THE TRADE SECRET STATUS OF HEALTH AND SAFETY TESTING INFORMATION: REFORMING AGENCY DISCLOSURE POLICIES

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Manufacturers of new drugs, pesticides, and other substances are often required by law to provide federal regulatory agencies with costly test results as a prerequisite to obtaining clearance to go to market. In this Article, Professors McGarity and Shapiro analyze the circumstances under which this information should be made available to the public. Balancing the interests for and against disclosure, they conclude that virtually all test results should be disclosed, although competitors should generally be forbidden for some period of time from making use of the disclosed information in their own test programs.

Recognizing that market mechanisms, even as enhanced by a tort compensation system, do not adequately protect man and the environment from the risks posed by new products, chemicals, and technologies, Congress has empowered several federal regulatory agencies to proscribe the sale of certain products which endanger the public. In making the risk-benefit assessment prerequisite to such a determination, an agency relies upon the results of experimental testing submitted by the proponents of the product. The controversial question whether, and to what extent, such data should be publicly disclosed has recently arisen in several contexts, including approval of new drugs, antibiotics, and food and color additives by the Food and Drug Administration (FDA); and approval of pesticides and chemicals by the Environmental Protection Agency (EPA).

In almost all of these instances, the private regulatees who submit the studies have successfully forestalled most efforts by

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agencies and interested citizens to disclose their contents by claiming that health and safety data are statutorily protected "trade secrets." Moreover, the recent Supreme Court decision in Chrysler Corp. v. Brown, by effectively allowing parties to assert trade secrecy claims against agencies, threatens to continue to restrict disclosure.

In Part I, this Article will examine the disclosure question, exploring the social costs and benefits of requiring publication of health and safety testing data. Powerful interests are at stake in balancing the desirability of disclosure against the need for confidentiality. Disclosure may, for example, reduce the incentives for new product research and development by preventing companies from fully recouping the high costs of generating the required test data, and by making it easier for competitors to duplicate and license breakthroughs. Nondisclosure, on the other hand, may hamper scientific progress, deny consumers the opportunity to make fully informed product use decisions, increase the risks that agency decisions based on faulty data or analysis will remain undiscovered, and encourage potentially hazardous duplicative human testing.

Following an explication of the competing policy considerations behind disclosure and nondisclosure, current law is examined in Part II. Present agency disclosure policies are governed by a patchwork of often inconsistent statutes, which generally prohibit agencies from releasing "proprietary information." This raises two important issues. First, where there is conflict between statutes or their underlying policies, agencies and courts must determine the scope of particular enactments and decide which policies shall prevail. Chrysler provides some guidance, but fails to cast light on the crucial question of what kinds of information should receive "trade secret" protection and is likely to chill salutary agency attempts to permit disclosure. Second, it is crucial to establish whether health and safety data fall within the scope of "proprietary information" or should be exempted from "trade secret" status. Absent specific statutory language to the contrary, agency regulations generally have uncritically labeled health and safety data as proprietary and thus exempted such information from disclosure under the Freedom of Information Act (FOIA).

An examination of various regulatory schemes in Part II reveals great disparities in the manner in which health and safety testing data are treated across product areas: drug test-

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1 441 U.S. 281 (1979).
ing data remain secret, antibiotic and additive testing data are fully disclosed, while chemical and pesticide data are disclosed subject to compensation for later use by competitors. No underlying principle justifies these differences in approach. This Article concludes that the competing interests for and against disclosure are best accommodated in each of the product categories by a system of full disclosure, with innovation incentives protected by means other than nondisclosure. While the pesticide and chemical approaches offer one such alternative, the costs of administering a compensation scheme are substantial. A better solution, elaborated in Part III, would be to couple disclosure with generic "exclusive use periods" which guarantee a data submitter that no one else can use its data to register a product for a specific number of years. Congress should act decisively to mandate such a system. If Congress does not act, specific agency action is recommended to improve the present systems and encourage congressional action.

Before proceeding, it is essential to clarify what sorts of information fall within the category "health and safety testing data." Under the approach recommended below, the breadth of this definition will determine the fate of large amounts of important, sensitive information. For our purposes, the definition of "health and safety study" adopted by the Toxic Substances Control Act (TSCA)\(^3\) will suffice: "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture."\(^4\) For drugs, efficacy data are also included. Therefore, the results of any product testing that involves laboratory animals or human subjects fall within the scope of health and safety testing data. The question whether background data, notably chemical identities, proportions, or manufacturing processes should be included is a difficult and sensitive issue discussed below.\(^5\) There are good reasons why the latter sorts of information may warrant protection even if study data are to be released.

I. WEIGHING THE POLICIES FOR AND AGAINST DISCLOSURE

Few would quarrel with the desirability of open government, with the inputs and outputs of governmental decision-

\(^4\) Id. § 2602(6).
\(^5\) See pp. 876-78 infra.
making subject to public scrutiny. This presumption in favor of disclosure was codified in the FOIA, which guarantees citizens access to certain information possessed by federal agencies. Public access to health and safety data is especially desirable since disclosure enables individuals to decide whether their use of a product poses an unacceptable risk to their own health despite generic agency approval. Nondisclosure may also hamper scientific progress and needlessly endanger human participants in product testing. Yet certain current federal regulatory schemes involving the submission of health and safety testing data effectively reverse the FOIA's salutary presumption in the name of "trade secret" protection. Nondisclosure is chiefly supported by the fear that disclosure will diminish research incentives by reducing the profitability of discovery.

As this Part will demonstrate, an analysis of the competing policy considerations demands that health and safety data be disclosed except where research incentives would be substantially and demonstrably hindered, and could not be protected by methods other than nondisclosure. The case for disclosure is clear; the case for nondisclosure is weakened by conflicting economic studies as well as the existence of alternative means for protecting research incentives.

A. Reasons for Disclosure

Strong policy considerations support disclosing fully the health and safety data submitted to administrative agencies. As this Section will develop, disclosure should improve agency effectiveness, permit better informed consumer choice, avoid wastefully duplicative testing, and promote scientific innovation.

1. Agency Effectiveness. — An agency faces a difficult task in predicting the likely social consequences of a product's use solely on the basis of experimental testing data submitted by the product's proponent. Data are often scientifically inconclusive, permitting reasonable scientists to arrive at different interpretations. Proper regulatory decisionmaking therefore requires the exercise of "scientific judgment." In addition, test sponsors, because of their financial interest in agency approval, often will design and report studies in the light most

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6 See, e.g., pp. 868–69 infra.

favorable to their products. After a product is approved, agencies rarely have the time and resources to reevaluate the original test data in light of changing scientific evaluational criteria. Thus, questionable industry interpretations can remain undetected for years. In one case, fifteen years elapsed between the original regulatory decision to accept the manufacturer's interpretation that the pesticide "heptachlor" did not cause cancer in rats and later evaluation of the same data, buttressed by independent experimentation, finding strong evidence which indicated that "heptachlor" was very likely carcinogenic.

Traditionally, the scientific community minimizes these problems and biases by subjecting one scientist's research results and methods to formal and informal review by other scientists. If, however, the data submitted to agencies may not be disclosed, the data and test methodology never enter the normal peer review channels and are therefore not subject

8 See Shapiro, Divorcing Profit Motivation from New Drug Research: A Consideration of Proposals to Provide the FDA with Reliable Test Data, 1978 DUKE L.J. 154, 162-63. This problem was graphically illustrated by a situation in which the FDA discovered that G.D. Searle & Co., a drug company, had "made a number of deliberate decisions which seemingly were calculated to minimize the chances of discovering toxicity and/or to allay FDA concern." Preclinical and Clinical Testing By the Pharmaceutical Industry, 1976: Joint Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare and the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, 94th Cong., 2d Sess., pt. 3, at 25 (1976) (statement of Alexander M. Schmidt, M.D., Comm'r, FDA). The discrepancies associated with Searle's presentation were so serious that FDA recommended to the Department of Justice that grand jury proceedings be instituted against Searle. Id. at 30. Over the FDA's objections, the U.S. attorney in Chicago dropped the case without presenting it to a grand jury. Washington Post, June 1, 1979, at A9, col. 1.


to scrutiny by independent scientists. Cast adrift in such scientific isolation, agency scientists may be more prone to misjudge the accuracy or usefulness of the data submitted. Although agency scrutiny is intended to prevent drug testers from making extravagant claims on account of their data, or even from falsifying the data, the FDA itself admits that its review "has not been entirely sufficient to ensure the integrity or usefulness of [submitted] data." Similarly, a recent independent review of EPA pesticide decisionmaking concluded that the data relied upon were woefully inadequate to support the agency's approval of certain pesticides.

Without traditional peer review, agencies also become prisoners of the expertise of their own scientists. A long series of both independent and FDA reports have documented serious deficiencies in the quality of scientists that can be attracted and retained by the agency. Ironically, this deficiency can be tied to the confidentiality problem. Where professional staff are prohibited from using any materials with which they work in normal peer activities such as publishing, the scientific atmosphere in the agency is stifled and the professional growth of its staff is seriously hampered.


12 There have been several prominent instances of such fraud. See Shapiro, supra note 8, at 166-68. Two former executives of Biometric Testing, Inc., a testing laboratory, recently pleaded guilty to charges of conspiring to falsify data for drug manufacturers. Washington Post, Oct. 6, 1979, at A3, col. 5.

13 Kennedy Letter, supra note 10, at 843.

14 See Staff of Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, 94th Cong., 2d Sess., The Environmental Protection Agency and the Regulation of Pesticides 34 (Comm. Print 1976) [hereinafter cited as Kennedy Report].


16 Many FDA scientists refuse to discuss their work with outsiders for fear of inadvertently disclosing trade secrets, thereby foreclosing practically all contact for these scientists with others in their respective fields. Letter from Anita Johnson, Health Research Group, et al., to HEW Hearing Clerk at 6 (n.d.).

17 Drug Regulation Reform Act of 1978: Hearings on S. 2755 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources, 95th Cong., 2d Sess. 645-46 (1978) (testimony of Anita Johnson, Environmental Defense Fund) [hereinafter cited as Senate Hearings on Drug Regulation Reform]; id. at 668 (testimony of Sidney Wolfe, Health Research Group); House Hearings on Drug Reg-
Nondisclosure also may foster a pro-industry bias in agency decisionmaking. Where health and safety data are withheld from the public, industry representatives confront overworked agency personnel under conditions where there is no opportunity for independent observers to scrutinize the existing data and advocate their own inferences based upon their independent policy judgments. As a result, the agency is more likely to accommodate the objectives of its regulatees and perhaps expose the public to serious health risks.

In an open system, by comparison, the agency would not be deprived of the pluralism that is vital to the exercise of informed scientific judgment. Instead, the agency would receive helpful assistance in assessing data from independent scientific and public interest groups and from other pharmaceutical and pesticide companies who may wish to comment. Although the pharmaceutical industry belittles these benefits, contending that few consumers or independent scientists would actually read the disclosed data, public interest groups, the EPA, and the FDA contend that even limited added participation can improve the quality of agency decisions. The fact that consumer representatives and independent scientific and public interest groups, the EPA, and the FDA contend that even limited added participation can improve the quality of agency decisions.
ent scientists lack the time or resources to scrutinize all health and safety data is an insufficient reason to deprive them of the opportunity to analyze that which they deem important. Moreover, an open system could have an important prophylactic effect. The threat of scrutiny by critical outsiders may motivate industry\textsuperscript{27} and agency scientific personnel\textsuperscript{28} to analyze health and safety data more carefully.

Agency isolation also has a deleterious impact on public confidence and agency morale. For example, the FDA asserts that present secrecy policies prevent it from satisfactorily answering its critics, limiting public confidence in its judgments\textsuperscript{29} and causing deep resentment among FDA staff, who cannot reveal data that would help rebut public attacks against their decisions.\textsuperscript{30} These attitudes, in turn, can result in a more inefficient process, slowing the approval of beneficial drugs or pesticides.\textsuperscript{31}

2. Independent Consumer Judgment. — The public’s interest in the full disclosure of health and safety data extends beyond the scientific accuracy of agency decisionmaking. Members of the public have a legitimate interest in knowing the full health effects of products which receive agency approval so that they can decide for themselves whether to use them. Indeed, information of this sort is essential to a true market economy.\textsuperscript{32} Agencies, of course, do strive to protect consumer safety, but do so via very broad risk-benefit determinations for classes of consumers.\textsuperscript{33} Since a licensed chemical


\textsuperscript{27} Senate Hearings on Drug Regulation Reform, supra note 17, at 626 (statement of Marcia D. Greenberger, Center for Law and Social Policy); id. at 670 (testimony of Anita Johnson, Environmental Defense Fund); Kennedy Letter, supra note 10, at 843.

\textsuperscript{28} Senate Hearings on Drug Regulation Reform, supra note 17, at 646 (testimony of Anita Johnson, Environmental Defense Fund).


\textsuperscript{32} See 2 P. Areeda & D. Turner, \textit{Antitrust Law} \textsuperscript{\textregistered} 402 (1978).

\textsuperscript{33} See generally Gelpe & Tarlock, \textit{The Uses of Scientific Information in Environmental Decisionmaking}, 48 S. Cal. L. Rev. 371 (1974); McGarity, supra note 7;
TRADE SECRETS

may harm certain individuals more than it helps them, individual consumers should have available to them information to make decisions, balancing personal risks and benefits.\textsuperscript{34} Even if most consumers would never take the time to read health and safety data before making purchasing decisions, consumer oriented media in consultation with scientific experts could use some of this information to inform the public of potential risks.\textsuperscript{35}

3. Unnecessary Duplicative Testing. — Where nondisclosure of health and safety data by one firm forces a second company to replicate the first company's tests in order to obtain approval for a substantially identical product, the second company's duplicative testing may pose unjustifiable risks to human test subjects and inflict unnecessary suffering on numerous additional laboratory animals. Such duplication also wastes scarce scientific resources. A system of full public disclosure of health and safety testing data, although not the only way to prevent these costs of duplicative testing,\textsuperscript{36} would be one way to minimize such costs.

In drug testing, and to a limited extent, pesticide testing, human experimentation is necessary since the human body may interact with a chemical in a manner different from that indicated by preliminary testing in animals.\textsuperscript{37} The possibility that human test subjects may suffer unpredictably adverse reactions to a drug in the initial experiment is thought justified by the assumption that such testing will lead to the wisest risk-benefit decision for society as a whole.\textsuperscript{38} By contrast, patients

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\textsuperscript{34} Knowledge of the data is particularly important for workers who tend to be "involuntary consumers" of toxic substances. Workers in pesticide plants have in the past been informed that the substances they were working with were harmless, when in fact health and safety data in the files of their employers and of the EPA led to the opposite conclusion. \textit{Kennedy Report}, \textit{supra} note 14, at 37-41.

\textsuperscript{35} Probably the most widely read periodical of consumer-oriented media is \textit{Consumer Reports}, which is published by Consumers Union, a frequent FOIA litigator. Interestingly, that magazine's recent report on the household insecticide diazinon (sometimes called spectracide) was impeded because the extent to which it was contaminated by a toxic impurity was considered by the EPA to be confidential as proprietary data. \textit{Poisons That Don't Belong at Home}, 44 CONSUMER REP. 364, 364 (1979).

\textsuperscript{36} Such systems include compensated use of disclosed information, see pp. 874-76 \textit{infra}, and abbreviated application procedures for previously licensed products, see, e.g., 21 C.F.R. § 314.2(f) (1979).

\textsuperscript{37} Wescoe, A Producer's Viewpoint, in \textit{National Academy of Sciences, How Safe is Safe?} 30 (1974) [hereinafter cited as \textit{How Safe is Safe?}].

\textsuperscript{38} See Dyck & Richardson, \textit{The Moral Justification for Research Using Human
in the duplicative test face risks which cannot be similarly defended. 39

In drug testing, duplication can needlessly deprive ill patients of proven treatments. In the typical drug testing experiment the medical performance of a group of ill patients given the test drug is compared to that of a control group of other ill patients who are usually given a placebo. Of necessity, the latter group of patients is temporarily denied effective treatment and put at risk for no other purpose than to replicate what is already known. Indeed, two German legal scholars have suggested that when such unnecessary inferior treatment predictably leads to a fatality rate higher for the control group than the group receiving the experimental drug, the treating physicians, under German law, would be guilty of manslaughter. 40 Duplicative drug testing can therefore pose risks to human subjects with very little corresponding social gain.

In addition to the special problem of human testing, duplicative testing can be socially wasteful since the safety of the product in question has already been demonstrated. 41 Duplication is particularly unaffordable because of the present shortages of scientific manpower in the fields of pharmacology and toxicology, 42 of clinical physicians available to conduct human drug trials, 43 and of adequate laboratory, animal, and clinical

Subjects, in Biomedical Ethics and the Law 243-44 (J. Humber & R. Almeder eds. 1976); Lowry, A Scientist's Viewpoint, in How Safe is Safe?, supra note 37, at 113.

39 Defenders of one system that requires such duplicative tests claim that they can eliminate this problem by cautioning duplicative testers against any unwarranted risks suggested by the original data. See, e.g., Letter from Pfizer, Inc., to FDA Hearing Clerk at 22–23 (Aug. 15, 1977) (comments on Drug Regulation Report, supra note 15); Letter from SmithKline Corp. to FDA Hearing Clerk at 6 (Aug. 11, 1977) (same).


It should also be noted that it is unlikely that the subjects in a duplicated test are fully apprised of the fact that the data the test will yield are almost exclusively for commercial purposes and have little to do with advancing medical knowledge. Hence, such researchers may well violate the legal and ethical requirements of obtaining the informed consent of the subjects. Crout, supra note 30, at 249.


43 See Personnel Needs, supra note 42, at 89–91; Mirkin, Drug Therapy and
test facilities. Moreover, committing scarce scientific resources to duplicative testing may act as a drag on scientific innovation by diverting research and development expertise to unproductive uses.

Duplication has been defended on the grounds that science normally verifies experimental results through replication. The duplication that occurs, however, is not intended as scientific verification; rather, it is performed only to obtain a drug license. It will occur only when business prospects make it attractive and then only to the extent necessary to pass agency approval. Moreover, if the original testing information were not treated as proprietary, it would be subject to an open process of peer scrutiny, which, like replication, could ensure some verification. Finally, regulatory processes that provide agencies with safety data based on actual consumer experiences to augment experimental data could lessen the need for additional verification.

4. Hampering Innovation. — Suppressing scientific data can also hamper innovation by preventing researchers from becoming fully apprised of scientific findings relevant to their work. A panel of the President's Science Advisory Committee asserted that "[n]ot allowing the academic research community access to the detailed results of safety testing can do

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46 See pp. 841, 843-44 supra.

47 The Senate has approved the FDA's request for the authority to approve certain drugs provisionally, conditional on the requirement that market experience be monitored by the manufacturer and reported back to the agency. S. 1075, 95th Cong., 1st Sess., §§ 128-129, 125 CONG. REC. 13,471 (1979). See generally, REVIEW PANEL ON NEW DRUG REGULATION, U.S. DEPT OF HEALTH, EDUCATION & WELFARE, INTERIM REPORT: EXPANSION OF FDA'S STATUTORY AUTHORITY IN THE PAST — MARKETING PERIOD FOR NEW DRUGS 13-19 (1977). In addition, the FDA is seeking to improve physician and hospital reports systems concerning adverse drug reactions. REVIEW PANEL ON NEW DRUG REGULATIONS, U.S. DEPT OF HEALTH, EDUCATION & WELFARE, INTERIM REPORT: ADVERSE DRUG REACTION REPORTING SYSTEMS 9-21 (1977).

much to slow our progress in the understanding of the presence or absence of unfortunate effects of chemicals on people." It might be argued that scientists will be alerted to new developments through information obtained informally from colleagues and published articles or directly from the sponsoring company or its investigators. But in fact, firms are not always willing to disclose health and safety data, since, if released, the data would no longer be proprietary. For example, some companies condition disclosure on the availability of patent protection. Also, if a company were to publish only some of its data, its selection of which data to reveal might not correspond to the needs of the scientific community. In the final analysis, while companies may occasionally publish data as a contribution to scientific knowledge, much data will be kept secret out of economic self-interest.

B. The Argument Against Disclosure

The case for nondisclosure reflects legitimate concerns, but is undermined by conflicting and uncertain evidence. The key question is whether confidentiality is necessary to foster research and innovation. This Section examines that dilemma and concludes that industry has not yet come forth with convincing evidence that research incentives would be appreciably harmed by disclosure of health and safety data. Moreover,

49 CHEMICALS AND HEALTH, supra note 48, at 126. See also Kennedy Letter, supra note 10 at 843:

FDA is one of the largest repositories of drug information in the world. On matters such as pharmacokinetics, estimation of human risks from animal studies, potential new uses for older drugs, and techniques to reduce human risk and increase the scientific validity of drug testing, information of immense value to humanity may be locked away in the agency's files. We lack the resources to explore that storehouse of data for information of general scientific interest. But if we are permitted to make those data available to scientists, I believe that some will take an interest, and that large benefits may well result.

50 Letter from R. Keith Cannan, Chairman, Division of Medical Sciences, National Research Council, to Senator Hubert Humphrey (n.d.), reprinted in Hearings on Interagency Coordination in Drug Research and Regulation Before the Subcomm. on Reorganization and International Organizations of the Senate Comm. on Government Operations, 88th Cong., 1st Sess. 1896 (1963).

51 See p. 862 infra.

52 Letter from Eli Lilly & Co. to FDA Hearing Clerk at 2 (Aug. 12, 1977) (comments on DRUG REGULATION REPORT, supra note 15) ("At Eli Lilly and Company our commitment to the free and full exchange of scientific information, in keeping with scientific tradition, is of long standing. After patent protection is established, our company and its scientists have a policy of submitting for publication all pertinent data . . ." (emphasis added)).

53 See Whyte, Drug Company Concerns and Opportunities — How We Will Cope, 30 FOOD DRUG COSM. L.J. 338, 340 (1975).
there are methods other than nondisclosure to protect research incentives.\textsuperscript{54}

\textit{i. Legitimate Concerns About Research Incentives.} — The slow current pace of discovery and innovation in industries subject to agency health and safety approval requirements warrants serious concern. For example, from October, 1975 to June, 1978, the FDA approved only six drugs that the agency regarded as "important" therapeutic gains,\textsuperscript{55} despite the fact that drug testing data was not disclosed.\textsuperscript{56} Present regulatory systems force a product down a tortuous path from discovery to marketability: the average drug requires between 4.5 and 8.5 years of testing at an average cost of 2.7 to 4.7 million dollars,\textsuperscript{57} while the average pesticide requires 5 to 7 million dollars.\textsuperscript{58} The fear is that the disclosure of health and safety testing data will further erode the ability of a company to reap the benefits of innovation, reducing the incentives to engage in research.

Potential detriments to an innovator from disclosure of health and safety testing data can be easily identified. Where a product is not protected by a patent, the data could be submitted by a competitor in support of an application to a regulatory agency for approval of an equivalent product.\textsuperscript{59} In light of the time and expense of testing, this would deprive an innovator of substantial lead time and impose on it a significant cost disadvantage. Pharmaceutical and pesticide manufacturers also allege that testing data could be used by competitors to obtain foreign licenses to market competing products.\textsuperscript{60} Such "piracy" may be aided by the fact that patent

\textsuperscript{54} See p. 857 infra.


\textsuperscript{56} See pp. 868–69 infra.


\textsuperscript{59} See F. Dworkin, Impact of Disclosure of Safety and Efficacy Data on Expenditures for Pharmaceutical Research and Development 12 (Apr. 1978) (Staff Paper, Economic Analysis Group, FDA Office of Planning and Evaluation). Apart from nondisclosure, this problem may be avoided by not permitting one company to submit another company's testing data, or by forcing the latter to pay the former. See p. 875 infra.

\textsuperscript{60} See, e.g., \textit{1977 FIFRA Hearings}, \textit{supra} note 11, at 465 (statement of Jack E. Early, President, Nat'l Agricultural Chems. Ass'n); \textit{1977 Agriculture Hearings}, \textit{supra} note 45, at 324 (statement of John E. Donald, Dow Chem. U.S.A.); \textit{Senate Hearings on Drug Regulation Reform}, \textit{supra} note 17, at 296–97 (testimony of C. Joseph Stetler,
protection may be unavailable in certain significant foreign markets. Disclosure of health and safety testing data may also provide competitors with insights concerning their own research in similar areas for related products. Such insights could lead to a breakthrough that would undermine the ability of the original innovator to reap the benefits of its innovation.

It might be argued that the nondisclosure of health and safety data is not necessary to protect innovating firms from competition since the seventeen-year monopoly granted by the patent system affords the needed shield. The drug and chemical industries, however, have identified three reasons why the patent system may be inadequate to protect their incentives for innovation.

First, some discoveries are unpatentable because they do not meet the statutory requirement of being new, novel and nonobvious. For example, innovations that are easily synthesized from other known chemicals or which constitute the discovery that a known drug can be used for a previously unknown purpose may be unpatentable because they will be considered "obvious." For pesticides, innovations lack patent protection if they are composed of active ingredients that were known to kill pests before the attempt to patent them or, possibly, if they are biological pesticides such as pest diseases.

The extent of protection that the patent laws provide is also affected by the fact that actual protection can be shorter than the prescribed seventeen-year period. Although in some

President, Pharmaceutical Mfrs. Ass'n; id. at 678 (testimony of Robert B. Clark, President, Hoffmann-LaRoche, Inc.).

61 Senate Hearings on Drug Regulation Reform, supra note 17, at 303 (Memorandum of Pharmaceutical Mfrs. Ass'n (Argentina, Brazil, Canada, India, Italy, Mexico, and Spain do not give meaningful patent protection for drugs). In addition, in major markets such as France, Germany, and Great Britain, some new drugs are not patentable and others, while patentable, may turn out to be difficult to protect against infringement. Id. at 305.

62 Dworkin, supra note 59, at 12; see Senate Hearings on Drug Regulation Reform, supra note 17, at 293 (statement of C. Joseph Stetler, President, Pharmaceutical Mfrs. Ass'n; id. at 674-75 (testimony of Robert B. Clark, President, Hoffmann-LaRoche, Inc.); Whyte, supra note 53, at 340; Letter from Pfizer, Inc., to FDA Hearing Clerk at 25 (Aug. 15, 1977).


64 Kitch, supra note 41, at 96-98; see 35 U.S.C. § 103 (1976).

65 See 1977 Agriculture Hearings, supra note 45, at 360 (testimony of J. Conner, General Counsel, Nat'l Agricultural Chems. Ass'n). Carbon tetrachloride and lead arsenate are two such ingredients. Id.

66 The Supreme Court has recently agreed to decide whether novel biological organisms are patentable. Application of Bergy, 596 F.2d 952 (C.C.P.A.), cert. granted, 100 S. Ct. 261 (1979).
cases, a pending patent application will deter competitors from marketing a substitute even before the patent is granted so that there is "effective" protection for more than seventeen years. In other cases, companies may shorten the "effective life" of a patent by filing an application as early as possible in the research and development process, often long before that process and agency approval are complete. The latter possibility occurs often enough so that the average effective life of a drug patent is estimated at only about twelve to thirteen years and that of a pesticide patent at only about seven to ten years.

Finally, a patent may offer effective protection from competition only for the time it takes competitors to invent a noninfringing substitute product. For drugs, a later substitute, known as a "follow-on" drug, may be a distinct innovation or merely a molecular modification of the innovation itself. These follow-on drugs are possible because the original innovator may not anticipate and patent all the chemical variants of its drug, thereby allowing the development of a competing product based on the concept embodied in the original patent. Follow-on drugs can rapidly follow an original drug innovation onto the market. For example, a survey of the markets for seven therapeutic drugs found that the mean time period between the marketing of the innovation and the appearance of the first follow-on drug was only three years.

2. Evaluation of the Nondisclosure Argument. — On the basis of current information, it is uncertain that disclosure of

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67 Kitch, supra note 41, at 84–85.
68 Id. at 85; Pracon, Inc., Study to Assess Impacts of Releasing Safety and Effectiveness Data on the Pharmaceutical Industry's Incentives to Invest in and Conduct Research and Development Program, FDA Contract 223-77-8052, at 81-82 (n.d.).
The range of protection, however, is considerable. About one-sixth of new drug innovations receive either greater than 17 years of effective protection and about another one-sixth receive effective protection for less than 10 years. D. SCHWARTZMAN, supra, at 170.
70 See 1977 Agriculture Hearings, supra note 45, at 236 (supplementary statement of Nat'l Agricultural Chems. Ass'n).
71 See D. SCHWARTZMAN, supra note 69, at 306.
health and safety data would actually have a serious adverse impact on innovation. First, disclosure of such data may not give competitors significant licensing and intelligence advantages. Second, empirical evidence is in conflict over whether profitability in the relevant industries is so precarious or sensitive that disclosure of health and safety data, where not currently permitted, would substantially destroy research incentives. Unless industry comes forward with better evidence in these two areas, uncertain fears about the incentives for innovation should not stand in the way of disclosure.

Strong evidence contradicts several of the arguments for nondisclosure. For example, HEW estimates that seventy-five percent of all drugs sold in 1976 were manufactured by only one source.73 Innovating companies may protect their patent positions by attempting to patent a broad spectrum of chemicals similar to the one under active investigation or may enforce their patent rights against related follow-on products under the "doctrine of equivalents."75 Under the latter concept, when two chemicals work in substantially the same manner and accomplish the same result, they may be considered the same for purposes of patent infringement even though they differ in name, shape or form.76 Even without patent protection, market imperfections can protect the ability of an innovator to reap monopoly benefits. In the drug area, for example, a recent Federal Trade Commission (FTC) study concluded that physicians display a strong and continued preference for the first brand of a product to appear and for follow-on brands marketed by the same firm.77 The study found that these preferences existed even where the innovative drug was not patented and thus subject to almost immediate competition.78 A useful example is Eli Lilly's patent on the analgesic

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73 Pricing of Drugs: Hearings Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources and Subcomm. on Antitrust and Monopolies of the Senate Comm. on the Judiciary, 95th Cong., 1st Sess. 29-30 (1977) (testimony of Robert Derzon, Adm'r, Health Care Financing Adm'n) [hereinafter cited as Pricing of Drugs Hearings].
74 Dworkin, supra note 59, at 12.
75 See 7 A. DELLER, WALKER ON PATENTS §§ 546, 571-572 (2d ed. 1972).
77 See FEDERAL TRADE COMMISSION, SALES PROMOTION AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS 76 (1977) (Staff Report) [hereinafter cited as FTC STAFF REPORT]; accord, Pricing of Drugs Hearings, supra note 73, at 31 (1977) (testimony of Robert Derzon, Adm'r, Health Care Financing Adm'n). However, the FTC did recognize that innovative competition may persuade physicians to alter their preferences. FTC STAFF REPORT, supra, at 76.
78 FTC STAFF REPORT, supra note 77, at 77. But see Pracon, Inc., supra note 68, at 53-55.
Darvon. Although its patent expired in 1971, Darvon still retained a ninety percent market share in 1979. While recent public interest in lower cost generic drugs could lessen the effect of physician brand loyalty, to date, acceptance of generic drugs has been slow.

The ability of competitors to use disclosed health and testing data to gain an advantage in obtaining foreign licenses must be seriously questioned in light of the findings of a FDA report. In a study of the nine foreign markets accounting for two-thirds of all foreign drug sales by American multinational firms, the FDA found that the effect of releasing data would be minimal in all but one of those countries. In some cases, data required by federal agencies would be either unacceptable or unnecessary to achieve foreign regulatory approval. The FDA also suggested that market imperfections would provide significant protection beyond that granted by foreign patent laws. An eminent economist has noted that American companies do not show substantially lower sales in countries where they are unable to obtain patent protection and where regulatory standards are low, enabling competitors to obtain a drug license by only submitting published medical journal articles. He therefore labeled estimates of the sales at risk from releasing data a “gross overstatement.”

Underlying the uncertainty about the effect on research

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83 Id. at 3. Based on data supplied by the Bureau of Drugs, the FDA analysis led to a prediction of minimal impact in all but one of the countries. When different data from the International Federation of Pharmaceutical Manufacturers and from FDA assessments were substituted, predictions were for a minimal impact in five and six countries, respectively, with somewhat more serious consequences predicted in the remaining countries. Id. at 2–3, 5.
84 Id. at 1, 7–9.
85 See Senate Hearings on Drug Regulation Reform, supra note 17, at 250 (testimony of Donald Kennedy, Comm’r, FDA).
86 FDA SUPPLEMENTARY ANALYSES, supra note 82, at 5.
87 House Hearings on Drug Regulation Reform, supra note 10, at 2162 (testimony of Prof. Roger Noll).
88 Id.
incentives of government disclosure policies is a conflict in empirical evidence about the profitability of the industries that must routinely obtain agency approval on health and safety grounds. In the case of the drug industry, which perhaps has received the greatest scrutiny from economists, there is support both for those who would argue that profitability is so low that any decrease in the benefits to be reaped from research could be catastrophic and for those who would argue that profitability is so high that substantially reduced protection of testing results would still not make investment in drug research worse than alternative investment opportunities.

One set of economists has suggested that ethical drug firms may be shifting resources away from drug research and development (R&D) and into activities offering more promising rates of return. Some empirical results support this conclusion and show that the rate of return on R&D for drugs is less than for comparable alternative investments. One such study found an expected average rate of return of three percent for drugs, as compared to an expected average rate of ten percent in other industries.

These results seem implausible. If the rate of return for drugs was in fact seven percentage points below other comparable investments, drug industry R&D investment would drastically decline. Instead, in constant dollars, it has been at a steady level or, at worst, has declined by some small amount. In absolute terms, most major pharmaceutical firms have consistently increased their research spending, while only a small number of firms have either eliminated or sharply reduced R&D expenditures. One explanation for this appar-

90 See D. SCHWARTZMAN, supra note 69, at 146; Clymer, The Economic and Regulatory Climate: U.S. and Overseas Trends, in DRUG DEVELOPMENT, supra note 72, at 137, 141-42.
91 D. SCHWARTZMAN, supra note 69, at 146, 160.
92 See Grabowski, Vernon & Thomas, supra note 89, at 53-54.
93 Schnee & Caglarcan, supra note 57, at 97. See also Temin, Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry, 10 BELL J. ECON. 429, 431 (1979). Professor Schwartzman believes that the increase in investment can be explained by the fact that some firms expect to do better than the average return based on their previous performance, that firms must maintain some research if they are to compete successfully, and that firms may simply be gambling that they can produce a drug which is immensely successful. D. SCHWARTZMAN, supra note 69, at 147-48. See also Clymer, The Economics of Drug Innovation, in THE DEVELOPMENT AND CONTROL OF NEW DRUG PRODUCTS 109, 126 (M. Pernarowski & M. Darrach eds. 1971). Another group of economists has suggested that the adjustment of R&D spending to lower rates of return might not have occurred yet because of a
ently irrational behavior may be that the foregoing return calculations are in error. The unavailability of accurate profit information from drug manufacturers on which to base estimates may have caused a substantial understatement of present research profit expectations.94

Some economists have argued that the conventionally calculated rate of return, which is historical in perspective, merely reflects the research success of companies in the 1960's and does not yet measure the less successful research results of the present period.95 They also contend that those accounting methods overstate profits by failing to match income generated, which occurs some years after the R&D, with the costs attributable to that income.96 Finally, these economists suggest that the resulting overstatement of income may be greater for the pharmaceutical industry than other domestic industries because it spends a disproportionately greater amount on R&D.97

In an attempt to avoid some of these accounting infirmities, economists have recalculated firm profit rates by capitalizing R&D expenditures instead of treating them as expenses — a mechanism which more fully reflects the relationship between later-arriving income and the expenses that created it.98 When R&D costs are capitalized, pharmaceutical profits decline, sometimes by a considerable amount.99 But when these studies compare the resulting rates to those of other industries, using various methodologies, the pharmaceutical industry still

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94 See Scherer, Commentary, in Drug Development, supra note 72, at 121, 121-22.
95 D. Schwartzman, supra note 69, at 63, 138.
96 Id. at 137-38; Ayanian, The Profit Rates and Economic Performance of Drug Firms, in Drug Development, supra note 72, at 81, 82-83; Brozen, Foreword to K. Clarkson, Intangible Capital and Rates of Return 7-8 (1977); Bloch, True Profitability Measures for Pharmaceutical Firms, in Regulation, Economics, and Pharmaceutical Innovation 147, 148 (J. Cooper ed. 1976); Stauffer, Profitability Measures in the Pharmaceutical Industry, in Drug Development, supra note 72, at 97, 99-101.
97 Ayanian, supra note 96, at 82; Stauffer, supra note 96, at 97, 112-13.
98 K. Clarkson, supra note 96, at 36-40; Ayanian, supra note 96, at 82-83, 88-91; Bloch, supra note 96, at 154-55.
99 K. Clarkson, supra note 96, at 64 (30% decrease); Ayanian, supra note 96, at 88 (25% decrease); Bloch, supra note 96, at 155.
remains significantly more profitable than average. In one such comparison, it still exceeded the mean average for other industries by thirty-three percent. This conflict concerning pharmaceutical profitability cannot be resolved on the basis of available public evidence. The economic studies seem to understate the present rate of return and accounting data appear to overstate it. This absence of relevant information confounds any attempt to determine how sensitive drug industry research incentives would be to switching from nondisclosure to disclosure of health and safety testing data. Information from the drug industry itself further contributes to the confusion. While belittling its profitability to stave off data disclosure, the industry has presented a more favorable profit picture to the readers of business publications who might purchase drug company stocks.

100 K. Clarkson, supra note 96, at 64 (12.89% versus median of 9.6% for selected industries); Ayanian, supra note 96, at 89 (13.69% versus median of 12.4% for firms in Fortune 500); Temin, supra note 93, at 432. See also Brozen, supra note 96, at 2.

Some economists have attributed some portion of this higher return to the fact that the drug industry is more risky than other industries. See Schnee & Caglarcan, The Economic Structure and Performance of the Ethical Pharmaceutical Industry, in The Pharmaceutical Industry 23, 38-39 (C. Lindsey ed. 1978). Other economists have disputed that any difference in risk exists since examples of unstable or occasionally below average company profits are difficult to find. Schifrin, The Ethical Drug Industry: The Case for Compulsory Patent Licensing, 12 Antitrust Bull. 893, 910 (1967). The capital asset pricing model predicts that ethical drug stocks are in fact riskier than the market, but not to the extent reflected in the higher returns seen above. A composite beta for the industry, computed by a weighted sales average of major corporations in the industry, is 1.10, suggesting that the ethical drug industry is only some 10% riskier than the risk level of the average market portfolio (which carries a beta of 1). See 4 Value Line Investment Survey 592-607 (Oct. 26, 1979). See generally Modigliani & Pogue, An Introduction to Risk and Return: Concepts and Evidence, in V. Brudney & M. Chirelstein, Cases and Materials on Corporate Finance 1156-63 (1979); Pogue & Lall, Corporate Finance: An Overview, in Modern Developments in Financial Management 26, 28-31 (S. Myers ed. 1976).

101 K. Clarkson, supra note 96, at 64.

102 A second confounding factor is the fact that a decision as to future investment decisions will be made by pharmaceutical industry managers whose individual management perspectives will affect their investment decisions. As a consequence, an FDA-sponsored study concluded:

We think a negative impact will occur if safety and effectiveness data are disclosed, but the net reaction of the industry will be largely determined by the managements of individual firms, each differing in terms of financial resources, risk-taking propensity, product mix, non-pharmaceutical diversification and general views — optimistic vs. pessimistic — about firm and industry futures.

Pracon, Inc., supra note 68, at 87.

103 See, e.g., Eli Lilly: New Life in the Drug Industry, Bus. Week, Oct. 29, 1979, at 134 ("Like the premature reports of Mark Twain's death, . . . the bleak assessments of the drug industry's future have proven to be highly exaggerated."); Baris, SmithKline's Revival, N.Y. Times, Sept. 16, 1979, § 3, at 7, col. 4.
C. Weighing the Interests For and Against Disclosure

Even were the choice merely between the polar extremes of pure disclosure and pure nondisclosure of health and safety testing data, current information would compel disclosure. Nondisclosure frustrates agency effectiveness and consumer free choice while imposing significant duplicative testing costs. Proof that secrecy is necessary to promote research investment is at best equivocal. Patents and market imperfections provide some protection for research incentives, even if data are disclosed. It is conceivable that industry may one day establish that profit rates are so dangerously low that nondisclosure of health and safety testing data is essential to facilitate product innovation. Since such information is uniquely within the control of industry and since the case for disclosure is substantial, the burden of establishing the need for secrecy properly belongs with the individual regulated industries.

The case for disclosure is stronger when one departs from examining only pure disclosure and nondisclosure systems. Along with a basic disclosure scheme one may build in protections for the intelligence and licensing advantages relinquished by data producers. Alternatively, a basic nondisclosure scheme may be supplemented with protections against duplicative testing or mechanisms to promote agency effectiveness. Some of these "mixed" systems will be evaluated in the next Part of this Article by examining several of the systems currently in operation.

II. An Examination of Current Law

This Part explores the manner in which present law accommodates the competing interests for and against disclosure of health and safety testing data by examining the general structure of the law, the specific regulatory frameworks, and the effect of recent court decisions. An agency, in deciding whether to disclose health and safety data, is faced with two separate questions. First, the agency must decide the extent to which "proprietary information" — a general term used here to encompass the terms "trade secrets," "confidential business information," or "privileged information" — may be disclosed to the public. This determination is complicated by the fact that a patchwork of statutes, including the FOIA, the Trade Secrets Act, and the agency's own substantive regulatory scheme, addresses the issue of disclosure of proprietary information.\(^{104}\) Second, the agency must determine whether

\(^{104}\) A number of separate statutes in the United States Code, many of which are safety statutes, contain some provision for protecting proprietary information in gov-
the health and safety data it has received qualify as proprietary information. Where it is ultimately found that the health and safety data should be disclosed, the agency must be prepared to answer the possible charge that forced disclosure constitutes a taking of property without just compensation. This Part will address these questions before examining specific agency practices.

A. Resolving the Statutory Tangle

The question whether an agency can release proprietary information is complicated by the existence of laws which both encourage and discourage disclosure. The FOIA requires agencies to release all governmental information except that which may fall into nine categorical exceptions. The pertinent exception here is "exemption four," which exempts "trade secrets and commercial or financial information obtained from a person and privileged or confidential." The Trade Secrets Act establishes criminal penalties for the disclosure of "proprietary information" unless such disclosure has been "authorized by law." Recently, in *Chrysler Corp. v. Brown*, the Supreme Court delineated the interaction among these two statutes and the provisions regarding disclosure in specific regulatory statutes.

106 Id. § 552(b)(4).
107 18 id. § 1905. The section provides:

Whoever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties ... which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than $1,000, or imprisoned not more than one year, or both; and shall be removed from office or employment.

(Emphasis added).

In *Chrysler*, the Chrysler Motor Corporation sued to enjoin the Defense Department from releasing information about Chrysler's employment of women and minorities pursuant to a private request for disclosure of the information under the FOIA. Chrysler claimed that the information was proprietary and that the FOIA and the Trade Secrets Act prohibited its release. The United States Supreme Court held that Chrysler enjoyed no direct private right of action to enjoin a violation of the Trade Secrets Act, but that a violation of the Act could be enjoined under section ten of the Administrative Procedure Act (APA), which provides that a reviewing court shall "hold unlawful and set aside agency action . . . not in accordance with law." The Court reasoned that "any disclosure that violates [the Trade Secrets Act] is 'not in accordance with law' within the meaning of the [APA]."

The Court opened the door to greater governmental disclosure by holding that the FOIA exemptions are not absolute and that an agency has discretion to release information within an FOIA exemption. The Court also held, however, that information that falls within the Trade Secrets Act may not be released. The Court rejected the government's argument that since the FOIA exemptions are discretionary, the FOIA itself authorizes regulations which permit the release of the information within the "authorized by law" proviso of the Trade Secrets Act. In rejecting this interpretation, the Court reasoned that since materials exempt from disclosure under the FOIA are outside that Act's mandate that information *must* be disclosed, the government could not rely on the FOIA as congressional authorization for the release of such information.

The government also argued that the provision commonly referred to as the "housekeeping statute," which provides

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111 441 U.S. at 318.
112 Id. at 294. The Court found that the language of the FOIA itself, the nature of the judicial review provisions which concern only the person requesting the information, and the legislative history all clearly indicate the nonmandatory nature of the exemptions. Id. at 290–94. The Court also noted that in other statutes, where Congress wanted to make an exemption mandatory, it clearly stated that purpose in the statute. Id. at 293 n.14.
113 Id. at 317–18.
114 Id. at 303–04.
115 Id.
116 5 U.S.C. § 301 (1976). The section provides:
The head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees,

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that an executive department may prescribe such regulations as are necessary to carry out its business, provided the authorization to release the information.\textsuperscript{117} Again, the Court disagreed with the contention and found instead that Congress intended that provision to authorize only "procedural" rules concerning the organization of an agency and not "substantive" rules permitting the release of proprietary information.\textsuperscript{118}

The \textit{Chrysler} Court served notice that for an agency's disclosure regulation to satisfy the Trade Secrets Act there must be some identifiable "nexus" between the disclosure regulation and the delegation of legislative authority for its promulgation.\textsuperscript{119} Two kinds of statutory authorizations conceivably can satisfy the Court's criteria. First, Congress occasionally has given an agency explicit authority to release particular kinds of information that otherwise might be subject to a trade secrecy claim.\textsuperscript{120} As will later be developed, both the Toxic

\textsuperscript{117} 441 U.S. at 308–09.
\textsuperscript{118} \textit{Id.} at 310–11. The Court in \textit{Chrysler} suggested one final way around the Trade Secrets Act. The Court cautioned that it had not attempted "to determine the relative ambi of Exemption 4 and \textsection~1905." \textit{Id.} at 319 n.49. The Court further postulated that if the material fell within \textsection~1905, but not within exemption four, as nonexempted information it would have to be released pursuant to the FOIA, satisfying the requirement of \textsection~1905 that disclosure be "authorized by law." \textit{Id.} But the Court warned that it was unlikely that the coverage of the two statutes differed in light of the similarity of language of the two provisions. \textit{Id.} Both statutes use the term "trade secrets," so at least for that type of information, the statutes are probably coextensive. \textit{Compare} 18 U.S.C. \textsection~1905 (1976) \textit{with} 5 \textit{id.} \textsection~552(b)(4). The language of exemption four concerning "confidential . . . commercial or financial information" is also similar to the coverage in \textsection~1905 of "the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any [entity]."


\textsuperscript{119} 441 U.S. at 304.
Substances Control Act and the Federal Insecticide, Fungicide and Rodenticide Act explicitly authorize the release of health and safety data and thus meet the Chrysler criteria. Second, Congress often gives an agency general rulemaking authority beyond that which the housekeeping statute confers. Arguably, such individual grants of authority would meet the Court’s criteria, but this is a much closer question under the “nexus” test than cases in which explicit disclosure authority is given.121

The Chrysler Court was correct in holding the APA available to plaintiffs aggrieved by threatened agency disclosure. In enacting the FOIA, Congress did not affirmatively remove the constraint of the Trade Secrets Act upon agencies. But to make that constraint anything more than academic, it must be enforceable. Given the draconian nature of the criminal penalties provided by the Trade Secrets Act for its violation, it was appropriate for the Court to effectuate another means of enforcement. By recognizing the applicability of the APA’s “in accordance with law” provision, the Court held that one who submits the information to the government may act to enforce administrative compliance with the Trade Secrets Act.

The consequence of Chrysler is that agencies will be unable to disclose proprietary information without fairly explicit statutory authority. Therefore, if health and safety data are proprietary information, agencies may not disclose the data without such a mandate. But the scope of “proprietary information” is an entirely separate question.

B. Defining “Proprietary Information”

The Trade Secrets Act, the FOIA, the Food, Drug, and Cosmetic Act, and most other federal statutes dealing with proprietary information, make no attempt to define that term.122 Therefore, it is open to question whether health and

121 The continued vitality of one pre-Chrysler case which dealt with such a situation is uncertain. In Westinghouse Elec. Corp. v. Nuclear Regulatory Comm’n, 555 F.2d 82 (3d Cir. 1977), Westinghouse sought to enjoin the Agency from enforcing regulations that provided for disclosure of proprietary information when the public interest in disclosure exceeded the submitter’s interest in secrecy. See 10 C.F.R. § 2.790 (1979). The Court of Appeals for the Third Circuit held that the Agency had validly issued the regulations under its authority to make such rules and regulations as may be necessary to carry out the purposes of the Atomic Energy Act, 42 U.S.C. §§ 2011–2281 (1976). 555 F.2d at 89. Therefore, information made public pursuant to the regulations came within the Trade Secrets Act’s exemption for disclosure authorized by law. Id. at 94. However, agency attempts to use general rulemaking authority to support disclosure regulations may find Westinghouse weak authority after Chrysler.

122 Congress has attempted to define “protected information” only in the context of health and safety information. See Toxic Substances Control Act § 14(b), 15 U.S.C.
safety testing data should receive the protections mandated for proprietary information. Traditionally, agencies and courts have employed the broad common law definition of trade secrets to set the boundaries of proprietary information, including health and safety testing results within its scope. But the applicability of such a definition to the public law context of information submitted to government agencies is undermined by the very different considerations which led to a broad definition of "trade secrets" in the private law area. In some limited circumstances, courts have defined proprietary information by balancing the need for privacy against the need for disclosure. While such a method is more responsive to the underlying policy considerations, its implementation may be troublesome. Recently, Congress has attempted to override the "trade secrets" problem in two pieces of legislation, the Toxic Substances Control Act (TSCA) and the amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), by explicitly excluding health and safety testing data from the ambit of proprietary information protection. While this is a tidy, and, as will be argued later, a desirable solution, it is not completely free of problems.

i. The Common Law Definition. — The Restatement of Torts, embodying the common law definition, defines 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." Strict application of this definition would classify virtually all undisclosed health and safety testing data as trade secrets since such data invariably give the owner a competitive advantage where competitors cannot market the same product without reproducing the data.


125 See note 122 supra.

126 RESTATEMENT OF TORTS § 757, Comment b at 5 (1939) (emphasis added). The oft-quoted factors for determining trade secrecy ensure very broad protection for plaintiffs:

Some factors to be considered in determining whether given information is one's trade secret are: (1) the extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and to his competitors; (5) the amount of effort or money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Id. § 757, Comment b at 6.

127 Courts have been unwilling to go so far as to conclude that all health and safety testing data is proprietary under the Restatement definition, but neither have
But the common law definition was tailored to private contexts where public policy almost exclusively focuses on the unjust enrichment and competitive harm resulting when someone acquires a business intangible through the breach of a contract or a confidential relationship. The essence of the common law concept of trade secret is thus wrongdoing on the part of the defendant. Although on rare occasions a court will suggest that the common law of trade secrets encourages research and development, the Restatement eschews any policy of encouraging innovation.

When the question of defining proprietary information appears in the public context of whether health and safety data submitted to an agency should be publicly disclosed, the interests of the public in disclosure and the protection of innovation incentives pose important considerations which the common law definition was not designed to handle. The Restatement approach, with its emphasis on culpability and misappropriation, is ill-equipped to strike an appropriate balance between the competing interests of regulated industries and the general public. Therefore, lumping health and safety testing data with all other types of proprietary information is inherently suspect.

2. Balancing Approaches. — In other contexts, courts have employed a test which balances the need for privacy against the need for disclosure in order to define proprietary information. For example, such a method has been recognized in determining whether information would be protected as proprietary during the discovery process under the Federal Rules...
of Civil Procedure and whether documents subpoenaed in certain agency rulemaking proceedings could be publicly disclosed by the agency or must be held confidential.

While a balancing approach to determining whether health and safety data are proprietary information would enable courts and agencies directly to consider the competing interests in the public's need to know versus the need to protect incentives for innovation, there are several problems. If the balancing approach is performed case-by-case, vast amounts of agency staff and lawyer time could be consumed in holding hearings, making determinations, and preparing for judicial review of decisions. Also, the fact that particular health and safety data would not qualify as proprietary information under the balancing approach does not mean that such data, although not eligible for full protection as proprietary information, should not receive some form of protection.

3. Wholesale Redefinition. — Completely excluding health and safety testing data from the protections afforded to proprietary information clears the way for a comprehensive scheme of disclosure and protections specifically geared to such data. Congress recently adopted such an approach in both the TSCA and the FIFRA, as amended. The desirability of this approach will be explored as specific regulatory schemes are examined in a later section. Its chief drawback lies in the problems created by making the definition of health and safety so crucial. Costly fights over the definition have already begun.

C. Constitutional Issues Regarding Forced Disclosure

While strong policy arguments favor disclosure of health and safety data, plaintiffs in several pending cases have argued that forced disclosure constitutes an unconstitutional taking of property without just compensation. While this argument


134 See note 122 supra.

135 See pp. 876–79 infra.

seems devoid of merit, at least one court has issued a preliminary injunction barring implementation of the 1978 amendments to the FIFRA pending resolution of the question.\(^\text{137}\) The current litigation raises two issues: (1) whether health and safety data submitted to the government pursuant to a licensing requirement is “property” within the meaning of the takings clause; and (2) whether government publication of such data constitutes a “taking” of the property.

1. Property. — While the issue is a fruitful subject for academic debate, it seems reasonable to conclude that proprietary information comes within the concept of property protected by the fifth amendment takings clause.\(^\text{138}\) In *Zotos International, Inc. v. Kennedy*,\(^\text{139}\) a federal district court held that the identity of the ingredients in Zotos’ cosmetics was property for purposes of due process protection.\(^\text{140}\) The FDA itself has apparently conceded that health and safety data are property.\(^\text{141}\)

2. Taking. — Assuming that health and safety data are property within the meaning of the takings clause, disclosure as a condition to receiving a license or registration nevertheless need not constitute an unconstitutional “taking.” In *Westinghouse Electric Corp. v. NRC*,\(^\text{142}\) Westinghouse challenged the Nuclear Regulatory Commission’s (NRC) rules governing the disclosure of proprietary information submitted during licensing and rulemaking proceedings. Under those rules,\(^\text{143}\) all information submitted in hearings was to be placed in a public file.\(^\text{144}\) The Third Circuit dismissed as “fanciful” Westinghouse’s claim that this scheme ran afoul of the takings clause.\(^\text{145}\) Stressing that license applicants are under no compulsion whatsoever to submit data to the agency, the court ruled that “[a] voluntary submission of information by an applicant seeking the economic advantages of a license can hardly be called a taking.”\(^\text{146}\) Like the petitioner in *Westing-


\(^{\text{138}}\) Trade secrets, like other business intangibles, fit well within the traditional Benthamite bundle of property rights with only one important exception: the right of the owner of a trade secret is never exclusive. The secret may always be discovered independently and used.


\(^{\text{140}}\) The court focused mainly upon the inadequacy of the notice that the FDA gave to Zotos of the basis for its conclusions prior to making a final decision. *Id.* at 278.


\(^{\text{142}}\) 555 F.2d 82 (3d Cir. 1977).


\(^{\text{144}}\) *Id.* § 2.790(a).

\(^{\text{145}}\) 555 F.2d at 95.

\(^{\text{146}}\) *Id.*
house, one who submits health and safety studies to the EPA or the FDA has a choice between maintaining the confidentiality of the information and obtaining a license or registration. Forcing the submitter to make that choice can hardly be called a taking.\textsuperscript{147}

Forced disclosure should survive a takings claim as a reasonable regulation of interstate commerce, analogous to a state's exercise of the "police power."\textsuperscript{148} The widely used balancing test which weighs the public benefit against the private harm,\textsuperscript{149} suggests that government publication of health and safety studies is constitutional. Even when disclosed, health and safety data still have a substantial residuum of value to the data producer.\textsuperscript{150} Most important, they allow access to the market, which is something the innovator did not have prior to producing the data and which is the reason for developing the data in the first place. The fact that the data are also available to competitors for the same purposes does not eliminate their value to the data producer. A statute requiring disclosure of health and safety data results in only a partial diminution in their legitimate value.

On the other side of the balance are the public interests in greater competition, in avoiding duplicative research, in monitoring and participating in regulatory decisions, and in making informed decisions in the marketplace.\textsuperscript{151} These are powerful

\begin{footnotes}
\item[147] An analogy to the well-established eminent domain law principle that government action can constitutionally take away value that it has created in the first instance, see, e.g., United States v. Fuller, 405 U.S. 488, 492 (1973); United States v. Cors, 337 U.S. 325, 334 (1949); Reichelderfer v. Quinn, 287 U.S. 315, 319 (1932), may be helpful. The property interest for which pesticide and drug companies claim compensation exists only because of a government-imposed barrier to entry into the market. Their claim that disclosure would deprive them of a commercial advantage depends entirely upon the fact that the government requires the data as a precondition to issuing a license. Thus, to the extent that a data submitter has any "property" interest as a result of this barrier to entry, it is "property" given by the government and hence no compensation need be paid upon disclosure.


\item[150] The Supreme Court relied partly on the substantial residuum of value left to the claimant in Penn Cent. Transp. Co. v. New York City, 438 U.S. 104, 136 (1978), holding that no "taking" occurred where the Penn Central was denied application to erect an office tower above Grand Central Station, a designated "landmark site." See also Andrus v. Allard, 100 S. Ct. 318, 326-28 (1979) (regulations prohibiting the sale of eagle feathers upheld since economic benefit of their possession not destroyed).

\item[151] See pp. 840-48 supra.
\end{footnotes}
public interests, going directly to the health, safety, and welfare interests underlying police power regulations. When weighed against the limited diminution in value, these interests tip the balance decisively in favor of constitutional legitimacy. The courts, not surprisingly, have agreed with this analysis in other contexts.\textsuperscript{152} A disclosure model reflecting a governmental determination that the public interest in disclosure outweighs any resulting competitive harm should be afforded considerable judicial deference under traditional commerce clause and police power analysis.\textsuperscript{153}

\section*{D. Specific Regulatory Policies}

Despite the fact that the question of disclosure versus non-disclosure of health and safety testing data implicates similar public policy considerations across several areas of regulation, very different regulatory responses have emerged in the several product areas. With respect to drug licensing, the harsh effects of a general "no disclosure" rule are mitigated only by the release of summaries and the use of outside advisory committees.\textsuperscript{154} In sharp contrast, information pertaining to the safety of antibiotics and food and color additives is routinely disclosed.\textsuperscript{155} Testing data for pesticides and toxic substances are also disclosed, but special compensatory devices have been fashioned for the original developer of such information.\textsuperscript{156} No principled reason is evident for such disparate treatment of essentially the same problem. This Section analyzes each of these systems, revealing that the use of the common law definition of trade secret creates several problems, and that administrative difficulties threaten the viability of any comprehensive solution to the present confusion.

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\item \textsuperscript{152} It is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its police power and in promotion of fair dealing, to require that the nature of the product be fairly set forth. Corn Prods. Refining Co. v. Eddy, 249 U.S. 427, 431–32 (1919); see, \textit{e.g.}, National Fertilizer Ass'n v. Bradley, 301 U.S. 178 (1937); Savage v. Jones, 225 U.S. 501, 524–25 (1912); Speert v. Morgenthau, 116 F.2d 301, 305 (D.C. Cir. 1940).
\item \textsuperscript{153} See generally L. TRIBE, \textit{AMERICAN CONSTITUTIONAL LAW} § 5–6, at 238 (1978) (broad protective scope of commerce power regulation; judicial review "largely a formality"); \textit{cf.} 4 R. ANDERSON, \textit{supra} note 148, § 25.26 (presumption of regularity of zoning decision pursuant to police power); G. GUNTHER, \textit{CASES AND MATERIALS ON CONSTITUTIONAL LAW} 191–94 (9th ed. 1975) (broad federal commerce power authority to regulate economic problems).
\item \textsuperscript{154} See pp. 868–72 infra.
\item \textsuperscript{155} See pp. 872–73 infra.
\item \textsuperscript{156} See pp. 873–76 infra.
\end{itemize}
\end{footnotesize}
Drugs. — Before a drug may be shipped in interstate commerce, its safety and effectiveness must be established by scientific experimentation. The FDA has taken the position that health and safety testing data supporting the approval of a new drug cannot generally be released to the public. The FDA applies the Restatement definition of trade secret to conclude that such health and safety testing data fall within the Food, Drug and Cosmetic Act's prohibition against "revealing . . . any information acquired under [this chapter] . . . concerning any method or process which as a trade secret is entitled to protection." FDA reasoning on the application of the Restatement definition is straightforward. A New Drug Application (NDA) "is personal to the manufacturer who files it." Therefore, a follow-on applicant may not rely on undisclosed information in an approved NDA in support of licensing even the identical drug. But, the FDA finds nothing in the regulatory scheme which would prevent it from accepting publicly disclosed health and safety data of a prior applicant in the NDA of a follow-on applicant. The FDA concludes that such information, if undisclosed, provides the developing company with significant cost and lead-time advantages over competitors and hence is a trade secret under the Restatement definition. The FDA's failure to consider any public policy interests in

157 21 U.S.C. § 355 (1976). The applicant submits the animal testing information, as well as other information, to the FDA in the form of a Claimed Investigational Exemption for a New Drug (IND) and may then ship the drug interstate for human testing if the FDA does not object within 30 days. 21 C.F.R. § 312.1(a) (1979). The human data is submitted to the FDA in the form of a New Drug Application (NDA). Id. § 314.1. For a description of the nature and organization of the human testing, see J. Gibson, Medication, Law and Behavior 124-45 (1976); Fines, A Primer on New Drug Development, FDA Consumer, Feb. 1974, at 12.


162 Id.

163 Id. at 44,612, 44,634; see p. 862 supra. The FDA was influenced in its choice of definitions by the fact that the Supreme Court, in holding that state statutes making it a crime to steal trade secrets were not preempted by federal patent laws, noted that the Restatement definition was widely relied upon. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 474 (1974); cf. Aronson v. Quick Point Pencil Co., 440 U.S. 257 (1979) (federal patent law held not to preempt state contract law). Although the Court used the Restatement definition solely for the purpose of defining the scope of the common law tort in the state of Ohio, the FDA could "find no reason why it should be utilized for determining commercial damages but not for purposes of the Freedom of Information Act." 39 Fed. Reg. 44,612 (1974).
favor of disclosure exemplifies the fallacy of applying the Restatement definition in the regulatory context.\(^{164}\)

This restrictive approach has led to pressure for greater disclosure. For example, the plaintiffs in *Johnson v. HEW*\(^{165}\) are seeking to compel the agency to disclose the animal testing data filed by Smith, Kline & French in behalf of their drug Tagamet. The fact that the drug is patented, the plaintiffs argue, makes it impossible to prove a "likelihood of substantial competitive injury" should the testing data be released.\(^{166}\) The intervening drug company contends that even when a drug is patented, it would still suffer competitive harm if the information were released, since competitors could use the information to license substitutes after the patent expired and to license the product immediately in foreign markets where United States patents are not recognized.\(^{167}\) The court has not yet resolved this issue.\(^{168}\)

Although drug safety and health testing data are not generally disclosed in full, the drug regulatory scheme does attempt to accommodate the policies underlying the pro- and antidisclosure arguments. The fact that follow-on manufacturers cannot rely on undisclosed testing data of competitors helps maintain research incentives by protecting an innovator's headstart and investment in testing. On the other side of the balance, the FDA does release summaries of data in order to inform the public of the basis for approving a new drug\(^{169}\) and employs outside consultants to improve agency effectiveness.

The FDA believes that it may make summaries public even

\(^{164}\) See p. 863 *supra*.


\(^{166}\) Id. at 337. Such a showing must be made if the information is to be covered by the trade secret exemption in the FOIA, 5 U.S.C. § 552(b)(4) (1976). National Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974).

\(^{167}\) 462 F. Supp. at 337.

\(^{168}\) The court held that the existence of a patent did not, as a matter of law, make the trade secret exemption unavailable, and ordered further proceedings. Id. at 338.


The FDA also decided not to protect testing information in two other limited circumstances. If the information had previously been lawfully disclosed to persons not within certain categories, the FDA will consider it available for public disclosure. 21 C.F.R. § 314.14(e)(1) (1979). The FDA reasons that secrecy is the essence of the definition of "trade secret." See Carson Prods. Co. v. Califano, 594 F.2d 453, 461-62 (5th Cir. 1979). Additionally, except in extraordinary circumstances, where the new drug application has been abandoned, disapproved, or declared unnecessary, the FDA will no longer protect the information. 21 C.F.R. § 314.14(f)(1)-(3); see 39 Fed. Reg. 44,637 (1974). FDA reasons that if the information will not support an NDA, it is of no commercial value to competitors.
where they contain some reference to testing information since an innovator can suffer no real competitive harm from the release of fragmented and limited data.\textsuperscript{170} This view has, however, been challenged in \textit{Syntex Corp. v. Califano}.\textsuperscript{171} The plaintiffs in that case are seeking to prevent the release of a report by FDA investigators which contains excerpts of the testing data submitted by the firm. The report examined the possibility that the FDA had approved a Syntex drug on the basis of fraudulent animal testing information.\textsuperscript{172} The company argued that although the information is in summary form, the report would reveal much of its testing data and thus have some intelligence value to competitors.\textsuperscript{173} The court refused to grant summary judgment for the FDA on the question of trade secrecy and ordered the matter to trial to determine if even the summary portions of the testing data could be released.\textsuperscript{174}

Even if their use survives legal challenge, "summaries" are hardly a replacement for the complete disclosure of testing information.\textsuperscript{175} The necessary selectivity of such conclusory summaries precludes normal peer review since the reviewer is unable to examine all of the data used.\textsuperscript{176} The FDA apparently agrees that summaries are insufficient substitutes for actual data, since it has asked Congress to authorize the release of all testing information.\textsuperscript{177} It also encourages its own advisory committees to evaluate the raw experimental data instead of relying on summaries\textsuperscript{178} and requires for its own approval process the use of "full reports" which include the raw experimentation data.\textsuperscript{179} If the FDA needs "full reports" to determine the sufficiency of the experiments undertaken, any mean-

\textsuperscript{171} [1978-1979 Transfer Binder] \textit{Food Drug Cos. L. Rep. (CCH) \(\dagger\) 38,221 (D.D.C. 1979)}.
\textsuperscript{172} \textit{Id.} at 38,897.
\textsuperscript{173} \textit{Id.} at 38,898.
\textsuperscript{174} \textit{Id.} at 38,899.
\textsuperscript{175} However, some officials in the pharmaceutical industry and some independent scientists believe that the summaries largely obviate the need to disclose testing information. \textit{See Senate Hearings on Drug Regulation Reform, supra} note 17, at 293 (statement of C. Joseph Stetler, President, Pharmaceutical Mfrs. Ass'n); \textit{id.} at 674 (statement of Robert B. Clark, President, Hoffmann-La Roche, Inc.); \textit{id.} at 767 (statement of Louis Lasagna, M.D.).
\textsuperscript{176} \textit{See Peer Review, supra} note 10, at 18–19; \textit{Kennedy Letter, supra} note 10, at 845.
\textsuperscript{177} \textit{See, e.g., Kennedy Letter, supra} note 10, at 847–47.
\textsuperscript{178} \textit{See Food & Drug Administration, Commissioner's Report of Investigation of Charges} 750 (1975).
\textsuperscript{179} 21 C.F.R. § 314.11(c)(2) (1979).
ingful independent scientific review would need to be based on information of the same scope.

To augment further its expertise and ease agency isolation, the FDA heavily relies on outside medical consultants organized into standing advisory committees. The pharmaceutical industry believes that the success of this system obviates the need to disclose testing data. While undoubtedly their use has served the FDA well, advisory committees are imperfect substitutes for open peer review. Although the Advisory Committee Act specifically provides that committees should represent balanced viewpoints, a recent study has found that most consultants are appointed at the suggestion of present members, resulting in an "old boy" network. Additionally, committees usually review only limited aspects of the research submitted; hence, they can only affect a limited portion of the FDA's responsibilities.

Finally, advisory committees are constrained by trade secret law in the same manner as the FDA. If the advisory committee deliberations involve proprietary information, the meeting must be closed and committee members may not discuss the data with outsiders. This impedes effective peer review of the committees, reduces the intellectual attrac-

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181 Senate Hearings on Drug Regulation Reform, supra note 17, at 674 (statement of Robert B. Clark, President, Hoffmann-La Roche, Inc.); id. at 682 (statement of Richard M. Furlaud, Chairman & Chief Executive Officer, Squibb Corp.); House Hearings on Drug Regulation Reform, supra note 10, at 1984 (statement of C. Joseph Stetler, President, Pharmaceutical Mfrs. Ass'n).


183 USE OF STANDING ADVISORY COMMITTEES, supra note 180, at 41–42, 44–45; see Peer Review, supra note 10, at 19. One government committee warns:

The "old boy network" is not without its advantages . . . . On the other hand . . . [i]t's chief danger is that it tends to become a self-perpetuating system for insiders, from which important segments of the scientific (or other) community may be excluded, and may result in decisions that are one sided and parochial.

USE OF STANDING ADVISORY COMMITTEES, supra note 180, at 45.


The FDA has established a system of priorities to determine which parts of its activities will be reviewed by its advisory committees. 21 C.F.R. § 14.171(a)–(c) (1979). Past experience has indicated that the committees spend almost all of their time reviewing selected NDA's and human (clinical) drug testing guidelines with little or no review of animal test results (investigational new drug notice files). USE OF STANDING ADVISORY COMMITTEES, supra note 180, at 22–25.


186 Without such peer review, some scientists believe that the advisory committee structure may not produce acceptable advice. See Peer Review, supra note 10, at 19.
tiveness of the job, and prevents advisory committee members from publicly defending their conclusions.

2. Antibiotics and Additives. — An antibiotic or a food or color additive is subject to seizure by the FDA unless it is marketed pursuant to an agency regulation stating the conditions of its manufacture and use. Such regulations are issued upon proof that an additive is safe or that an antibiotic is safe and effective for the uses for which it is intended. Normally, the applicant submits animal tests for both types of products and human tests for antibiotics. Once the regulation is approved for antibiotics or a regulation is proposed for additives, in the absence of extraordinary circumstances, the FDA releases almost all of this test data.

The FDA's disclosure of the test data may be subject to

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187 See p. 842 supra.
188 See p. 844 supra.
189 An "antibiotic drug" is "any drug intended for use by man, containing . . . a substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance)." 21 U.S.C. § 357(a) (1976).
190 A "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." Id. § 321(g). See generally Lehmann, More Than You Ever Thought You Would Know About Food Additives (pt. 1), FDA CONSUMER, Apr. 1974, at 10; Sunshine, Regulatory Aspects of Food Additives — Yesterday, Today and Tomorrow, 31 FOOD DRUG COSM. L.J. 264 (1976).
191 A "color additive" is any material which when added to a food, drug, or cosmetic, or to the human body, is capable of imparting color thereto. 21 U.S.C. § 321(t)(1) (1976).
192 See id. § 334(a) (general seizure authority); id. § 357(b) and 21 C.F.R. §§ 431.1-20 (1979) (for antibiotics); 21 U.S.C. § 348(c)(1) (1976) and 21 C.F.R. § 170.10 (1979) (for food additives); 21 U.S.C. § 376(b) (1976) and 21 C.F.R. § 171.20 (1979) (for color additives).
195 21 C.F.R. § 430.20(b)(6) (1979) (antibiotics); id. § 171.1(c) (food additives); id. § 71.1(c) (color additives).
196 Id. § 430.20(b)(6)(ii).
197 Id. § 431.71(e)-(f) (antibiotics); id. § 171.1(h) (food additives); id. § 71.15(a)-(b) (color additives). See also 39 Fed. Reg. 44,602, 44,631-32 (1974).
challenge. Since the issuance of a regulation allows a competitor to market an identical product without duplicating the original testing data, the FDA believes that the data have no value to others and therefore lack any proprietary value.\textsuperscript{198} But this conclusion ignores the fact that test data may be valuable to competitors seeking regulatory permission to sell the product for additional uses.\textsuperscript{199} The FDA's position may thus be legally vulnerable because under the \textit{Restatement} definition of trade secrets, to which the agency generally adheres, information only need be of "some" commercial value to be considered proprietary.\textsuperscript{200}

While the FDA's interest in promoting disclosure is commendable, its position may be reversed by the courts. Even if permitted to stand, the regulatory schema for antibiotics and additives may provide no real protection for research incentives apart from that offered by patents and market imperfections. To the extent that these provide incomplete protection, the pace of innovation may be undesirably slowed.\textsuperscript{201}

3. \textit{Pesticides and Toxic Substances.} — The FIFRA, as amended, and TSCA share a common approach to the health and safety data confidentiality problem that distinguishes them from the statutes that the FDA administers. Rather than leave the confidentiality question to the relevant agency, the EPA, Congress attempted in both statutes to make health and safety data available to the public and to protect the original innovator by either forcing those who rely upon a registrant's data to compensate the data producer for its use or preventing such use for a fixed period of years. After briefly describing the applicable statutes, this subsection will focus on the compensated disclosure idea.

Under the FIFRA, as amended,\textsuperscript{202} any manufacturer of a chemical that may be used to control any pest must obtain a registration for that product from the EPA.\textsuperscript{203} Applicants for

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\item \textsuperscript{198} 39 Fed. Reg. 44,602, 44,632 (1974).
\item \textsuperscript{199} Since an additive will often be approved for a limited purpose, such as use in a particular food, the testing data may be valuable to others who seek approval of the additive for other uses. \textit{See} Sunshine, \textit{Food Company Concerns and Opportunities — How We Will Cope}, 30 \textit{FOOD DRUG COSM. L.J.} 345, 347 (1975). However, the industry has not attacked the disclosure scheme, in part because it has been the normal practice of the relevant industries to disclose the information in scientific journals, or to customers or other scientists. 39 Fed. Reg. 44,602, 44,632 (1974).
\item \textsuperscript{200} \textit{See} p. 862 \textit{supra}.
\item \textsuperscript{201} \textit{See} pp. 850–51 \textit{supra}.
\item \textsuperscript{202} 7 \textit{U.S.C.A.} \textsection{} 136 (West Supp. 1979).
\item \textsuperscript{203} In order to register a pesticide product, a manufacturer or formulator must demonstrate that:
\begin{itemize}
\item (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other material required to be submitted comply with [FIFRA];
\end{itemize}
\end{itemize}
a new registration must provide, inter alia, comprehensive animal studies designed to ascertain the probable effects of the pesticide upon humans. Moreover, if at any time after registration, the EPA has reason to believe that the studies available to it do not adequately support the prior regulatory approval, it may require the registrant to produce additional "defensive" data. The TSCA grants the Administrator of the EPA power to order testing of any chemical substance or mixture of substances if he or she finds that the chemical may present an unreasonable risk of injury to health or the environment, that insufficient data exist to predict the health effects of the chemical, and that testing is necessary to develop such data.

(a) Overview: Compensated Disclosure. — Both the TSCA and the FIFRA as amended specifically exempt health and safety studies from the protections otherwise afforded to proprietary information. This type of provision falls squarely

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(C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

Id. § 136a(c)(5).

204 See 43 Fed. Reg. 37,336 (1978) (to be codified at 40 C.F.R. § 163.80-.86). In addition to these requirements, the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301–392 (1976), provides that raw agricultural commodities that are contaminated with pesticide residues shall be deemed adulterated (and therefore subject to seizure) unless the EPA has prescribed a tolerance for that pesticide and the residue is within the limits of that tolerance. Id. § 346(a). Registrants of pesticides that will be applied to farm crops must therefore submit a petition for a tolerance to the EPA with accompanying health and safety studies. Interestingly, the pesticide tolerance section of the FFDCA is not included in that statute's prohibition against the release of trade secrets. Id. § 331(j). Thus, while data to support pesticide registrations is subject to the FIFRA's explicit trade secret prohibition, the same data, when used to support a tolerance is only subject to the general prohibition of the Trade Secrets Act, 18 U.S.C. § 1950 (1976).


206 15 U.S.C. § 2603(a) (1976). The Administrator must promulgate the testing requirement by rule. The rule must include the identification of the substance to be tested and standards for the development of test data. Interested persons must be given an opportunity to comment upon the rule, including an opportunity to present testimony orally. Id. § 2603(b)(i), (g).

Reporting requirements are another source of information on the health effects of chemicals subject to the Act. The Administrator must promulgate rules requiring manufacturers to submit lists of health and safety studies conducted by them, known to them, or reasonably ascertainable by them. Id. § 2607(d).

207 Id. § 2613(b); 7 U.S.C.A. § 136h(d)(1) (West Supp. 1979) (FIFRA).

The term health and safety study means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical and ecological studies.
within the "except as otherwise provided by law" proviso of the Trade Secrets Act and therefore satisfies Chrysler. Both statutes obviate the need for duplicative testing; the TSCA excuses a company from testing a chemical if such would be duplicative of other tests already performed or in the process of being performed and the FIFRA generally permits competing registrants to rely upon data already in EPA's files. However, both statutes do provide significant protections for innovators. Under the TSCA, a manufacturer may seek reimbursement from other companies that use its test results to gain an exemption from testing within five years of submission of those results. If the parties cannot agree upon adequate compensation, the EPA Administrator must determine a "fair and equitable" reimbursement. Under the 1978 FIFRA amendments, a complex scheme permits later registrants and the public to use the data of initial registrants: (1) Later registrants may use data submitted prior to 1970, without compensation to or permission from the originating party. (2) Data submitted after January 1, 1970 in support of pesticides containing active ingredients registered prior to the effective date of the 1978 FIFRA amendments may be used without compensation only after fifteen years from the date that the data are submitted. For use before that time, the later registrant must pay compensation as agreed between the parties or, if no such agreement can be reached, as determined by an arbitrator appointed by the Federal Mediation and Conciliation Service, whose decision will be subject to appeal only for fraud, misrepresentation or other misconduct. (3) Data submitted in support of pesticides containing active ingredients that are initially registered after 1978 may be used only after the ten years of exclusive use, the later registrant must compensate the data producer for fifteen years from the submission of the data in accordance with sentence (2) above. In cases where the EPA orders data to be produced


208 See p. 858 & note 107 supra.

209 See p. 860 supra.


213 Id. § 2603(c)(4)(A).

to maintain an existing registration, existing registrants must share in the costs of producing the data or face cancellation of their registration.\footnote{\textit{Id.} \textsection 126a(c)(2)(B).} Disputes over the proportion of costs attributable to each registration are to be resolved by arbitration.\footnote{\textit{Id.} \textsection 126a(c)(2)(B)(ii).}

In enacting both the TSCA and the 1978 FIFRA amendments, Congress balanced the public interest in disclosing health and safety data against the public interest in the innovation that would result from keeping them secret and defined "proprietary information" to exclude all health and safety data. These Acts, however, have raised major administrative problems which threaten their viability.

\textit{(b) Problems with Compensated Disclosure.} — The TSCA and the FIFRA, as amended, mandate disclosure while requiring reimbursement for the costs of health and safety studies. However, exactly what falls within the rubric "health and safety study" is unclear. The TSCA, for example, prevents disclosure to the extent that manufacturing processes would be revealed,\footnote{15 U.S.C. \textsection 2613(b)(1)(A) (1976).} but the scope of the exception may be the subject of future litigation. Substantive and administrative problems also plague the computation of compensation awards. The following subsections will address these difficulties and search for solutions.

\textit{(i) Scope of "Health and Safety Study."} — The principle problem in determining the scope of "health and safety study" has arisen with respect to the question whether the identity of a tested chemical must be disclosed as part of a health and safety study. This question is unique to the TSCA, because the identities of marketed products such as pesticides, food additives, drugs, and most chemicals are generally easily ascertained through chemical analysis. The TSCA, however, can require health and safety studies to be performed for chemicals such as catalysts that may never enter the stream of commerce.\footnote{See Eastman Kodak Co., Comments on Proposed Premanufacture Notification Requirements and Review Procedures 16–17 (Mar. 23, 1979).}

Environmental groups argue that the TSCA's legislative history strongly supports an interpretation of "health and safety study" that would include chemical identity.\footnote{See Premanufacture Notification Requirements and Review Procedures, 44} More-

\begin{footnotesize}
\footnote{\textit{Id.} \textsection 136a(c)(2)(B).}
\footnote{\textit{Id.} \textsection 136a(c)(2)(B)(iii).}
\footnote{See Premanufacture Notification Requirements and Review Procedures 16–17 (Mar. 23, 1979).}
\end{footnotesize}
over, they argue that the nondisclosure of chemical identity prevents independent scientists from conducting additional tests comparing the tested chemical to others whose toxicological effects are better known, and searching the scientific literature for assistance.\textsuperscript{220}

Industry representatives deny these allegations, noting that it is standard practice to test a substance "blind" (without any knowledge of its chemical identity).\textsuperscript{221} They also doubt that environmental groups or independent scientists will perform additional tests on very many products.\textsuperscript{222} Confidential manufacturing processes frequently can be deduced from knowledge of the chemical structure of a substance\textsuperscript{223} and the knowledge of the mere existence of a chemical can be an important commercial advantage to competitors.\textsuperscript{224} For example, a company might manufacture a chemical and then stockpile it for several years to preserve its option to market it at an economically propitious time. Revealing even the fact that a particular company is manufacturing a particular chemical could destroy this marketing advantage.\textsuperscript{225}

A proposed EPA solution that would mask the chemical identity until production begins\textsuperscript{226} provides an appropriate resolution for the vast majority of chemicals. This would protect a company's headstart while providing interested parties with the chemical identity at the time that full-scale manufacturing begins so that they may evaluate the studies and begin environmental and workplace monitoring. Once production begins, the public interest in knowing the identity of chemicals to which it is being exposed probably outweighs whatever

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\item See Letter from James T. O'Reilly, Proctor and Gamble Co., to Blake A. Biles at 4 (July 15, 1978). One company has even offered to make samples available to bona fide public interest groups for testing. See Lubrizol Corp., supra note 221, at 94-95.
\item See U.S. Dep't of Commerce, Comments on Proposed Premanufacture Notification Requirements and Review Products 11 (Mar. 26, 1979) [hereinafter cited as Commerce Department Comments].
\item See Lubrizol Corp., supra note 221.
\end{enumerate}
\end{footnotesize}
marketing advantages are lost through revealing chemical identities with health and safety studies, especially since competitors can in most cases analyze a product to determine the unrevealed identities of chemicals contained therein.\textsuperscript{227}

For a small minority of chemicals, however, the EPA's proposed rules could cause hardship. Some companies use chemicals in undetectable forms or quantities in certain products. While the amount of chemical used is small, it can perform an exceedingly important role in the marketability of the final product.\textsuperscript{228} Other companies use some chemicals only as intermediates or catalysts within the confines of the company; these chemicals never become available to competitors for analysis.\textsuperscript{229} Disclosure of such chemical identities could cause great economic harm to an innovating company without providing appreciable benefits to the public at large. One solution might be to reveal chemical identity for these substances only to bona fide market and public interest groups subject to enforceable protective orders. This, however, would require the agency to draw difficult distinctions between bona fide and non-bona fide groups. Alternatively, the EPA could specify some minimum amount of product below which generic chemical identification would be possible. Small amounts of a chemical should result in very little exposure to nonworkers, and workers' safety can be protected by informing them of the properties of the generically named chemical and labelling that chemical generically in the workplace. A "small quantities" exception would require labor and public interest groups to trust the EPA to make adequate evaluations of the studies for those chemicals subject to the exception. It would also require the EPA to spend time addressing claims that particular chemicals fell within the exception. On the whole, however, these disadvantages seem small in comparison to the potential loss of incentives to invest in the development of such chemicals that might otherwise result. Unfortunately, because the TSCA relies on a broad definition of "health and safety study,"\textsuperscript{230} the agency is probably precluded from administratively promulgating a "small quantities" exception. Ultimately, Congress may have to resolve this question.

Apart from the question of chemical identities, there is

\textsuperscript{227} See Commerce Department Comments, supra note 223, at 11.

\textsuperscript{228} Examples of this problem include perfumes in consumer products and trace chemicals in photographic supplies. See Proctor and Gamble Co., Comments on Proposed Premanufacture Notification Requirements and Review Procedures (Mar. 26, 1979); Eastman Kodak Co., supra note 218, at 16-17.

\textsuperscript{229} See Eastman Kodak Co., supra note 218, at 17.

\textsuperscript{230} See p. 839 supra.
another problem associated with the scope of "health and safety study." Neither the TSCA, nor the FIFRA, as amended, specifies who has the burden of "sanitizing" new and existing health and safety reports that may include information that does not come within the definition of "health and safety study" and is legitimately considered proprietary. Agency employees will understandably be reluctant to send full copies of health and safety reports to data requesters if doing so might run afoul of the Trade Secrets Act\footnote{18 U.S.C. § 1905 (1976).} or a similar proscription in the agency's own statute.\footnote{See, e.g., 7 U.S.C.A. § 136h(f) (West Supp. 1979) (FIFRA).} But the agency is equally reluctant to scour each of the hundreds of pages in the reports for possible proprietary information. The EPA has attempted to solve this dilemma by requiring the original data submitter to mark clearly all portions of health and safety studies that it considers proprietary.\footnote{44 Fed. Reg. 59,764, 59,773-77 (1979); 45 Fed. Reg. 59,050, 59,061-62 (1978).} While this approach may place some outer bounds on the data that the agency will not disclose, unless data producers modify their recently adopted practice of stamping every page of health and safety data "trade secret," the EPA will still have to monitor industry claims. Under the TSCA, the EPA intends to require the data submitter to substantiate any trade secrecy claims at the time it submits the data.\footnote{44 Fed. Reg. 59,764, 59,773-77 (1979).} The difference between the two monitoring approaches is reflected in the fact that the EPA currently has hundreds of thousands of unsanitized health and safety studies for pesticides while its TSCA files are presently empty.

The fact that all confidentiality determinations are subject to judicial review makes the TSCA approach the preferred one. Under that approach, confidentiality litigation will begin before humans and the environment are exposed to the chemical. Under the FIFRA approach, persons are likely to request data only after the product has been on the market for some time. At this point, the delay of litigation will operate in favor of the manufacturer who asserted the secrecy claim. The longer it can litigate about whether data should be released to environmental groups, the longer it will be before those groups have the opportunity to petition the agency to take the product off the market. The TSCA approach will initially be more burdensome to the agency, because it will require agency employees to resolve some confidentiality claims that might not otherwise be questioned and may encourage unnecessary litigation. However, once the agency and the courts have decided
a few early cases, the TSCA approach should have the salutary
effect of encouraging data submitters to make realistic claims
at the outset. In addition, harsh penalties for bad faith assertion
of trade secrecy protection could help prevent abuses.

(ii) Measuring and Apportioning Compensation. — While
the idea of requiring follow-on manufacturers to compensate
the original innovator for its testing costs is an appealing
solution to the disclosure problem, fashioning a workable com-
ensation scheme presents severe practical difficulties. Since
the TSCA and the FIFRA seek to allocate a portion of the actual costs of producing the data, they fail to compensate
the original submitter for its lost monopoly profits. Hence,
the protection for research incentives is incomplete in compar-
ison to that provided by forcing later applicants to reproduce
health and safety tests. But a cost system is more practical
than other candidates. A “fair market value” approach to
measuring compensation is a highly abstract test in the data compensation context where there are no relevant markets that
the decisionmaker may use for comparison. The “cost of pro-
duction” test at least has the advantage of being reasonably ascertainable; the fair market value test has no moorings. A
“reasonable royalty” test is also fraught with problems. This
approach, commonly used for setting damages in patent in-
fringement cases, sets compensation at the level “which a licensee would be willing to pay and still make a reasonable
profit out of use of the patented article.” Like the market
value approach, the reasonable royalty test could lead to long

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236 The FIFRA is somewhat unclear. It requires the follow-on applicant to make an offer “to compensate the original data submitter.” 7 U.S.C.A. § 136a(c)(1)(D) (West Supp. 1979). Conceivably, this language would authorize an award not limited to cost. However, another provision states that “defensive data” produced at the request of the Administrator after a pesticide is registered may be used by any current registrant, but only on the condition that it agree to pay a portion of the cost of producing the data. Id. § 136l(c)(2)(B). This suggests that Congress meant for data compensation in general to include only the cost of producing the data.

237 Note that the discussion here concerns only those chemicals that are unpatent-
able or that have expired patents.

238 If incentives suffer, a “cost plus a fixed percentage” system could be used. Such a system would not hurt the practicality of a cost-based system.


and difficult compensation proceedings that would necessarily have to be carried out on a case-by-case basis.\(^\text{241}\)

Even the cost of production test will involve some difficulties in determining and allocating costs. The FIFRA suggests no method for apportioning the costs of data production among users. The TSCA, however, directs the Administrator to consider, among other factors, "the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed."\(^\text{242}\) While apportionment according to market share may seem simple, the problems of determining the relevant market and assessing market shares can be formidable.\(^\text{243}\) The suggestion is also meaningless in the typical situation where the follow-on producer has not yet begun to manufacture the product and therefore has a market share of zero.\(^\text{244}\) In any event, in light of the wide discretion afforded the EPA under the TSCA, and the Federal Mediation and Conciliation Service under the FIFRA, few advance compensation agreements and much litigation and arbitration can be expected.

Another problem lies in determining what portion of an innovator's costs should be eligible for reimbursement. A follow-on applicant might legitimately argue that all of the data generated by the original applicant were not necessary to obtain the license. The EPA avoids having to resolve these sorts of disagreements under the FIFRA by requiring every follow-on applicant for a technical grade registration to cite all data in the EPA's files and to offer to compensate all of the producers of those data.\(^\text{245}\) In addition to the administrative


\(^{242}\) 15 U.S.C. § 2603(c)(3)(A) (1976). See also id. § 2604(b)(2)(B). The House Report indicates that the purpose for including these guidelines was to protect small businesses. H.R. REP. No. 94-1341, 94th Cong., 2d Sess. 21 (1976). Beyond this, Congress was willing to give the agency very little guidance. See id.


\(^{244}\) The EPA has recognized the possibility of assessing market share at the end of some predetermined period following testing and marketing. Id. at 54,287. This, of course, would delay the compensation of the data producer.

burden that would otherwise result, the EPA stresses that sound scientific decisions must be made on the basis of all of the information available to the decisionmaker.\textsuperscript{246} Compensated disclosure therefore imposes substantial transaction costs upon the parties and the agency. In implementing this approach, the agency should attempt to make the process function as smoothly as possible. The EPA could eliminate a great deal of future friction by promulgating guidelines for measuring and allocating compensation.\textsuperscript{247} It is interesting to note that many of the implementation problems are absent during the ten year exclusive use periods which the FIFRA applies to data submitted in support of pesticides containing active ingredients that are initially registered after 1978.\textsuperscript{248} This thought will be pursued in the next Part.

III. RECOMMENDATIONS FOR REFORM

In the context of the policy considerations presented in Part I, the specific schemes presented in Part II may be succinctly critiqued. Application of the common law definition of trade secrets has been unsatisfactory since it has resulted in nondisclosure of drug health and safety data without regard to the public policy interests in favor of disclosure, and because it has led to full disclosure of antibiotic and additive safety data where no other special protections for research incentives exist. Neither of these outcomes strikes any real balance between the reasons for disclosure and the need to retain incentives for innovation. The TSCA and the FIFRA, by excluding health and safety data from the ambit of proprietary information, permit development of a scheme specifically geared to health and safety testing data. The resulting pattern of compensated disclosure protects innovation incentives while at the same time permitting disclosure, but the costs of arriving at proper reimbursement awards may be substantial. These conclusions suggest the desirability of finding new methods of striking the balance.

\textsuperscript{246} See 1979 FIFRA Compensation Regulations, supra note 245, at 27,946.

\textsuperscript{247} The EPA has made public its intention to establish precisely such guidelines for the TSCA. See 44 Fed. Reg. 54,284 (1979) (to be codified at 40 C.F.R. § 774).

\textsuperscript{248} See p. 875 supra.
A. Recommended Congressional Action: Exclusive Use Periods and Full Disclosure

In enacting the TSCA and amending the FIFRA, Congress has implicitly recognized that disclosure is desirable and that the interests that would be protected by nondisclosure can be safeguarded by other means. This conclusion is supported by the FDA's failure to find any satisfactory substitute for the full disclosure of drug safety testing data. And even if the conclusion is wrong, the affected industries are better able to come forward with information supporting any request for increased protection than is the public to negate industry's claim.

Congress could require the disclosure of all health and safety testing data and protect innovation by increasing patent protection or directly subsidizing research. But extending patent protection poses special problems and additional direct funding may be of doubtful political feasibility. The exclusive use period mechanism suggested in the FIFRA points to the most attractive solution to the problem across all of the relevant fields. Under this approach, the health and

249 See pp. 869–72 supra.
250 See pp. 851–52 supra.
251 In the patent area, chemical and drug patents could be made easier to obtain and/or longer lasting. Federal encouragement could come by way of direct payment or tax incentives. Government subsidization of drug and pesticide research is already sizeable. For example, the National Cancer Institute's 1978 budget included $52.7 million for detection and diagnostic research. U.S. OFFICE OF MANAGEMENT & BUDGET, THE BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 1980, app., at 406 (1979). Also, the Division of Research Resources of the National Institute of Environmental Health Sciences in 1978 planned to spend $49.0 million for research at university-affiliated hospitals, $21.7 million for laboratory animal and primate related research, and $38.3 million for biomedical research. Id. app., at 416.
252 Congress may be reluctant to provide individual exceptions to the patent laws' general provisions, especially because it might affect treaty obligations. See Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583, T.I.A.S. No. 6923.
253 In the 1978 FIFRA Amendments, Congress gave the originator of an active pesticide ingredient a 10-year lead time during which its data could not be used by another company. However, Congress superimposed upon this a scheme that requires compensation for data used during the 15-year period following submission. See p. 875 supra. Since this combined approach is subject to all of the undesirable elements of the data compensation approach, it is less desirable than the pure lead time approach.
254 Such a "head start" is also finding increasing favor in common law trade secret cases. See, e.g., Analogic Corp. v. Data Translation, Inc., 371 Mass. 643, 647–49, 358 N.E.2d 804, 807–08 (1976); Carboline Co. v. Jarboe, 454 S.W.2d 549, 552–53 (Mo. 1970). See also Northern Petrochem. Co. v. Tomlinson, 484 F.2d 1057, 1061 n.5 (7th Cir. 1973).
safety data would be immediately available to the public, but competitors could not use the data to register competing products for a fixed period of time. While informing the public to the same extent as the FDA's full disclosure approach to food additives, the exclusive use period would place the data producer in almost the same position for a pre-determined period that it would occupy under the FDA's nondisclosure approach for drugs. The only detriment to the data producer stems from the "intelligence value" that the data may provide for competitors. Nevertheless, the producer's "headstart" will be very valuable and should provide protection for research incentives.

The exclusive use period approach has several advantages. First, it recognizes that the public interest in disclosure of health and safety data can only be served by actual disclosure. Second, the duration of the exclusive use period can be adjusted to ensure adequate research incentives. Third, it balances the relevant competing interests generically, thereby avoiding the transaction costs that inevitably accompany case-by-case determinations. Yet, it provides the flexibility to permit different exclusive use periods for different product categories (for example, drugs), if warranted by differential concerns for innovation.

The exclusive use period approach is not without its disadvantages, however. Since it relies on monopoly profits as an indirect stimulus to innovation, consumers will have to pay monopoly prices during the exclusive use period. However, prices will be tempered by the fact that competitors may duplicate the testing data in order to enter especially attractive markets. Second, because the use period is established generically, it is probable that some data submitters will receive too much of an advantage, while others not enough, than if a balance were struck on a case-by-case basis. Given the modest ability of economists to predict the incentive stimulating and competition enhancing effects of any particular regulatory action, this criticism of a generic approach, however, may well presume an accuracy for the case-by-case method that does not in fact exist. While the exclusive use period approach may not be the ideal solution to the balancing problem, it is probably the best solution that is not hopelessly quixotic.

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255 See pp. 872-73 supra.
256 See pp. 868-69 supra.
257 See p. 850 supra.
258 Another potential problem with the exclusive use period involves data required by the agency after the product has been on the market for some time, commonly called "defensive data." Strict application of the exclusive use period approach would
A more telling criticism of the exclusive use period approach is that it would permit duplicative testing of drugs, posing potential health hazards to those involved. This period could be minimized by giving the FDA authority to ban any duplicative testing that would endanger patients during the exclusive use period. After such a determination, the FDA should also be permitted to shorten the exclusive use period to reflect the increased barrier to entry.

It is certainly possible that the drug and chemical industries need long exclusive use periods. Yet since the information needed to support this conclusion is peculiarly within their control, the burden should be upon them to justify the necessity of any particular exclusive use period. To date, the wide ranging and unfocused congressional hearings on this subject, especially concerning pesticide and drug reform, have not yet actually called upon the companies to justify their contentions that the monopoly profits attributable to exclusive use of data are socially desirable. This is not to suggest that a congressional committee is incapable of conducting this sort of inquiry. However, it is likely that the industries will continue to avoid answering the crucial questions that make or break their case for monopoly profits if the only forum continues to be the congressional hearing. An independent commission, the General Accounting Office, or the Office of Technology Assessment might be more effective forums for gathering the necessary information. Alternatively, the FDA or the EPA might, pursuant to general grants of rulemaking authority, conduct such investigations. Whatever the locus of the investigation, it is important that the investigator have subpoena

give the first competitor to produce the required data a fresh exclusive use period. While this is an inefficient solution to the problem, it would be unfair to allow the remaining competitors to take a "free ride" on the data producer's work effort. The best solution to the defensive data problem is to force all licensees to agree before the research is started to share the costs of producing the data requested by the agency. If the licensees cannot agree how to proportion the costs among themselves, a pro-rata apportionment could be statutorily imposed.

259 See pp. 845-47 supra.
260 See pp. 851-52 supra. Whoever sets the exclusive use periods should consider (i) the extent of protection already afforded by the patent system; (2) how much extra consumers will pay because of the added anticompetitive effects of a given period of exclusive use for unpatented products; (3) how much of this additional profit will be channelled into research and development of new products; and (4) how many new products would likely result. Data bearing on these points would include current profit margins in competitive versus noncompetitive markets, current production levels in those markets, the percentage of current profits invested in R&D in the relevant industries, and historical comparisons between new products produced and dollars invested. It should be noted that these are the sorts of data that have been noticeably absent from congressional consideration of recent pesticide and drug reform packages.
power to verify for itself industry claims.\textsuperscript{261} Once the information is available, the duration of the exclusive use period necessary to strike the balance between innovation and competition could be determined by Congress, or, perhaps more efficiently, by the relevant agency pursuant to a congressional grant of authority. But until the crucial information becomes available, it is not likely that Congress or any other decision-maker will strike an adequate balance.

\textbf{B. Recommendations for Agency Action:}
\textit{The FDA Should Abandon the Restatement Definition}

The FDA is on record as having asked Congress to authorize the release of all drug testing information.\textsuperscript{262} If Congress does not act as recommended by the preceding section, the FDA may not be helpless. In light of the inappropriateness of the \textit{Restatement} definition of trade secrets in the regulatory context,\textsuperscript{263} the willingness of courts and Congress to adopt more restrictive definitions of "proprietary information,"\textsuperscript{264} and the lack of any definition of that phrase in the applicable drug regulation statutes,\textsuperscript{265} the FDA should abandon the \textit{Restatement} definition. In its place, the FDA should substitute a balancing test\textsuperscript{266} and proceed to weigh the interests for and against disclosure. The FDA's authority to promulgate such a regulation lies in its power to make regulations for the efficient enforcement of its statutory duties.\textsuperscript{267} As Part I demonstrated, unless the drug industry comes forward with very persuasive evidence of the need for protection, the rulemaking should conclude that all health and safety test data are not proprietary information and hence should be disclosed. Such action by the FDA would probably force the drug industry to

\textsuperscript{261} Recently, the FDA's Office of the Assistant Secretary for Planning and Evaluation was forced to abandon a study of the economic impact of various alternative trade secret policies on industry research incentives, partly because drug sponsors said they were unable to identify R&D expenditures in a manner that would have satisfied the study design. \textsc{Review Panel on New Drug Regulation, U.S. Dept of Health, Education & Welfare, Interim Report: An Evaluation of FDA's Trade Secrets and Freedom of Information Policies} 72 (1977).

\textsuperscript{262} See Kennedy Letter, \textit{supra} note 10, at 847–42.

\textsuperscript{263} See p. 863 \textit{supra}.

\textsuperscript{264} See pp. 863–64 \textit{supra}.

\textsuperscript{265} See p. 868 \textit{supra}.

\textsuperscript{266} This would require the FDA to abandon its position that action would more appropriately be left to Congress. See 39 Fed. Reg. 44,634 (1974).

\textsuperscript{267} 21 U.S.C. § 371(a) (1976); see 21 C.F.R. § 10.40 (1979). An agency may reverse a prior interpretation of a regulatory statute with an adequately documented conclusion that the former construction was inappropriate, erroneous, or contrary to the public welfare. See K. Davis, \textit{Administrative Law Text} § 17.07 (1972).
seek redress from Congress, if not the courts. This in turn might spur Congress to give drug health and safety testing data the scrutiny that it deserves. If the actions taken under the TSCA and the FIFRA are any indication of Congress’ pulse, Congress will take health and safety testing data out of the realm of proprietary information and establish special protections for innovation incentives. As noted in the previous Section, this would be desirable.

IV. CONCLUSION

The public has for too long been deprived of the information necessary to judge the performance of agencies involved with health and safety protection and to make informed individual health and safety decisions concerning drugs and pesticides. The industries that produce products posing possible health and safety threats to the public have been surprisingly successful in convincing or forcing regulatory agencies to protect health and safety data under an inappropriate definition of “proprietary information” that focuses exclusively upon competitive harm. Fortunately, Congress has intervened in the pesticide and toxic substance regulatory arenas to provide that health and safety data are not proprietary. To protect the incentives allegedly jeopardized by making health and safety data public, Congress provided a data compensation scheme that operates at great administrative cost. Especially in light of these costs, an exclusive use period approach would be preferable to the compensation approach.

Unfortunately, Congress has failed entirely to address the parallel, but much more serious problem of drug health and safety data. It would be desirable if the pharmaceutical industry, to eliminate the social waste and possible human injury associated with duplicative testing, would join the FDA in devising an acceptable solution — possibly along the lines of the exclusive use period approach advocated here. But if the industry continues its opposition to the FDA’s reform efforts, the FDA could possibly precipitate the needed congressional action by abandoning its nondisclosure approach and, by redefining “proprietary information,” adopt instead a full disclosure approach. This would force drug manufacturers to take their “lost innovation” claims directly to Congress, a result that is entirely appropriate, because manufacturers ought to bear the burden of demonstrating that the need for further innovation justifies monopoly profits.

Congress could react to drug company pressure in one of three ways. First, it could simply reverse the agency and
make it clear that health and safety data should receive absolute proprietary protection. The FIFRA experience, however, indicates that Congress is not likely to disregard the substantial policies favoring data release to secure the benefits of the possible innovation that may flow from further research. Second, Congress might do nothing and allow the public to suffer whatever deleterious effects might result from lost innovation. Congress, however, is not likely to adopt a posture of benign neglect in the face of drug industry protests that the “drug lag” is endangering the health of American patients, despite the present lack of substantial evidence that monopoly profits will reduce this lag.

The fairest and most practical option is the exclusive use period approach. Congress could ratify the FDA’s redefinition of “proprietary data” or, if the FDA proves unwilling to take the initial step, redefine the term itself so as to exclude health and safety data as it has recently done in the chemical and pesticide areas. Then, after an appropriate body has made a thorough investigation of the facts and has made reasonable predictions about the efficacy of barriers to entry in stimulating drug research, Congress or the agency pursuant to congressional authority could provide for a generic period of exclusive use that represents a balance between the need for innovation and the policies of encouraging competitive pricing and discouraging duplicative testing. In addition, Congress should give the FDA the authority to ban duplicative tests that endanger their human participants.

Congress has in the past studiously avoided resolving this continuing paradox in the American free enterprise system. No free enterprise economy can function properly unless consumers are informed. Yet consumers cannot become informed if industry-generated data on important aspects of products they consume remain secret; nor can competition produce an efficient marketplace when secrecy erects barriers to entry. On the other hand, competition and consumer sovereignty do not breed innovation. An innovator must be secure in the knowledge that he will reap the benefits of his efforts. Congress has moved to resolve these inherent contradictions in the toxic substance and pesticide areas. Congress should take parallel action with respect to drug regulation. FDA pressure, in the form of changing its antiquated approach toward proprietary information, could prove to be the necessary catalyst.