutory exclusivities have expired.[113] She agrees in a footnote that released data can be used in foreign jurisdictions, and I believe this risk should be highlighted in today's global pharmaceutical economy. But the real concern is that where the data is released and available, an abbreviated application may not be required by the regulator.[114] A full application can be submitted. This effects an end run around regulatory exclusivity, which prohibits only approval, or sometimes submission, of abbreviated applications. And even if a full application is not accepted, a literature-based or hybrid application may be accepted, even in Europe or the United States.[115] Literature-based applications are theoretically

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112. *See, e.g.*, Webb v. Dep't of Health & Human Servs., 696 F.2d 101, 103 (D.C. Cir. 1982) ("If a manufacturer's competitor could obtain all the data in the manufacturer's NDA, it could utilize them in its own NDA without incurring the time, labor, risk, and expense involved in developing them independently.").

113. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 381 (2007).

114. *See, e.g.*, Second Declaration of Nancy B. Sager at ¶¶ 14–15, 17, Gov. Accountability Project v. HHS, No. 07-01702 (D.D.C. Apr. 15, 2009) ECF No.19.1 ("If FDA were to disclose the information that the agency has withheld as confidential commercial information, a competitor could use that in information to support its own new drug application ('NDA') without having to incur the time and expense involved in developing the information itself.") (making this point long after enactment of Hatch-Waxman and focusing on full applications). The same point can be made about biologics applications, and, if anything, the risk is greater because the statute is drafted so loosely. FDA interprets the PHSA requirement as only "data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency." 21 C.F.R. § 601.2(a). It does not require that the data be owned by the applicant or that the applicant have a right of reference to it.

115. FDA approves literature-based drug applications under section 505(b)(2) of the FDCA. Also, EU regulatory authorities have a record of approving—during the data exclusivity term—marketing authorization applications, including pioneer data obtained by the applicant under transparency laws. For instance, in 2008, generic versions of clopidogrel were approved by the German authorities during the data exclusivity period and on the basis (in large part) of data in the public domain, including summary reviews obtained from the U.S. FDA under FOIA. *Update: The German Plavix Case: Loopholes in European Data Protection?*, JONES DAY COMMENTARY (2008), *available at* http://www.jonesday.com/files/Publication/16a3768f-10a5-4f6d-9525-5efa157b154f/Presentation/PublicationAttachment/3ba3b1c0-57c1-4e57-b838-0629d789527a/Update%20German%20Plavix.pdf; Duncan Curley & Marleen H.J. van den Horst, *Patents and Regulatory Data Exclusivity for Medicinal Products*, *in* OVERLAPPING INTELLECTUAL PROPERTY RIGHTS 119, 123–24 (Neil Wilkof & Shamnad Basheer eds., 2012). The European Commission later issued a statement opposing this practice, but the EMA retains flexibility with respect to so-called "mixed" applications (partially bibliographic and partially based on the applicant's own data), and applications based substantially on information released to the public are legally possible. Press Release, The Pharma

possible in countries like Australia, Brazil, Canada, China, India, and Japan.[116] Of particular concern, some of these countries issue Certificates of Pharmaceutical Products (CPPs), which can be used in other countries as the basis for marketing authorization, creating a domino effect.[117] There is also a risk that disclosure in one country would be taken in other countries to terminate the exclusivity period.[118] In some jurisdictions, it may also be possible to use this content to partially bolster approval of a product that is not even claimed to be the same or similar. That is, a competitor might be able to justify a fairly small data package for a new use of an already approved

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Letter, European Commission, Health: Germany Receives Final Warning to Comply with EU Rules on Well Established Medicinal Use (May 5, 2010), *available at* http://europa.eu/rapid/press-release_IP-10-536_en.htm.

116. This assertion reflects the views of regulatory lawyers in the jurisdictions in question, with whom the author has worked in the past, regarding what their regulators are likely to accept in practice. Literature-based applications are accepted in Australia for orphan drugs. *See* AUSTRALIAN GOV'T, DEP'T OF HEALTH AND AGING, THERAPEUTIC GOODS ADMIN., LITERATURE-BASED SUBMISSIONS (2003), *available at* http://www.tga.gov.au/industry/pm-literature-based-submissions.htm. Brazilian authorities may accept hybrid applications for subsequent entrant biologics pursuant to the individual development pathway described in Resolution RDC No. 55/2010. Nonclinical, phase I, and phase II data may be deleted, and although full reports are technically required for phase III, data from another country might persuade the regulator to approve all indications on the basis of data with respect to only one indication. ANVISA, Agency Collegiate Board Resolution-RDC No. 55 , 80–81 (December 16, 2010), *available at* http://portal.anvisa.gov.br/wps/wcm/connect/935aed0048bd2755a7cdaf9a6e94f0d0/Registro_Produtos_Biologicos_Hemoterapicos_10102011_WEB.pdf?MOD=AJPERES. Canadian authorities have significant discretion with respect to the contents of new drug submissions and could in theory rely (at least in part) on data that supported another company's product in another jurisdiction. Chinese authorities have broad discretion when determining which data are required for the different types of drug and biologic applications as well as the weight given to different types of data. Indian regulatory authorities have the discretion to waive the requirement that new drug applications contain clinical data if the data are available from other countries. *E.g.*, CDSCO, DRAFT GUIDANCE ON APPROVAL OF CLINICAL TRIALS & NEW DRUGS, at 27 (2011), *available at* http://www.cdsco.nic.in/Guidance_for_New_Drug_Approval-23.07.2011.pdf. It is possible this would be applied in practice to include data relating to another company's product. In Japan, there is at least a question whether the contents of released clinical trial reports would be deemed in the "public domain" and allow approval of second entrants during the re-examination period that follows approval of new drugs. *See* Yakujihō [Pharmaceutical Affairs Law], Law No. 145 of 1960, art. 14 (Japan) *translated in* PHARMACEUTICAL AFFAIRS LAW OF JAPAN (ENGLISH EDITION) 9 (Yakugyo Jiho Co. ed. 1962).

117. For instance, Brazil issues CPPs, and parts of the Asia-Pacific region, the Middle East, Africa, and Latin America accept CPPs. *See generally* WHO, *Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*, Working document QAS/10.374 (May 2010), *available at* http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/. Thus release of the clinical module in one country could lead to approval in Brazil and in turn to approval in countries that participate in the CPP scheme.

118. For instance, Article 25A of the Australian Therapeutic Goods Act provides five years of exclusivity for information relating to certain active components of new therapeutic goods, provided that the information is "not available to the public." *Therapeutic Goods Act* 1989 (Cth) s 25 pt 3-2 div 2 (Austl.). If a clinical module is released to the general public by another regulator, Australian authorities could take the position that the same information—submitted to Australia—was no longer subject to data exclusivity in the country.

medicine, by showing the regulator a robust data package that supported the same use of a previously approved (but not identical) medicine in the same class.

There is more at issue than just whether the raw data might be used to support marketing authorizations. The clinical module also provides valuable competitive intelligence. Well-run and efficient clinical development programs are essential to successful drug development and marketing approval, and the effective presentation of the resulting information is the key to timely marketing approval. A competitor with access to the content that supported approval would know exactly how much, and what sort of, data were required to obtain a given regulatory objective—as well as how to design and run its clinical development program, how to analyze the results, and how to present and package its application. To be more concrete, the clinical study protocols and rationales for study design decisions (as well as decisions which studies to conduct and which not to conduct) reflect the marketing authorization holder's investment, expertise, and experience, and they could simply be copied by the competitor. The clinical module could also provide advance warning of, and solutions to, design and execution challenges with the studies. Information about how the marketing authorization holder documented and tracked clinical information, and the responsibilities it maintained in-house or assigned to vendors, is sensitive business strategy and can be copied or could inform differing approaches in order to gain a competitive advantage. The company's statistical methodologies, actual statistical analyses, and conclusions could be cribbed. They may shed light on ways to address missing data or other complications in data interpretations. Information about the marketing authorization holder's meeting with regulators would tell the competitor what to expect and how to handle it. The company's characterizations of and conclusions concerning its data, which appear in the clinical study reports, contain and reflect scientific judgments and regulatory strategy, all validated by regulatory approval.

The notion that this information is highly valuable to a company's competition should not be controversial.[119] Nor is it speculative. Instead, it is well documented that biopharmaceutical companies are deeply interested in obtaining the information in the applications of their competitors. As early as 1976, lawyers at FDA complained to Congress "of being forced to fund

119. Professor Lemmens suggests that the industry's concerns about the competitive advantage of the confidential information have been overstated because much of the information is available anyway. *See* Lemmens, *supra* note 29, at 81. He focuses mainly on patent applications and competitive intelligence, but these sources of information rarely overlap in any meaningful way with the actual contents of clinical modules. *Id.*

'industrial espionage' through the agency's FOIA procedures."[120] As late as 2013, the EMA disclosed that a substantial percentage of requests for clinical modules under the European Transparency Regulation were filed by private competitors rather than public interest groups.[121] In nearly forty years, little has changed. Not surprisingly, companies go to great lengths to ensure the continuing confidentiality of their safety and efficacy data and information.

Of course, not all companies seek to keep this information confidential, or to keep it confidential permanently. The value of the information and of its continued secrecy can change over time. If a product is no longer a significant source of revenue for a company, the benefit of maintaining secrecy—to prevent others from piggybacking and marketing copycat products—may not be worth the cost. Some companies may routinely disclose clinical study reports, perhaps considering the resulting public goodwill a benefit to their business, for reasons that are uniquely their own. Others may have calculated that given their particular structure and business model, as well as international commercial strategy (sequencing of applications and approvals around the world as well as markets targeted), regulatory exclusivity or the patents in their portfolio—or both—are sufficient to maintain an acceptable profit margin even if competitors are able to piggy-back on their research. Smaller companies might release information to stimulate capital investment. And sometimes companies do not know that their data have been leaked or released, or do not know in advance—for instance in countries with leaky regulators or regulators that are not fully committed to procedural protections for trade secrets. In any case, whatever their reasons, some companies release or acquiesce to the release of their safety and efficacy information. The vast majority have historically gone to great lengths to keep this material secret.

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120. *See* Pharm. Mfrs. Ass'n v. Weinberger, 411 F. Supp. 576, 579 n.7 (D.D.C. 1976) (citing *Hearings on Appropriations for Fiscal Year 1977 (FDA) Before the Subcomm. on Agric. & Related Agencies of the S. Comm. on Appropriations*, 94th Cong. 717–18 (1976) (discussion with Richard A. Merrill, Asst. Gen. Counsel, FDA)); *Business Record Exemption of the Freedom of Information Act: Hearings before the Gov't Info. & Individual Rights Subcomm. of the H. Comm. on Gov't Operations*, 95th Cong. 69 (1977) (statement of Donald Kennedy, Comm'r, FDA) ("about 80 percent of the Freedom of Information requests we receive are from business entities, private attorneys, and FOI service companies who are requesting records on behalf of corporate clients"); *see* MILGRIM, *supra* note 36, at § 12.03 ("[I]t has long been apparent that information placed in the hands of the government is more apt to be sought for competitive use than any public purpose.").

121. Peter Doshi & Tom Jefferson, *Research Letters: The First 2 Years of the European Medicines Agency's Policy on Access to Documents: Secret No Longer*, 173 JAMA INTERNAL MED. 380, 381–82 (2013) ("David Mackay, BVetMed, MSc, PhD, MRCVS, of the European Medicines Agency, closely reviewed the manuscript for accuracy and provided many clarifications about the EMA's policy."). This document suggests that roughly one-third of the requests were filed directly by competitors. A substantial percentage of the requests filed by lawyers and consultants are likely filed on behalf of competitors. *Id.*

Because this information plays both an instructive role and a regulatory role, it is possible to permit some use and prevent other use. To give a concrete example, if the EMA released a company's clinical data over its objection, other governments can still—and most probably will—preserve regulatory exclusivities (i.e., decline to accept or approve abbreviated applications for the period of time laid down in local law). They could also refuse applications from competitors that include those data in support of their own products (full applications) and otherwise maintain trade secret status for the corresponding clinical module in their countries.[122] The right to prevent competitors from using that research in regulatory filings, to support their own market access with their own products, is analytically distinct and can therefore be preserved. Understanding the content as property (rather than trade secret)—and understanding the right to exclude broadly—thus provides a solution to the problem of operating in a multinational regulatory state. The property right need not evaporate upon disclosure.[123]

A robust reading of the right to exclude, combined with a full view of the regulatory context for this content, helps to explain why this content should not be perceived as a true public good. Conventional wisdom holds that non-excludable and non-rival goods are "public goods."[124] More specifically, it must be technically difficult to prevent others from using the good free of charge, and the use of the good by one person must not detract from the ability of another to use it. The discussion above shows, however, that it is legally and technically possible for a regulator to decline to permit use of publicly available information to support approval of a medicinal product.[125] Safety and effectiveness information is, in that sense, excludable. Moreover, a plausible argument can be made that they are not non-rival. A second entrant's use of

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122. See by way of analogy the decision of the D.D.C. in its Memorandum Opinion in ACLU v. Dep't of State, 878 F. Supp.2d 215, 218 (D.D.C. 2012) (mem.) (allowing the Department of State to redact, citing exemption 1, information that had already been placed in the public domain by Wikileaks).

123. Professor Stedman wrote in 1962 that "[i]t is, indeed, a strange form of 'property' that disappears when the information it embraces becomes public . . . ." John C. Stedman, *Trade Secrets*, 23 OHIO ST. L.J. 4, 21 (1962). I do not agree with Professor Stedman that this means trade secrets are not property. Professor Milgrim, citing this article, refers to trade secrets as an evaporating or disappearing property right. MILGRIM, *supra* note 88, at 2-23 n.17. While this may be true as to some trade secrets, at least with respect to the content at issue here, the fact that it is possible to prevent some uses even after disclosure means that the right has not disappeared.

124. *See generally* Uwe E. Reinhardt, *An Information Infrastructure For the Pharmaceutical Market,* 23 HEALTH AFFAIRS 107, 110 (2004).

125. This is what happens under orphan drug exclusivity schemes. During the orphan exclusivity term, any application for the same drug for the same use will be rejected, even if it relies on publicly available information. *See* 21 U.S.C. § 360cc(a)(2) ("[T]he Secretary may not approve another application under section 355 . . . or issue another license under section 262 of title 42 for such drug for such disease or condition . . . .").

the information, for instance, to support its own competing product, directly diminishes the value of the information to the person that created it. It is correct, however, that one person's use of the module to support approval of his own product does not exhaust the module, and that an infinite number of subsequent entrants can use the module to support their products. In this sense, multiple people *can* stand on the same spot at the same time. A positivist would say that a grant of property rights can solve the public good problem,[126] but a more robust understanding of the right to exclude—combined with the natural rights premise—may undermine the public good assumption in the first instance.[127]

D. Implications

1. Application of Takings Principles

The conclusion that this content is property leads principally to the conclusion that the Fifth Amendment applies to government actions. The Supreme Court's takings jurisprudence is muddled by distracting lines between *per se* and regulatory takings, distinctions between intellectual and real property, and debates over the merits of *ad hoc* balancing tests. It is easy to get tied in knots over whether a government action fully takes a portion of property or partially takes the entire property, i.e., over what actually has been taken. Where the property right itself is prone to being misconstrued too narrowly, as happens with respect to the content at issue here, the muddle impedes analysis.

A conventional approach would begin with *Monsanto*, which appears on point because it related to disclosure of data—characterized by the Court as trade secrets and, therefore, property—submitted to support regulatory approval. This case leads to the correct conclusion that forcible disclosure constitutes a taking. But Justice Blackmun's reading of the right to exclude is too narrow for the content at issue here, and it leads to an incorrect conclusion that disclosure (and taking) precludes any further Fifth Amendment arguments about non-consensual use.

At issue in *Monsanto* were statutory provisions that authorized the EPA to disclose health and safety data submitted in pesticide registration applications and to use them for the benefit of subsequent applicants. Provisions dating to

126. *See, e.g.*, Samuelson, *Information as Property*, *supra* note 80, at 371.

127. Some might respond that the excludability just described is a function of regulatory structures and not an intrinsic feature of the information. *See* Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1052 n.87 (2005) (making that point about information in general). But the content in question here—case report forms, data that have been manipulated and tabulated for a regulatory purpose, clinical study report narratives written for a regulator—owes its existence to the regulatory structure; the two are not severable.

1972 allowed an applicant to designate some of the data as "trade secret or commercial or financial information." A separate provision prohibited the EPA from publicly disclosing any data that in its judgment contained, or related to, trade secret or commercial or financial information. Following a series of court cases in the 1970s clarifying that the phrase "trade secrets" was as broad as the Restatement and applied to health, safety, and environmental data, Congress amended the statute in 1978 to permit disclosure of these data to qualified requestors notwithstanding the freestanding prohibition, which remained intact.[128]

Justice Blackmun, for the majority, wrote that the term "property" in the Takings Clause has generally been used "to denote the group of rights inhering in the citizen's relation to the physical thing, as the right to possess, use and dispose of it."[129] The right to exclude, he noted, is "generally one of the most essential sticks in the bundle of rights that are commonly characterized as property."[130] With respect to a trade secret, "the right to exclude others is central to the very definition of the property interest."[131] Finally, "[o]nce the data that constitute a trade secret are disclosed to others, or others are allowed to use those data [the other aspect of FIFRA at issue in the case], the holder of the trade secret has lost his property interest in the data."[132] This led to a takings analysis.

The problem lies in Justice Blackmun's comment that disclosure of the data in question eviscerates the property interest. This outcome may have been correct as to pesticide registration data, perhaps because qualified requestors did not include foreign or multinational companies, or because of concurrent amendments to the scheme that governed use in second entrant applications. But it is not correct with respect to the safety and effectiveness information in drug applications. Although black letter trade secret law holds that widespread disclosure of a trade secret eliminates trade secret status, finding that disclosure eliminates property status—where the information has both regulatory and informational uses—is inconsistent with the full right to exclude and thus with the property status of the content in the first instance. Understanding this content as trade secret before understanding the content as property—as Justice Blackmun did—leads to absurd results.[133]

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128. *Ruckelshaus*, 467 U.S. at 993.

129. *Id.* at 1003 (quoting *General Motors*, 323 U.S. at 377–78).

130. *Id.* at 128.

131. *Id.*

132. *Id.*

133. Professor Bone, for instance, writes that "once someone learns information, there is no way to erase that knowledge and therefore no means of excluding the person in fact." Bone, *supra* note 57, at 254. Accordingly, he concludes, "exclusivity must have seemed oddly inappropriate." *Id.*

Instead, *Loretto* provides a helpful launching point for beginning to think through the taking.[134] This case concerned a New York law requiring landlords to permit cable companies to install cable facilities on their property. The cable equipment in question used up a portion of Loretto's apartment building roof and the side of her building. Justice Marshall, writing for the Court, found a permanent physical occupation of Loretto's property—not an easement—and concluded that this occupation "is a taking without regard to the public interests that it may serve."[135] Justice Marshall purported to apply the *Penn Central* balancing test,[136] but "when the physical intrusion reaches the extreme form of a permanent physical occupation," he wrote, the "character of the government action" becomes dispositive.[137] (In *Monsanto*, the interference with reasonable investment-backed expectations became dispositive.) In one sense, full disclosure of a clinical module—to the general public without attendant constraints on the uses to which the data can be put—is analogous, because it represents permanent and irrevocable destruction of the right to exclude. Unlike *Penn Central*, but like *Loretto*, this is not a situation where the property owner's use of its own property is regulated. The information may still be used, but it must be shared.[138]

The Court in *Loretto* noted, however, that government occupation of land destroys all rights in the bundle as to the portion of land occupied, i.e., "chops through the bundle, taking a slice of every strand."[139] These concepts do not apply comfortably to forcible information sharing, for the same reason that

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And for this reason, "secrecy was the *sine qua non* of possession and thus of common law property rights in information." *Id.* at 255. This may be true outside the regulatory context. But where the content is created in order to overcome a multi-national barrier to market entry, secrecy is only part of possession. Professor Stroud proposes a "hybrid property/relationship" theory of trade secrets that would permit prospective exclusion where parties obtain a trade secret innocently through publication (e.g., via the internet), so that the innovator can recoup its investment. *See generally* Stroud, *supra* note 72. He argues mainly from the need to protect substantial investments and from modern developments like the internet. *Id.* The conclusion seems right from a public policy perspective, and the proposed approach to trade secrets is intriguing, although this article takes a different analytical approach.

134. Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419 (1982).

135. *Id.* at 426.

136. *Penn Central* involved the government imposing a restriction on the property owner's use of his own property, which is not the case here. *See* Penn Cent. Transp. Co. v. New York, 438 U.S. 104 (1978); *see also* Epstein, *supra* note 85, at 63. Here the Court identified three factors to be considered when assessing whether a government action is a taking: (1) whether the government action "interfered with distinct investment-backed expectations," (2) the economic impact of the government's action on the property owner, and (3) the nature of the government action. *Penn Cent. Transp. Co.* 438 U.S. at 124.

137. *Penn Cent. Transp. Co.* 438 U.S. at 123.

138. *Cf. Loretto*, 458 U.S. at 430 (distinguishing between "a permanent physical occupation, a physical invasion short of an occupation, and a regulation that merely restricts the use of property").

139. *Id.* at 435.

some think information is a public good. Two *can* use the clinical module at the same time. For this reason, *Kaiser Aetna* may be the most relevant precedent.[140] This case involved a marina that had been created by Kaiser Aetna, at considerable expense, by dredging and filling Kuapa Pond and connecting the pond to Maunalua Bay and through that bay to the ocean. The federal government concluded that this action made the pond-now-marina subject to the "navigational servitude" of the federal government and that the general public now held a right of access. Justice Rehnquist agreed that the dredged pond constituted "navigable waters" and that the Commerce Clause permitted Congress to assure the public a free right of access as a result. But, he noted, the takings question was separate.[141] The Court did not apply the *ad hoc* inquiry derived from *Penn Central* and used in *Monsanto*.[142] Because the government's action resulted in loss of "one of the most essential sticks in the bundle of rights that are commonly characterized as property"—the right to exclude—the government's action amounted to a taking under the diminution-of-value reasoning of Justice Holmes's opinion in the coal mining case, *Pennsylvania Co. v. Mahon*.[143]

In *Mahon*, Justice Holmes observed that when "[diminution of value] reaches a certain magnitude, in most if not in all cases there must be an exercise of eminent domain and compensation to sustain the act."[144] The case involved mining for coal underneath the land to which Mahon owned only surface rights, with the Pennsylvania Coal Company owning rights to remove all coal below the surface. A statute passed subsequent to the sale of surface rights to Mahon forbade mining that would cause subsidence of structures used for human habitation. The issue before the Court was the statute's destruction of the company's property rights. Justice Holmes pointed out that "the right to coal consists in the right to mine it" and that making it "commercially impracticable to mine certain coal has very nearly the same effect for constitutional purposes as appropriating or destroying it."[145] Further, "while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking."[146] This gave rise to "regulatory takings" doctrine. The statute in *Mahon* eviscerated the property owner's ability to make profitable use of its property.

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140. Kaiser Aetna v. United States, 444 U.S. 164 (1979).

141. *Id.* at 172.

142. If one *were* inclined simply to apply the *Penn Central* factors, one could reason from either *Monsanto* (interference with reasonable investment-backed expectations) or *Kaiser Aetna* (nature of the government action, analogous to a physical invasion), either of which would be dispositive here.

143. 260 U.S. 393 (1922).

144. *Id.* at 413.

145. *Id*. at 414.

146. *Id.* at 415.

Disclosure of drug application contents, when combined with an environment that permits, or fails to prevent, use (including use by regulators), would perhaps be analogous. Disclosure in an environment that safeguards against some use, however, might not be analogous. But the "diminution in value" concept should still lead to the conclusion that a compensable taking had occurred.

Lucas v. South Carolina Coastal Council relies on *Mahon* to articulate a similar principle.[147] Lucas bought residential lots in 1986 on which he intended to build single-family homes. The South Carolina legislature in 1988 enacted a statute that had the direct effect of barring him from erecting habitable structures on those parcels. Justice Scalia concluded that a regulation eliminating all economically beneficial use of real property requires compensation, unless the regulation makes explicit restrictions that were inherent in the title itself. Indeed, he noted, quoting Sir Edward Coke, "what is the land but the profits thereof?"[148] While the disclosure of a company's clinical modules to its competitors does not prevent that company from obtaining approval of its product or using the information in future research, it does effectively remove its ability to license that content to third parties (i.e., eliminates a revenue stream) and substantially reduces, possibly eliminates entirely, the profit it could have realized from the module in the first instance (i.e., by creating competition at a fraction of the price).

As the Court wrote in 1960, the primary purpose of the Takings Clause is "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole."[149] It seems axiomatic that if the public has a broader interest in the fruits of the labor of the pharmaceutical industry, the public should bear the burden of paying for the fruits in question (or generate its own). At the same time, a robust understanding of the right to exclude with respect to property that has multiple functions—regulatory as well as informational—shows that disclosure is not the same thing as use. And this in turn leads to a conclusion that the scope of the taking, and perhaps compensation, will vary with the nature of the disclosure and with other aspects of the law. Disclosure to parties that may not make competitive use of the information, for instance, or disclosure combined with explicit rules precluding use in marketing applications and in the regulatory process is meaningfully different from a Fifth Amendment perspective from disclosure to all, or disclosure combined with silence about subsequent use, ambiguous rules on use, or rules expressly permitting use. And

147. 505 U.S. 1003, 1014 (1992).

148. *See id.* at 1017 (quoting 1 E. COKE, INSTITUTES, ch. 1, § 1 (1st Amend. Ed., 1812)).

149. Armstrong v. United States, 364 U.S. 40, 49 (1960).

this leads to the public policy question.

2. Public Policy Should Shape the Taking and Ancillary Legal Reform

The most compelling argument for disclosure of the contents of clinical modules in marketing applications is that the information might be used by others in ways that would benefit the public health and that the owners themselves either will not do so (lacking the incentive) or cannot do so (because they lack the necessary information, e.g., for a meta-analyses of data from multiple products). This leads to two public policy solutions: (a) incentives for sponsors to perform research of this sort, individually or collectively, and (b) limited release by regulators (i.e., of the information necessary, such as protocols, case report forms, and statistical analyses) to third parties (e.g., nonprofit researchers) for the purposes in question (e.g., aggregation and meta-analysis), subject to just compensation.

The second solution, limited release to appropriate third parties with just compensation, only partly responds to the "right to health" argument for disclosure advanced by Professor Lemmens. Professor Lemmens argues for free flow of this information among a larger array of stakeholders, including private scientists (presumably competitors), patients, and prescribers, as a way to promote evidence-based decision-making in healthcare.[150] Making the information available to private industry scientists is, however, not essential to ensure a meaningful contribution to evidence-based medicine, and it collides squarely with the most compelling argument against disclosure of the information in question—the fact that competitors may use this information to free-ride on the work of the first entrant. Making the information available to patients and prescribers could also undermine the quality of dialogue between physician and patient. Releasing all of the safety and effectiveness data and information in approved applications, including the broader file as supplemented over time, will prompt third parties—some with good intentions, others with nefarious intentions—to collect, interpret, analyze, manipulate, and republish the information and their own conclusions and recommendations. As it stands now, a patient researching her symptoms or a medication that her doctor has recommended is faced with a dizzying array of information sources, many legitimate, but some not. These will proliferate, if the contents of marketing applications become available.

Indeed, broader disclosure could have a deleterious effect on the role of FDA in our public health system. Professor Laakmann suggests that non-disclosure undermines faith in the industry, approved medicines, regulators,

150. *See* Lemmens, *supra* note 29, at 89–91.

and the regulatory process.[151] But at least in the United States, with its culture of free speech, junk science, and patient empowerment through the internet, an unfiltered information dump is more likely to have the opposite effect. FDA derives a great deal of its perceived legitimacy and thus effectiveness from playing a pivotal—and frequently premarket—role with respect to the safety, and often effectiveness, of nearly twenty-five percent of the consumer economy.[152] Releasing the information wholesale will prompt third parties to generate their own recommendations on the safe and effective use of approved medications and their own views on safety issues—in essence, parallel systems of warnings, precautions, and contraindications. The impact of parallel systems—one official, others highly credible but differing, and others less credible and careful but perhaps more accessible or compelling to lay persons—on physician and patient behavior, and the public health, should be explored.[153] We have a profound interest in a strong centralized regulator with the ability to make definitive judgments on safety, efficacy, and labeling of medicines and the authority to enforce those judgments. A world of semi-persuasive wiki-labeling would not serve the public interest.[154]

Nor would an official process of peer-reviewing FDA decisions further the primary public policy goal identified by Professor Laakmann, that of restoring confidence in the regulatory scheme. Post-hoc peer review of approval and labeling decisions runs the same risk of suggesting the regulator's conclusions are not, in fact, definitive or reliable. Moreover, when FDA decides that a product is safe and effective, meaning that its benefits outweigh its risks when used as the manufacturer proposes to label it, the agency is also making a policy decision based in part on our collective level of risk tolerance. The agency is accountable for its decisions through its Senate-confirmed executive as well as

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151. Laakmann, *supra* note 4, at 326–27.

152. *See* FDA, EXECUTIVE SUMMARY: STRATEGIC PLAN FOR REGULATORY SCIENCE (Jan. 16, 2013), *available at* http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm268095.htm ("In the U.S., FDA-regulated products account for about 25 cents of every dollar spent by American consumers each year—products that touch the lives of every American every day.").

153. Further, if FDA's role and authority with respect to safety and effectiveness of medicines are undermined, its effectiveness with respect to other public health functions (e.g., product recalls and food safety) could also be undermined.

154. Moreover, federal agency approval and labeling decisions affect what can and cannot be said about the products (and by whom), what will and will not be paid for (and by whom), and what does and does not give rise to product liability. If these decisions are stripped of their certainty and viewed by stakeholders (such as physicians, patients, medical licensure and standards organizations, pharmacists and pharmacy boards, insurers, plaintiff lawyers, and prosecutors) instead as opinions, these other bodies of law will be affected. Thus, as Professor Cahoy suggests, the impact of disclosure on products liability theory must be examined. *See* Cahoy, *supra* note 29. To the extent that claims are currently predicated on failure to alert physicians in the approved labeling of a particular safety risk that was hidden in the confidential file, after disclosure one might easily argue those claims must simply fail.

through Congressional oversight. And the agency's decisions are driven by precedent, policy, and consideration of collateral consequences. No academic or non-profit organization performing peer review is similarly positioned to consider precedent, public policy, and collateral consequences, nor is any similarly accountable.

In any case, there is already a considerable amount of truthful and accurate information in the public domain for physicians and patients about the clinical trials performed on approved medicines. This includes the approved labeling.[155] It also includes the action package on the FDA website, which includes detailed memoranda prepared by agency scientists who reviewed the trials.[156] And it includes the clinical study results database maintained by the National Institutes of Health at www.clinicaltrials.gov.[157] Biopharmaceutical

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155. This labeling contains two sections describing the clinical research performed to support approval. Section 12 describes clinical pharmacology studies, and section 14 describes the remaining clinical studies. FDA regulations require the latter to discuss the studies that "facilitate an understanding of how to use the drug safely and effectively." The description includes a "discussion of study design, population, endpoints, and results." Also, if a specific study is mentioned anywhere in the labeling because it is essential to understanding the information in that section, that study must be discussed in section 14. Section 6 of the package insert describes "the overall adverse reaction profile of the drug based on the entire safety database." Where adverse reactions have significant clinical implications, the labeling includes details about "the nature, frequency, and severity of the adverse reaction and the relationship of the adverse reaction to drug dose and demographic characteristics, if those data are available and important." 21 C.F.R. § 201.57(c)(7), (13), (15) (2013).

156. The action package includes documents generated by FDA related to review of the application; documents pertaining to the format and content of the application generated during drug development; labeling submitted by the applicant; a summary review that documents conclusions from all reviewing disciplines about the drug; and the Division Director and Office Director's decision document. 21 U.S.C. § 355(l) (2006). The materials generally include medical reviews, chemistry reviews, pharmacology reviews, statistical reviews, and clinical pharmacology and biopharmaceutics reviews. These documents describe the application in detail and explain the reviewing scientist's views and conclusions. Many action packages include administrative documents and correspondence, including memoranda from teleconferences, meeting minutes, letters responding to requests for information from FDA, and other internal memoranda relating to FDA's review of the application. The agency applies exemption 4 of FOIA before posting the material.

157. 42 U.S.C. § 282(j)(2) (2006). This scheme applies to any controlled clinical investigation, other than a phase 1 investigation, of a new drug. Among other things, the responsible party provides, and NIH posts: (1) a table of the demographic and baseline characteristics of the patient sample, overall and for each arm of the trial, including the number of patients who dropped out and the number of patients excluded from the analysis; (2) primary and secondary outcome measures (as submitted to the registry), and a table of values for each primary and secondary outcome measure for each arm of the trial, including the results of scientifically appropriate tests of the statistical significance of the outcome measures; (3) a table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency in each arm of the trial; and (4) a table of anticipated and unanticipated adverse events not included in the serious adverse events table and that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency in each arm of the trial. Enforcement is tied to federal funding and to acceptance and approval of regulatory submissions. A further expansion through rulemaking, though authorized by statute, has not yet happened. *Id.* at § 282. Eventually, the database will include summaries of the trial, and its results,

companies and the external investigators they employ to conduct clinical trials also discuss their research at scientific conferences and in scientific journals. The major safety and efficacy trials relating to new medicines are almost always presented at professional conferences and often published in peer-reviewed medical journals.

Other policy arguments for broad disclosure of the contents of clinical modules overlook less drastic means to accomplish their objectives. There is, for instance, an argument that readily accessible information about study results is inherently biased—because biopharmaceutical manufacturers decline to release or publish the results of negative trials, or because the medical journals prefer to publish positive trials.[158] The result, it is said, is that prescribers and patients lack complete and unbiased information on which to make their decisions.[159] The question, however, is whether public release of the full data and analysis for every trial for every approved drug is an effective way to solve this issue, assuming the assertion is substantiated. A requirement to register every trial and to post summaries of the results, understandable to healthcare professionals and understandable to lay persons, would seem to solve most of the problem. Federal law already imposes this requirement,[160] and if the summaries are not sufficiently robust to elucidate the negative aspects of the trial results, the solution is to revise the requirements for the format, content, and scope of the summaries. A requirement to report to the national regulatory authority the result of every trial relevant to safety and effectiveness of the drug, a requirement that product labeling not be misleading by virtue of omission of material facts, and regulatory authority to mandate safety-related labeling changes when warranted would seem to solve the rest of the problem. Again, federal law already embraces these concepts.[161] If there is a substantiated concern that these requirements are flouted, or the regulator weak, the solution

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for both patients and healthcare professionals (if the Secretary determines that they can be included without being misleading or promotional) and either the full protocol, or the information about the protocol to help to evaluate the trial results; and perhaps other appropriate information.

158. *E.g.*, Lemmens, *supra* note 29, at 92–93 (citing studies that "indicate that industry-sponsored trials are much more likely than other trials to conclude that drugs produced by the sponsoring company are safe and effective"); Joanna K. Sax, *Protecting Scientific Integrity: The Commercial Speech Doctrine Applied to Industry Publications*, 37 AM. J.L. & MED. 203, 206–07 (2011) (arguing that industry manipulates the public through the publication of misleading studies and citing reports that company-sponsored research is more likely than non-profit research to report favorable results).

159. *See also* Eisenberg, *supra* note 113, at 382 ("Publicly available data would permit patients, doctors, and insurers to make better choices of drugs.").

160. *See supra* note 157.

161. 42 U.S.C. § 282(j)(3), (4)(C) (relating to reporting clinical trial results), 21 U.S.C. § 321(n) (relating to misleading labeling or advertising), 21 U.S.C. § 352(a) (relating to false or misleading labeling), 21 U.S.C. § 355(o)(4) (relating to safety labeling changes).

lies in strengthening its authority and enforcement capabilities—not in implicitly undermining it with a parallel structure of medicine review.

If broad disclosure were instead required, public policy considerations might compel parallel reform to other bodies of law. For instance, biopharmaceutical manufacturers are subject to strict rules regarding what they can and cannot say about their approved medications. FDA's regulatory regime generally prohibits speech about approved prescription drugs outside the drug's approved package insert, unless specifically exempted by the agency from its requirements governing labeling, even if the speech is truthful, informative, and fully consistent with the approved uses of the drug. To give a concrete example: the agency routinely objects to companies providing information to physicians about subgroup analyses that do not appear in the approved physician labeling—such as information that the drug may work particularly well in specific groups and not in others.[162] To give another example, where a company scientist speaks publicly about the company's approved drugs and receives a question from the audience that calls for a response that is outside the labeling, current agency guidance indicates the speaker must respond privately and outside the public forum.[163] If, however, the safety and effectiveness data and information have been released publicly, it seems unfair, arguably inconsistent with the premise for disclosure, and possibly contrary to the public health, to preclude the entity that generated the data, information, and analysis in question from engaging freely in the ensuing discussion.

Takings considerations inherently counsel for limited disclosure. Public policy considerations similarly counsel for limited disclosure: to non-profit scientific and academic researchers and institutions, for general medical research that will benefit the public health—aggregation and meta-analyses of work performed on a particular molecule by different companies, for instance, or research to detect issues of safety and efficacy related to an entire class. Peer review of approval and labeling decisions risks undermining the central role of

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162. *See, e.g.*, Letter from Marybeth Toscano, PharmD, Regulatory Review Officer, Division of Professional Drug Promotion, Office of Prescription Drug Promotion, et al. to Alexandra Burtoft, Associate Program Director, Commercial Regulatory Affairs, Genentech, Inc., (Oct. 3, 2012), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM323628.pdf; Letter from Thomas W. Abrams, RPh, MBA, Director, Division of Drug Marketing, Advertising, and Communications to Three Rivers Pharmaceuticals, LLC (Mar. 21, 2011), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259249.htm.

163. FDA, GUIDANCE FOR INDUSTRY RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES: DRAFT GUIDANCE, at 10–12 (2011), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf.

the regulator, and broader dissemination risks flooding physicians and patients with alternative and non-credible analysis. Only the information necessary to perform this research should be shared, which would protect a fair amount of the narrative in clinical study reports. And the information should be shared with enforceable confidentiality restrictions in place, with some care given to ensure that the resulting conclusions and research can be published for stakeholders. The other arguments for disclosure, and an approach of broader (public) disclosure, seem insufficient to outweigh concerns about undermining incentives to innovate. At the very least, if broad disclosure to the public is implemented, manufacturers should be allowed to engage freely in discussion about their products, and liability arguments that they have failed to disclose safety information to patients should fail.

3. Just Compensation Follows

Limiting the taking to this disclosure and expressly precluding use by competitors may reduce the compensation owed.[164] Whether the disclosure is broad or narrow, the U.S. government can limit the content's use by competitors, by confirming that it will not rely on the released information to support applications, nor use it to guide or advise applicants. It can honor rights to reference and otherwise confirm that it views the contents of the applications as private property with at least some strands of the property bundle intact. Controlled disclosure with confidentiality agreements in place, regardless of these ancillary non-use protections, might not even eliminate trade secret status for purposes of conventional trade secret law.[165] But it is clearly government action stripping the property owner of some rights, and thus just compensation is required.

Just compensation for the taking can be achieved through any of various mechanisms, including establishment of panels to calculate the recovery, as was done for the data in pesticide applications.[166] Certain fundamental

164. Fla. Rock Indus. v. United States, 18 F.3d 1560, 1569 (Fed. Cir. 1994) ("Logically, the amount of just compensation should be proportional to the value of the interest taken as compared to the total value of the property . . . ."). *But see Ruckelshaus*, 467 U.S. at 1011–12 ("With respect to a trade secret, the right to exclude others is central to the very definition of the property interest. Once the data that constitute a trade secret are disclosed to others, or others are allowed to use those data, the holder of the trade secret has lost his property interest in the data. That the data retain usefulness for Monsanto even after they are disclosed . . . is irrelevant to the determination of the economic impact of the EPA action on Monsanto's property right. The economic value of that property right lies in the competitive advantage over others that Monsanto enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge.") (internal footnotes omitted).

165. *See* CHISUM, *supra* note 82, at 200 n.5 ("Today, secrecy must only be 'relative,' or the subject of efforts that are 'reasonable under the circumstances.'") (citation omitted).

166. *See* Amendment to the Federal Pesticide Act of 1978, Pub. L. No. 95-396, § 2(a)(1), 92

principles guide just compensation determinations, though these principles may be tricky to apply in this setting. Just compensation seeks to compensate for the owner's loss, not the taker's gain.[167] The owner's loss is usually interpreted as the fair market value of the property, meaning what a willing seller and a willing buyer would agree to on an open market.[168] But this property and this taking have characteristics that present special challenges for the application of these principles. First, this property is by its nature confidential, and there is no open market or comparable piece of property to use as a reference for determining its fair market value. Second, one would have to determine the portion of the total value taken by the confidential disclosure to academic researchers for purposes of general research. If the willing seller would release this content to these entities for this purpose for a fairly minimal payment, then that is just compensation. But that must be determined as to each property owner. An alternative to compensation panels would be some sort of statutory *quid pro quo*, such as patent term restoration or special exclusivity. If in fact the value taken varies, however, a procrustean bed will not satisfy the Fifth Amendment. The statutory *quid pro quo* will need to be flexible, or Fifth Amendment considerations will require that companies have the option to seek monetary compensation instead. Further, due process considerations may dictate that a *quid pro quo* not be forced onto companies that have already generated and submitted this content.

4. The International Dimension

Disclosure in a multi-national environment could moot the just compensation question. A foreign regulator may take the first step, whether releasing all of the content to the general public or releasing some of the content to a smaller contingent. But the Takings Clause is grounded in the principle that the government is not free to commandeer private property for public

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Stat. 819, 820–22. The 1978 amendments to FIFRA removed responsibility for arbitrating disputes over data compensation from EPA and delegated it instead to an arbitration service, whose decisions would not be reviewable by any court except for fraud, misrepresentation, or misconduct.

167. United States v. Twin City Power Co., 350 U.S. 222, 228 (1956); United States v. Gen. Motors Corp., 323 U.S. 373, 378 (1945); Kimball Laundry Co. v. United States, 338 U.S. 1, 5 (1949) (citing McGovern v. New York, 229 U.S. 363 (1913)); United States ex rel. T.V.A. v. Powelson, 319 U.S. 266 (1943)); *see also* 4 NICHOLS ON EMINENT DOMAIN § 12.01[5] (J. Sackman ed., 3d ed. 2009); David G. Oberdick, Comment, *The Taking of Trade Secrets: What Constitutes Just Compensation?*, 48 U. PITT. L. REV. 247, 247–48 (1986).

168. United States v. Petty Motor Co., 327 U.S. 372, 377 (1946); Whitney Benefits, Inc. v. United States, 18 Cl. Ct. 394, 407–08 (1989), *corrected,* 20 Cl. Ct. 324 (1990), *aff'd*, 926 F.2d 1169 (Fed. Cir. 1991); Christopher Serkin, *The Meaning of Value: Assessing Just Compensation for Regulatory Takings*, 99 NW. U. L. REV. 677, 678, 682 (2005); Glynn S. Lunney, Jr., *Compensation for Takings: How Much is Just?*, 42 CATH. U. L. REV. 721, 725 (1993); NICHOLS, *supra* note 167, at § 12.01.

purposes without paying just compensation. Where the same property resides simultaneously in the hands of multiple governments, any of which could take the property and effect a taking in all jurisdictions at the same time and for the benefit of all jurisdictions, the principles behind the Fifth Amendment should not permit the U.S. government to eschew cabining the impact on U.S. property rights. Even where release is broad (e.g., outright disclosure in Europe over the objection of the property owner), U.S. property law can accommodate preservation of other sticks in the bundle, and the moral imperative of the Fifth Amendment requires that it do so. FDA should decline to use the released data for the benefit of second entrants. This is the final reason the trade secret label leads to an absurd result. The suggestion that forced disclosure terminates all property status—all sticks in the bundle of rights—makes no sense doctrinally (unless one does not believe the content is property in the first instance), and it is untenable from a policy perspective in a multi-jurisdictional regulatory environment.[169]

An alternative policy approach would be for the United States to implement incentives for the industry to share the information with nonprofit researchers. As noted earlier, industry has announced a voluntary cabined data-sharing program.[170] Implicit in this volunteerism, however, is the specter of broader disclosure by a foreign regulator against whom takings claims are not tenable. But the law has two ways to achieve socially beneficial use of privately owned property where that socially beneficial use presents a negative risk/benefit balance to the property's owner and will not be voluntarily undertaken: the law of eminent domain, on the one hand, and the offering of an incentive that shifts the property owner's risk/benefit balance, on the other hand. In the real property context, the states and federal government offer a variety of incentives to encourage the best and most socially beneficial use of land. The statutory *quid pro quos* mentioned earlier, patent term restoration and market exclusivity, could be considered by the U.S. government as incentives to engage in this volunteerism, or they could be offered in the spirit of compensation where the EMA has moved first. The elegance of a truly voluntary approach *with* incentives in place is that the resulting property reallocation would inherently take into account the multinational impact of the disclosure.

169. As noted, however, one could also reach this result under trade secret law, because the secrecy required is only that which is reasonable under the circumstances. Arguably testing data remain sufficiently secret for misappropriation concepts to apply in the United States, where there has been disclosure abroad limited to a specific class of entities (academics) for a specific purpose (additional research).

170. *See supra* note 28.

CONCLUSION

The public interest will be advanced by ensuring that the data and scientific analyses supporting the conclusions that medicines are safe and effective are shared on a confidential basis with nonprofit researchers for generalized research in the public interest. Broader approaches (more information, more recipients) present serious risks that are not justified by any increased public health benefit. Public release would give competitors information to support their products and guide their research and development strategies—government-sanctioned "free-riding" that would imperil the privately-funded research and development model. Peer review of individual approval and labeling decisions may collide with our interest in a robust, respected, and final decisions by a central medicines authority.

At the same time, the content is property. No matter how narrowly tailored the disclosure or how robust or effective the confidentiality restrictions, releasing this content constitutes a taking under U.S. law that requires just compensation. But particularly when cabined in this fashion, it need not be understood as inherently obliterating all property rights in the data. Ancillary legal reforms (prevention of regulator use) will further limit the taking and arguably the required compensation. In short, where it is possible for regulators to disentangle disclosure from use and to disentangle indirect use from direct use, the narrowest taking that achieves the public health goal should be effected. To the extent that a compensable taking has occurred in the United States, policymakers can consider statutory in kind compensation. If the disclosure has been effected by a foreign regulator, policymakers can and should blunt the impact in the United States by preserving the other strands in the property right in the United States. As a policy matter, they can and should also consider offering the same in kind compensation, to ensure that the impact on property rights does not affect incentives to innovate.