

# Sequestered Science: Secrets Threatening Public Health

by Rena Steinzor and Matthew Shutz

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## Overview

A common thread running through American public health, safety, and environmental statutes is the requirement that regulatory agencies use the “best available science” to make decisions. “Best available science” means many things. It means that an experiment is properly designed to test a given hypothesis and that data were collected using proper procedures to minimize error and bias. It also means robust statistical analysis, and accurate reporting of results. In sum, “best available science” depends upon a disinterested and transparent scientific process.

This paper focuses on an issue fundamental to the integrity of the scientific process – the dissemination and diffusion of scientific information. In virtually all contexts, barriers to the release and distribution of existing information have proliferated. These barriers, which originated from the legitimate goal of protecting trade secrets and confidential business information, have steadily expanded to the point that they undermine, too often fatally, efforts to protect public health and natural resources. As we will see, excessive secrecy undermines the scientific process and puts people and natural resources at risk of unnecessary harm. The remedy for such unwarranted claims ends up being compensation after-the-fact for injuries that could and should have been prevented by public health and safety laws at the federal and state levels.

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The paper opens with an explanation of how the legal system enables, and often promotes, a culture of secrecy that obscures science on the adverse effects of consumer products and toxic chemical waste. Key provisions of several environmental, health, and safety laws are compared, with a focus on the disparate treatment of “confidential business information” (CBI), a term of art that encompasses trade secret claims. The paper is designed to serve as a starting point for a long overdue debate on how to reform these laws and policies, which have not been amended in any significant way in the last several decades.

## Why Secrecy Is a Problem

In the high stakes arena of chemical and pharmaceutical regulation, information is the penultimate commodity. The side effects of a new anti-depressant or the toxicity of occupational exposure to a new reagent can be the deciding factor in determining whether a promising development will ever enter the stream of commerce. Pharmaceutical and chemical manufacturers spend millions of dollars on studies to prove that their newest inventions are safe for public consumption. When the science shows that a product is not safe we are confronted with the most obvious problem regarding secrecy in the context of chemical and pharmaceutical regulation – the failure to prevent injury. For example, in 1984, DuPont officials received a confidential memorandum describing research that documented adverse health effects among plant workers who were exposed to perfluorooctanoic acid (PFOA), an important ingredient in the process of making Teflon. Not only did the company fail to alter its manufacturing practices, it withheld this information from regulatory officials for over 20 years, subjecting countless workers to these severe hazards. In a similar vein, Eli Lilly failed to inform regulators or the public of clinical trial data that showed Prozac could cause suicidal and violent behavior, allowing the drug to be marketed to unsuspecting consumers for many years.<sup>1</sup> Johnson & Johnson, A.H. Robins, Merrel Dow, and the asbestos, vinyl chloride, and tobacco industries have also concealed evidence of adverse health effects of economically valuable products.<sup>2</sup>

The problem of secrecy in the regulatory arena goes beyond the failure to prevent injuries from specific products. Even when studies show that a chemical or pharmaceutical is safe, rapid disclosure is essential for three reasons. First, disclosure is the predicate of peer review, which makes it possible to determine with objectivity the strength or weakness of the original study. Second, completion of a study is merely the end of the first iteration of the scientific process. Dissemination of results gives the broader scientific community the opportunity to assess how the original study can shape the direction of further research. The advancement of the scientific process rests entirely on the fact that experts are able to review one another's work. Third, members of the public, whether a manufacturers' competitor or a public interest group, cannot participate in the regulatory process in a meaningful way unless they have access to the underlying data (including its design models) that were used to produce research that might have an influence on final decisions. When secrecy works to interrupt these aspects of the scientific process, the process loses its legitimacy, and all of the output from that process is tainted.

Another extraordinarily damaging implication of excessive secrecy is that withholding data introduces significant inefficiency and imposes heavy social costs. Technological innovation thrives on the dissemination and broad diffusion of new ideas. When manufacturers withhold research data and results, resources that could have been used to develop new studies (or new chemicals, or new drugs) will be wasted on duplicative tests. At best, the secret information might reveal the formula for a new and beneficial drug with negligible side effects. Without it, manufacturers of generic drugs must start from the whole cloth when developing their products, forcing consumers to pay inflated prices and, in the case of the uninsured, denying drugs to people who need them most. At worst, information kept secret might show that a certain chemical is more toxic than once believed. In that case, human health remains at risk and insufficient resources are

allocated to preventing injury and developing safer alternatives.

One final aspect of the problem is that a dysfunctional regulatory system caused by secrecy in science – and the structure of the laws that allow this secrecy – raises issues of social and environmental justice, especially as government functions are privatized. For example, insurance companies can contract with the Department of Health and Human Services (HHS) to administer the Medicare and Medicaid programs. The companies are allowed to decide which drugs and medical devices will be available to Medicare beneficiaries within their local jurisdiction. Often, the coverage decisions are not uniform across the country. When a discrepancy arises, the Centers for Medicare and Medicaid Services (CMS), a federal agency within HHS, is responsible for making a final determination binding on all contractors. These decisions are based on all of the data that CMS can gather about a drug's safety and efficacy.

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However, CMS has a policy of disclosing all information about the bases for their coverage decisions. Since this policy contradicts the Food and Drug Administration's (FDA) policies for protecting trade secrets, FDA withholds such information from CMS. As a result, Medicare and Medicaid beneficiaries are not getting all of the life-saving pharmaceuticals that they could.<sup>3</sup>

## **Legal Balancing Act**

**T**hree federal laws attempt to strike a balance between scientific transparency and the legitimate protection of confidential business information:

- The Toxic Substances Control Act (TSCA) gives the Environmental Protection Agency (EPA) the authority to review new chemicals before they are marketed, as well as the hazards posed by chemicals already in commerce;

- The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA to register toxic chemicals used as pesticides, herbicides, and rodenticides;
- The Federal Food Drug and Cosmetic Act (FFDCA) gives the Food and Drug Administration authority to review new and existing drugs before and during their marketing.

All three statutes rely on similar schemes for promoting the collection and sharing of information about pharmaceuticals and toxic chemicals. Each contains testing requirements that generate information about potential adverse health effects. Each mandates that manufacturers submit these test results to a federal agency. The statutes instruct the agencies to review the results to determine whether products are safe for sale. Finally, manufacturers are required to continue updating the appropriate agency with any new information after the initial submission.

A primary problem with these provisions is government's failure to exact penalties that will deter future misconduct. For example, EPA recently settled with DuPont in the PFOA/Teflon for \$16.5 million, a fraction of the amount that DuPont earned in profits on the sale of Teflon during the 20 years it hid information about the chemical's toxic effects.<sup>4</sup> A critical, in-depth analysis of the government's enforcement of information-sharing mandates in various federal laws is beyond the scope of this paper, but it is an important topic that must be addressed in order to determine how TSCA, FIFRA, and FFDCA should be reformed.

In addition to these enforcement problems, while the statutes contain strong disclosure schemes, they also allow regulated entities to protect information deemed "trade secrets" or "confidential business information" without submitting much, if any, proof that these designations are legitimate and without any significant agency review of the legitimacy of those claims when they are made. As a result, the structure of the laws individually and as they relate to each other creates a tension that tends to draw information away from the public domain. Because no threshold substantiation of claims is required under FIFRA and FFDCA, and is required in only limited circumstances under TSCA, companies routinely stamp submissions "CBI," in effect placing the burden on those seeking access to the information to persuade the government that it should be released.

While TSCA, FIFRA, and FFDCA have generally similar statutory structures with respect to requirements that

manufacturers of pharmaceuticals and toxic chemicals test their products, important differences in the language and enforcement of the statutes that make them relatively more or less effective in ensuring scientific transparency.

## Disclosure Mandates

Under TSCA § 5, manufacturers of new chemicals and processors who wish to use existing chemicals for a new use must submit to EPA a premanufacture notification.<sup>5</sup> This notification must include any data showing that the chemical will not present an unreasonable risk of injury to health or the environment.<sup>6</sup> Obviously, this pre-manufacture notification requirement solves only half of the problem: regulated parties need only submit data showing their products are safe, there is no requirement that they submit any data that might show the products are unsafe. TSCA § 8 addresses this issue by authorizing EPA to require manufacturers and processors to submit "[a]ll existing data concerning the environmental and health effects" of a regulated chemical.<sup>7</sup> Furthermore, under § 8(e), chemical manufacturers are required to apprise EPA of any new information that "supports the conclusion that [a chemical manufactured or processed by that firm] presents a substantial risk of injury to health or the environment."<sup>8</sup>

TSCA's relatively robust information disclosure requirements do not apply to certain chemicals, most importantly those that are regulated as pesticides under FIFRA and pharmaceuticals regulated under FFDCA.<sup>9</sup> Both FIFRA and FFDCA have information disclosure provisions that parallel TSCA's requirements. Like TSCA's premanufacture notification, FIFRA requires that pesticide manufacturers register all new pesticides, including in the registration application data sufficient to convince EPA that the pesticide can be used for its intended purpose "without unreasonable adverse effects on the environment."<sup>10</sup> Similarly, FFDCA requires drug manufacturers to apply to FDA for approval of any new drugs and the new drug application must contain "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use."<sup>11</sup>

After registration of a pesticide or approval of a drug, the information disclosure mandates found in FIFRA and FFDCA begin to differ. FIFRA § 6(a)(2), much like TSCA § 8(e), requires pesticide manufacturers to submit to EPA any "additional factual information regarding unreasonable adverse effects on the environment" of a registered pesticide.<sup>12</sup> The strength of this mandate on paper,

however, is undone by poor enforcement of the statutory language. Manufacturers only tend to report the most serious incidents of acute toxicity and, consequently, EPA has garnered little to no information about chronic effects of pesticides through § 6(a)(2).<sup>13</sup>

FFDCA's post-approval information-gathering provisions, unlike TSCA § 8(e) and FIFRA § 6(a)(2), are not even strong on paper. The statute contains mandatory requirements that manufacturers report to FDA data about the safety or efficacy of their drugs once FDA has approved them.

However, the decision whether to generate such information is left to the manufacturers' discretion to a large extent.

FDA's statutory authority to require post-marketing studies is limited to four situations: when using the accelerated approval process,<sup>14</sup>

when a drug might be used for pediatric patients,<sup>15</sup> when a drug is approved based solely on animal studies because pre-approval testing on humans is unethical,<sup>16</sup> and when FDA is considering revoking approval.<sup>17</sup> FDA is able to resort to these statutory mandates in only rare instances.<sup>18</sup> As a result, when FDA wants to know about the large scale effects of use of a new drug, the Administration cannot simply require the manufacturer to monitor the drug's use and report the results to the agency. Instead, FDA must negotiate with the manufacturer to conduct post-marketing studies.

The inadequacy of this system has received some attention from Congress recently. Sen. Edward M. Kennedy proposed legislation in early 2005 that would require pharmaceutical manufacturers to provide FDA with post-marketing studies demanded by the Secretary of HHS.<sup>19</sup> The bill gained little traction in the face of a strong pharmaceutical lobby, which supports instead a voluntary system of information disclosure. A voluntary system has been in place for several years, but evidence suggests that pharmaceutical manufacturers are refusing to publish results from clinical trials of drugs that have been approved by FDA.<sup>20</sup> Clearly, FFDCA is in need of reform.

## Labeling Requirements

The information disclosure rules discussed above govern only disclosure to the government. For products like pesticides and pharmaceuticals that are marketed directly to consumers, disclosure of hazard and risk information to the government alone is insufficient. Consumers must also be apprised of the potential hazards of the products they buy. Regulations promulgated under both FIFRA and FFDCA contain substantial rules about product labeling. The effectiveness of these labels is

beyond the scope of this paper.

Unfortunately, however, in addition to those issues, the rules governing the content of product labels provide yet another opportunity for firms to keep secret important hazard information.

For example, FIFRA regulations only require pesticide

manufacturers to list by name the active ingredients in a pesticide. All the other ingredients can be lumped together on the label as "inert ingredients." But the active/inert distinction is misleading. "Inert" does not necessarily mean "harmless," as the average consumer would expect. Instead, in the case of pesticide labels, "inert" just means "not active." And since "active" ingredients are defined narrowly – only those ingredients in the pesticide that are designed to kill a specific pest – the "inert" ingredients in a pesticide include a broad array of other chemicals. Often they are put into the pesticide to promote spreading or adhesion to plant leaves; but since they are not included to kill a specific pest they are labeled as "inert," regardless of their toxicity.<sup>21</sup>

This loophole causes serious problems. The New York State Attorney General's office has documented instances where manufacturers have hidden such toxic chemicals as chloroethane, naphthalene, and toluene as "inert" ingredients.<sup>22</sup> EPA convened a special work group to look into this problem several years ago, but the group's 2002 report, complete with suggested regulatory changes, fell on deaf ears. FIFRA labeling regulations continue to provide pesticide manufacturers with opportunities to hide important toxicological information from consumers.

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## Ubiquitous CBI

As mentioned earlier, when firms submit information about their products to regulatory agencies, the law grants them the right to claim that some or all of the submission is confidential business information. Information dubbed CBI is confined to agency file rooms, undermining the implementation of public health and environmental laws that function best when hazard information is widely disseminated to decisionmakers and the general public.

## Toxic Substances Control Act

TSCA §14(c) gives any chemical manufacturer, processor, or distributor who submits data to EPA in accordance with the statute's information gathering mandates the right to designate any or all of the information submitted as CBI.<sup>23</sup> The only exception to this rule is for "data from health and safety studies" required under § 8(d), which cannot be identified as CBI.<sup>24</sup> However, there is an exception to this exception that allows chemical manufacturers to claim that certain information in health and safety studies is CBI – any part of a study that could reveal a confidential process, "quantitative mixture composition," company name or address, financial statements, or internal company product codes.<sup>25</sup> For all other data submitted to EPA under TSCA, including § 5 premanufacture notification and § 8(e) notices of substantial risk, manufacturers may claim their submissions should deserve CBI protections.

Under this scheme, some 95 percent of premanufacture notifications include a CBI claim.<sup>26</sup> A smaller, but not insignificant, percentage of § 8(e) submissions also assert that some of the information is CBI.<sup>27</sup> The disparity in the percentage of submissions with CBI claims under § 5 and § 8(e) exists in large part because of different requirements as to up front substantiation of the CBI claims. For § 5 premanufacture notification, firms may claim some or all of the submission is CBI without providing justification.<sup>28</sup> By contrast, § 8(e) submissions must be accompanied by an explanation of why any alleged CBI deserves confidential protection.<sup>29</sup> Requiring up front substantiation of CBI claims is an effective way for regulatory agencies to strike a fair balance between manufacturers' legitimate trade secret concerns and the agency's duty to effectively utilize all available information about toxic substances.

The flaw in this scheme is that up front substantiation is only an effective tool when an agency diligently assesses the claim. A recent Government Accountability Office (GAO) report uncovered the startling fact that EPA only has the resources to review approximately 14 CBI claims per year.<sup>30</sup> GAO further discovered that nearly all of the claims reviewed result in disclosure of the data once claimed to be worthy of confidential protection.<sup>31</sup> It is important that better oversight occur, because CBI claims are often used to mask the name of chemicals, making the information submitted to the agency virtually useless to the public. CBI claims are also used to mask the toxic effect of chemicals, based on the argument that the certain effects are so unique that disclosure would reveal sensitive information.<sup>32</sup> Thus, effective CBI policy requires up front substantiation of CBI claims to be coupled with adequate resources to analyze the claims when they are first made.

## Federal Insecticide, Pesticide, and Rodenticide Act

FIFRA's CBI provisions are also complex and weighted heavily in favor of promoting secrecy. As described above, FIFRA requires pesticide manufacturers to submit copious amounts of scientific information about the environmental and human health effects of their products. FIFRA § 10(d) includes language that, acting alone, could provide the public with much valuable information about the potential dangers of pesticides:

All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public.<sup>33</sup>

Unfortunately, this language is undermined by the limitations on the statute's disclosure requirements. These limitations prevent EPA from providing the public with any information that would disclose (a) "manufacturing or

quality control processes,” (b) “details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or” (c) “the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.”<sup>34</sup> Given that many pesticides sold to consumers are comprised of anywhere from 50-99 percent “inert” ingredients, and that these “inert” ingredients are not necessarily inert in the common sense of the word, these non-disclosure provisions give pesticide manufacturers broad power to keep valuable toxicological information secret.

Of course, these loopholes allowing pesticide manufacturers to withhold data about manufacturing processes, quality control, and inert ingredients are not the only means for manufacturers to avoid the information sharing mandates of FIFRA. When a manufacturer submits scientific information to EPA for pesticide registration purposes, the manufacturer may “mark any portions [of the application] which in the applicant’s opinion are trade secrets or commercial or financial information” deserving confidential treatment.<sup>35</sup> The only redeeming aspect of this scheme is that, under FIFRA, any claim that information is CBI must be accompanied by some minimal substantiation of that claim.<sup>36</sup>

## ***Freedom of Information Act***

The two previous sections describe how TSCA and FIFRA regulate the manner in which firms submit information to EPA. But what happens when a third party – say, a doctor, scientist, or public interest advocate – requests information from EPA that a firm has claimed is confidential? TSCA and FIFRA describe how information goes in to EPA, but they do not describe under what circumstances that information can leave EPA. To fill in this hole and harmonize the Agency’s treatment of CBI under TSCA and FIFRA,<sup>37</sup> EPA drafted another set of regulations under the authority of the Freedom of Information Act (FOIA).<sup>38</sup>

Unfortunately, this effort to establish a uniform system for processing public requests while preserving legitimate claims for confidentiality is skewed in favor of maintaining secrecy. When EPA receives a FOIA request, it must make an initial determination as to whether there is any information being requested that is entitled to confidential treatment as CBI.<sup>39</sup> If the requested information has been claimed as CBI by its submitter, EPA will look at the substantiation for that claim to determine if it is valid. If the submitter did not provide upfront substantiation, EPA

will contact the submitter and ask for substantiation before disclosing the information to the FOIA requester.<sup>40</sup>

Even when no business has made a claim of CBI with regards to the requested information, if there is “any business which, although it has not asserted a claim, might be expected to assert a claim if it knew EPA proposed to disclose the information, the EPA office shall contact a responsible official of each such business to learn whether the business asserts a claim covering the information.”<sup>41</sup> So, in other words, any “business information” (which is “any information which pertains to the interests of any business, which was developed or acquired by that business, and (except where the context otherwise requires) which is possessed by EPA in recorded form”)<sup>42</sup> is assumed to be confidential and EPA will give any potentially affected business the opportunity to make a case for why it should be considered confidential.

The assumption that every last bit of data submitted to EPA by a regulated business is likely confidential and should not be disclosed is the direct result of the heavy penalties the laws establish for unwarranted disclosure. TSCA and FIFRA provide that government officials who unlawfully disclose protected CBI can lose their jobs, be fined tens of thousands of dollars, and even be thrown in jail.<sup>43</sup> While prosecutions rarely, if ever, occur, it is difficult to imagine that these provisions do not deter aggressive challenges to industry confidentiality claims.

## ***Federal Food Drug and Cosmetic Act***

FFDCA prohibits:

[t]he using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of ... this title concerning any method or process which as a trade secret is entitled to protection...<sup>44</sup>

The Act says little else about trade secrets or CBI. It does not even define what a “trade secret” is. With such minimal guidance from Congress, FDA has broad authority to determine how to deal with pharmaceutical manufacturers’ claims that information they submit to the Agency deserves confidential protections. Much like EPA’s treatment of CBI under TSCA and FIFRA, FDA

developed a regulatory scheme that heavily favors secrecy and withholding information from the public.

One fundamental point at which FDA's CBI regulations diverge from EPA's is the fact that FDA tackles the definitional issue head on, rather than simply defining procedures through which the Agency will rule on confidentiality claims. Of course, this was more a matter of necessity than good governance: in *Public Citizen Health Research Group v. FDA*, the D.C. Circuit Court of Appeals ruled that FDA must define "trade secret" using what the Agency terms a "narrow definition ... [that] requires a direct relationship between the information being protected and the productive process."<sup>45</sup> FDA's definition of trade secret reads:

A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.<sup>46</sup>

Notwithstanding this allegedly narrow definition of "trade secret," the remaining FDA regulations governing CBI create a system that gives pharmaceutical manufacturers great leverage in hiding information about their products from the public. Any information submitted to FDA can be designated in whole or in part as CBI.<sup>47</sup> Then, each public request for information from FDA is screened to determine whether any of the information requested has been claimed as CBI.<sup>48</sup> If so, FDA must notify the firm that originally made the CBI claim and offer that firm the opportunity to substantiate the claim.<sup>49</sup>

These regulations would seem to create a heavy pro-secrecy bent in FDA's treatment of data submitted under FFDCA. However, there exists one more, rarely cited regulation that completely contradicts the regulations cited above. It states that marking records as confidential

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raises no obligation by the Food and Drug Administration to regard such records as confidential, to return them to the person who has submitted them, to withhold them from disclosure to the public, or to advise the person

submitting them when a request for their public disclosure is received or when they are in fact disclosed.<sup>50</sup>

This rule might provide an argument for broader disclosure of pharmaceutical data. However, the severe penalties available under FFDCA for disclosing trade secrets is likely too much of a disincentive for any FDA official to ignore a firm's CBI claim. FFDCA, like TSCA and FIFRA, provides for both fines and jail time;<sup>51</sup> and, as a result, FDA officials are much more prone to follow the process of allowing firms to substantiate CBI claims when the public requests allegedly confidential information than to ignore the claims and disclose the data immediately.

The discussion above shows how TSCA, FIFRA, and FFDCA treat information that firms claim must be withheld from the public because it is CBI. The penalty provisions of the laws have tipped the scales in favor of chemical, pesticide, and pharmaceutical manufacturers, enabling them to hide information from each other and from the general public. Given the real costs of creating this culture of secrecy (in money, human health, and environmental safety), it seems imprudent to leave the laws as they stand. But in order to make wise reform, it is

necessary to understand why the laws exist in their present form.

## Justifications for Secrecy

The justifications for allowing and enabling firms to withhold scientific data from the public are based on common law principles of property, contracts, and torts and economic theory.

### Common Law

The genesis of modern American trade secrecy law can be found in an 1860s dispute between a manufacturer of burlap sacks and one of his employees.<sup>52</sup> Francis Peabody was in the business of crafting gunny sacks from jute fibers. After he discovered a novel approach for using jute butts in making the sacks, John Norfolk, an engineer Peabody had hired to build the necessary machinery, took the idea to a competing firm. Peabody sued, arguing that Norfolk should be enjoined from divulging the secret process to anyone else. At the time, there was no concise justification for protecting unpatented ideas, but when the case reached the Massachusetts Supreme Judicial Court, Justice Gray took the opportunity to weave together a number of related principles in support of Peabody's claim. The end result was a theory of trade secret law that rested on basic precepts of property law.

The court held that when a person “invents or discovers, and keeps secret, a process of manufacture, whether a proper subject for a patent or not . . . he has a property in it.”<sup>53</sup> This holding was developed more fully by other jurists and legal scholars, who argued that ideas could be likened to wild animals: the person who expends energy to “capture” an idea can then take exclusive possession of the idea by keeping the idea secret; in maintaining this exclusive possession, then, she deserves property rights in the idea.<sup>54</sup> To this day, proponents of robust trade secret laws maintain that researchers have cognizable property rights in their discoveries, even going so far as to claim that forced disclosure of some information to the government should be considered a taking subject to constitutional scrutiny.<sup>55</sup>

This property law-based justification for industrial secrecy is incomplete, of course. The essential problem is that ideas do not have the same finite characteristics as objects of personal property. An idea can be shared among many individuals without degrading its quantity or beneficial quality for each individual. While property law

can adequately define illegal methods of acquisition and disclosure of personal property, it does not have the same capacity with respect to ideas.<sup>56</sup> For instance, under the property law theory of trade secrets, a person certainly could not steal another's records to determine the ingredients of some secret chemical mixture. But could that person surreptitiously follow the other, taking careful notes of the various raw materials she purchases? Property law does not adequately answer this question.

Legal scholars of the late nineteenth and early twentieth century recognized the weakness of these justifications and shifted their focus from property law to contracts and torts. The change in perspective was rooted in a shift from looking at the characteristics of the object at hand (trade secrets) to the characteristics of the defendant's actions. Under this new paradigm, trade secrets could be justified as contractual obligations of employees and employers or elements of privacy that deserve protection under tort law.

In attempting to justify trade secrets law on principles of contract law, “the idea is to show that all firms would agree to the rules of trade secret law if they could bargain with one another in a suitably defined hypothetical bargaining situation.”<sup>57</sup> The problem is that the real world is not a suitably defined hypothetical bargaining situation. There might be unanimous consent to trade secret law if we only concern ourselves with bargains between competing firms. Each firm might reason that, though it may lose in some situations because another firm is keeping valuable information secret, it will be the holder of valuable secrets on enough occasions to make the expected value of a “secrets are okay” design sufficient to justify the rule. But when we bring consumers into the equation, and assume that they are part of the bargaining process, this theory crumbles. Allowing for disclosure of information leads to competition that benefits the consumer by increasing the number of suppliers and driving down prices.

Furthermore, the contracts-based theory only holds when the information being kept secret can, in and of itself, provide some benefit to the firm holding the secret. That is, the theory only holds for “positive” information. When the information is “negative,” when it is information about toxic effects of a new pesticide for instance, any bargain that involves shielding the information from the public should be considered unenforceable as contrary to public policy.

The tort law justification for industrial secrecy rests on the legal principles that prohibit nonconsensual invasions

into one's personal affairs.<sup>58</sup> However, the concept of privacy is rooted in principles of personal autonomy inherently bound up with an emotional distinction between one's self and the rest of the world. It is not clear that a corporation can claim to hold those same feelings. Second, privacy law only protects from public disclosure those aspects of one's personal affairs that a person can reasonably expect deserves confidential treatment. The law is meant to protect love letters, not data showing a chemical can cause birth defects. Third, the scope of the tort law justification is too narrow, focusing only on the alleged bad acts of the defendant. The argument assumes that the plaintiff was justified in withholding information from others. But when the information being withheld is about harm caused by the plaintiff's products or actions, the assumption is not valid.

## Economics

Advocates of strong CBI and trade secret protection most often cite economic factors as their primary basis for asserting that the government should support secrecy in science. Ironically, traditional free market economists would argue that secrecy is a bad policy. Secrecy concentrates information resources in the hands of those who are most adept at discovering ideas, rather than in the hands of those most adept at using the ideas in a manner that promotes maximum social benefit. From the outset, then, we see that secrecy causes economic inefficiency. The question is whether it promotes offsetting efficiencies.

The main economic argument in support of secrecy in science is that allowing firms to maintain trade secrets complements intellectual property law in a way that ensures each firm can maximize its return on investments in research and development. Many firms argue that the copyright and patent protections of U.S. law cannot adequately protect the information they develop through

such efforts. For instance, many new chemical mixtures or new uses of chemicals are not novel enough to be afforded patent protection under U.S. law. Thus, firms argue, if they want to ensure that they recapture the costs of developing the new mixture or use, they need to keep as much information about the new mixture or use secret, to slow the development of copy-cat products. They argue that information about the product itself, plus information about health and environmental effects must be kept secret to maintain exclusive market shares. In the end, the argument goes; full disclosure of all information will hinder innovation by driving down the returns firms are able to obtain on investments in R&D.

The problem with this argument is that R&D expenses do not always produce profitable products.<sup>59</sup> Because of their risky nature, it is often difficult to link present R&D expenditures to future earnings. Countless new chemicals are synthesized every year, with only a relatively small percentage ever becoming marketable for new pesticides, drugs, or other beneficial uses. Notwithstanding the difficulty in linking present costs to future earnings, R&D today does produce future income, and so it should be treated as some form of capital, rather than present expenses.<sup>60</sup>

Second, R&D is not as risky as many manufacturers claim. For instance, in the pharmaceutical industry, a significant percentage of the hundreds of millions of dollars spent each year on drug development is actually grant money from NIH. In fact, contrary to what industry would argue, full disclosure of scientific data regarding human health and environmental effects might actually promote innovation. In disclosing this information, firms would have to compete to deliver products with the same benefits but minimal adverse effects. In the end, fuller disclosure, not trade secret protection, will foster innovation and economic efficiency.

***Advocates of strong CBI and trade secret protection most often cite economic factors as their primary basis for asserting that the government should support secrecy in science. Ironically, traditional free market economists would argue that secrecy is a bad policy. Secrecy concentrates information resources in the hands of those who are most adept at discovering ideas, rather than in the hands of those most adept at using the ideas in a manner that promotes maximum social benefit.***

The American tort system has given rise to a second economic argument in support of secrecy in science. Merck, manufacturer of the once-popular Vioxx, can attest to the fact that publication and broad dissemination of negative study results can open manufacturers up to a barrage of products liability lawsuits. Not only does publication of the information help plaintiffs identify defendant corporations, it also gives them evidence necessary to prove causation. In an era when products liability lawsuits can carry punitive damages totaling hundreds of millions of dollars, firms can stave off litigation by withholding any negative information they discover.

The problem with this argument is that it fails to take into account other market mechanisms that can work to prevent litigation, if provided with adequate information about hazards. One mechanism is the regulatory system itself. With sufficient knowledge of the negative health and environmental effects of a chemical, pesticide, or drug, federal agencies can regulate the sale and use of the product so as to avoid injuries from occurring in the first place. The second mechanism is consumer choice. Withholding negative information also minimizes the degree to which manufacturers can rely on consumers to prevent injury. Consumers who know of the negative health or environmental effects of a product can choose to minimize their exposure, thus preventing the sort of injury that might later be litigated. In the end, firms will do better to avoid litigation by disclosing all information about their products.

## Recommendations

Justifications for maintaining a legal and regulatory structure that allows for – and even encourages – secrecy in science are particularly weak when applied to scientific data revealing potential adverse health and environmental effects. Unfortunately, laws and regulations have been crafted on the assumption that the justifications outlined above were sufficient. In order to promote the precautionary mandate of modern American public health and environmental laws, the CBI and trade secrets provisions in those laws should be reformed.

Potential reforms could fall into two categories: minor reforms designed to improve the existing system of trade secret protection by preventing abuse of the system, or

major reforms that would constitute a complete overhaul of trade secret protections in the environmental and public health arena. Minor reforms include:

- 1.) Requiring upfront substantiation of all trade secret claims. The substantiation should include evidence that economic or competitive harm would result from public disclosure of the alleged CBI, as well as an explanation of the conditions under which the alleged CBI would lose its confidential status (e.g., when a chemical is sold on the open market and is easily identifiable).
- 2.) Requiring a top corporate official to sign CBI claims and their correspondent substantiations, attesting to their validity and accepting responsibility for any false claims.
- 3.) Creating penalties for specious assertions of CBI or misleading justifications.
- 4.) Creating administrative processes whereby agency officials would automatically analyze the propriety of a random subset of incoming CBI substantiations. The added costs of these processes could be distributed amongst all manufacturers submitting data to the agency through flat rate review and classification fees.

Note that the first three of these suggested reforms are not unprecedented – each is an aspect of the CBI provisions in the Emergency Planning and Community Right to Know Act (EPCRA).<sup>61</sup> The frequency of CBI claims under EPCRA is much lower than under either TSCA or FIFRA.<sup>62</sup>

More significant reform to the trade secret protections afforded under TSCA, FIFRA, and FFDCRA might involve removing the right to claim CBI on information submitted to federal agencies, but tempering the potential adverse economic effects through the use of alternative patent schemes<sup>63</sup> or exclusive use periods.<sup>64</sup> These reforms would shift the balance in trade secret law in favor of full disclosure, recognizing that the full effect of public health and environmental laws can only be accomplished through broad disclosure of hazard information. By granting the original submitter protected commercial use of the information for a set period of years, the reforms would maintain economic incentives for novel R&D while at the same time promoting distribution of information to competitors who might use the protected information to expand R&D into other domains.

## Notes

1. Jeanne Lenzer, "FDA to Review 'Missing' Drug Company Documents," *British Medical Journal* 330, no. 7481 (2005): 7.
2. Wendy Wagner and David Michaels, "Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research," *AM. J.L. & MED.* 119, 126-128 (2004).
3. See Stanly S. Wang and John J. Smith, "Potential Legal Barriers to Increasing CMS/FDA Collaboration: The Law of Trade Secrets and Related Considerations," 58 *FOOD & DRUG L.J.* 613 (2003).
4. Environmental Working Group, "EPA finds DuPont guilty of withholding Teflon blood and water pollution studies," at [http://www.ewg.org/issues/pfcs/tzca8e\\_teflon/index.php](http://www.ewg.org/issues/pfcs/tzca8e_teflon/index.php) (last visited January 29, 2007).
5. 15 U.S.C. § 2604.
6. *Id.*
7. 15 U.S.C. § 2607(a)(2)(E).
8. 15 U.S.C. § 2607(e).
9. 15 U.S.C. § 2608.
10. 7 U.S.C. § 136a(c)(5)(C).
11. 21 U.S.C. § 355(b).
12. 7 U.S.C. § 136d(a)(2).
13. GAO, "Pesticides: Improvements Needed to Ensure the Safety of Farmworkers and Their Children," 11, GAO/RCED-00-40 (March 2000).
14. 21 U.S.C. § 356.
15. 21 U.S.C. §§ 331-334.
16. 21 C.F.R. §§ 314.610, 314.620.
17. 21 U.S.C. §§ 355(e), 355(k).
18. Department of Health and Human Services, Office of the Inspector General, "FDA's Monitoring of Postmarketing Study Commitments," 2, OEI-01-04-00390 (June 2006).
19. 109<sup>th</sup> Congress, S. 16, § 121 (introduced in the Senate, January 24, 2005).
20. Alex Berenson, "Despite Vow, Drug Makers Still Withhold Data," *N.Y. TIMES*, May 31, 2005, A1.
21. New York State Office of the Attorney General, "The Secret Ingredients in Pesticides: Reducing the Risk," available at [http://www.oag.state.ny.us/press/reports/inerts/table\\_of\\_contents.html](http://www.oag.state.ny.us/press/reports/inerts/table_of_contents.html) (May 2000) (last visited January 29, 2007).
22. *Id.* at 7-8.
23. 15 U.S.C. § 2613(c)(1).
24. 15 U.S.C. § 2613(b).
25. 15 U.S.C. § 2613(b); 40 C.F.R. § 176.55(a).
26. GAO, "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program," GAO-05-458 (June 2005), at 5.
27. See EPA, "Previous TSCA 8(e) and FYI Submissions," at <http://www.epa.gov/opptintr/tzca8e/pubs/previous8e.htm> (last visited January 29, 2007).
28. See 40 C.F.R. § 702.80.

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29. See EPA, “Support Information for Confidentiality Claims,” at <http://www.epa.gov/oppt/tsca8e/pubs/cbi.htm>.
30. GAO, “Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program,” GAO-05-458 (June 2005), at 33.
31. *Id.*
32. See, e.g., TSCA § 8(e) submission available at <http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2005/october05/fyi-xx05-01502a.pdf>. The entirety of the § 8(e) submission is claimed CBI, including the name of the chemical, its CAS number, the name of the company submitting the information, and even the description of what is submitted. The publicly available document reads, in full: “FYI-XX05-01502A, Entire Submission Is TSCA Confidential Business Information, (Converted from 8EHQ-XX05-16106).”
33. 7 U.S.C. § 136h(d)(1).
34. 7 U.S.C. § 136h(d)(1)(A)-(C).
35. 7 U.S.C. § 136h(a).
36. 40 C.F.R. § 152.50(f)(2)(iii).
37. Christopher J. Lewis, “When is a Trade Secret Not So Secret? The Deficiencies of 40 C.F.R. Part 2, Subpart B,” 30 ENVTL. L. 143, 158 (Winter 2000).
38. 5 U.S.C. § 552 *et seq.*
39. 40 C.F.R. § 2.204(a)(1).
40. 40 C.F.R. § 2.204(e).
41. 40 C.F.R. § 2.204(c)(2)(i).
42. 40 C.F.R. § 2.201(c).
43. See, e.g., 15 U.S.C. § 2613(d) (TSCA provides for penalties of \$5,000 and a year in jail), 7 U.S.C. § 136h(f) (under FIFRA, government officials could be fined \$10,000 and put in jail for a year).
44. 21 U.S.C.A. § 331(j)
45. 59 Fed. Reg. 531 (January 5, 1994).
46. 21 C.F.R. § 20.61(a).
47. 21 C.F.R. § 20.61(d).
48. 21 C.F.R. § 20.61(e)(1).
49. 21 C.F.R. §§ 20.61(e)(1)-(2).
50. 21 C.F.R. § 20.27.
51. 21 U.S.C. § 333.
52. *Peabody v. Norfolk*, 98 Mass. 452 (1868).
53. *Id.* at 457.
54. See Robert G. Bone, “A New Look at Trade Secret Law: Doctrine in Search of Justification,” 86 CAL. L. REV. 241, 255 (March 1998) (hereinafter “A New Look”), citing *Werkmeister v. American Lithographic Co.*, 134 Fed. 321 (2nd Cir. 1904).
55. The takings arguments are especially weak in the case of chemical and drug regulation. “[V]oluntary submission of information by an applicant seeking the economic advantages of a license can hardly be called a taking.” *Westinghouse Electric Corp. v. U.S. Nuclear Regulatory Comm’n*, 555 F.2d 82, 95 (3rd Cir. 1977).
56. This passage borrows heavily from Robert G. Bone, “A New Look,” *supra* n.55, at 258.
57. Robert G. Bone, “A New Look,” *supra* n.55, at 289.
58. Again, borrowing heavily here from Robert G. Bone, “A New Look,” *supra* n.55, at 284-88.
59. Thomas O. McGarity and Sidney A. Shapiro, “The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies,” 93 HARV. L. REV. 837, 854-56, citing K. Clarkson, INTANGIBLE CAPITAL AND RATES OF RETURN 36-40 (1977); Aynian, THE PROFIT RATES AND ECONOMIC PERFORMANCE OF DRUG FIRMS, IN DRUG DEVELOPMENT AND MARKETING 81, 82-83, 88-91 (R. Helms ed. 1975); Bloch, TRUE PROFITABILITY MEASURES FOR PHARMACEUTICAL FIRMS, IN REGULATION, ECONOMICS, AND PHARMACEUTICAL INNOVATION 147, 155 (J. Cooper ed. 1976).
60. K. Clarkson, INTANGIBLE CAPITAL AND RATES OF RETURN 7 (1977).
61. See 40 C.F.R. 350.7 (requiring upfront substantiation of all CBI claims and certification by an owner, operator, or senior corporate official); 42 U.S.C. § 11045(d)(1) (authorizing civil, administrative, and criminal penalties for frivolous CBI claims).
62. Wagner and Michaels, *supra* n.2, at 153.
63. Mary Lyndon, “Secrecy and Innovation in Tort Law and Regulation,” 23 N.M. L. Rev. 1, 52-55 (1993).
64. McGarity and Shapiro, *supra* n.59, at 883-86.

## ***About the Center for Progressive Reform***

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation and improved public access to information. Direct media inquiries to Matthew Freeman at [mfreeman@progressivereform.org](mailto:mfreeman@progressivereform.org). For general information, email [info@progressivereform.org](mailto:info@progressivereform.org). Visit CPR's website at [www.progressivereform.org](http://www.progressivereform.org). The Center for Progressive Reform is grateful to the Beldon Fund and the Deer Creek Foundation for their generous support of its work.



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