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FDA Disclosure of Safety and Efficacy Data: The Scope of Section 301(j)

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FDA DISCLOSURE OF SAFETY AND EFFICACY DATA: THE SCOPE OF SECTION 301(j)

INTRODUCTION

The Federal Food, Drug, and Cosmetic Act of 1938 (Act)[1] requires a drug manufacturer to submit safety and efficacy data on new drugs[2] to the Food and Drug Administration (FDA or Agency) before the drug can be introduced into interstate commerce.[3] Consumer groups[4] and drug manufacturers[5] attempt to acquire this data by requesting it under the Freedom of Information Act (FOIA).[6] Their reasons for requesting the data vary. Drug manufacturers seek to gain a competitive advantage from access to a competitor's safety and efficacy data, while practitioners and consumer groups wish to verify independently the drug's safety and effectiveness. Indeed, commentators and the FDA itself suggest that disclosure of safety and efficacy data would make the Agency more accessible to the public, thereby promoting public confidence in the drug approval process.[7]

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1. Ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-92 (1982)).

2. A "new drug" is defined as a drug whose composition is not generally recognized "as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling," or a drug whose composition has been so recognized as a result of investigations, but which has not "been used to a material extent or for a material time." 21 U.S.C. § 321(p) (1982). See *infra* notes 24-26 and accompanying text.

3. The Act provides that no person shall introduce into interstate commerce any new drug without premarket approval from the Secretary of Health and Human Services certifying that the drug is safe and effective for use. 21 U.S.C. § 355(a), (b) (1982). All delegable functions vested in the Secretary by the Act have been delegated to the Commissioner of Food and Drugs. 21 C.F.R. § 5.10(a)(1) (1983).

4. *See, e.g.*, Public Citizen Health Research Group v. FDA, 539 F. Supp. 1320, 1324 (D.D.C. 1982) (seeking disclosure of safety and efficacy data on medical devices), *aff'd in part, rev'd in part and remanded*, 704 F.2d 1280 (D.C. Cir. 1983); Johnson v. United States Dep't of Health, Educ. & Welfare, 462 F. Supp. 336, 336 (D.D.C. 1978) (seeking disclosure of raw animal test data); *cf.* Webb v. United States Dep't of Health & Human Servs., 696 F.2d 101, 103-04 (D.C. Cir. 1982) (private practitioner requesting data).

5. The FDA estimates that over 80% of its FOIA requests originate from business. *Business Record Exemption of the Freedom of Information Act: Hearings Before a Subcomm. of the House Comm. on Gov't Operations*, 95th Cong., 1st Sess. 93 (1977) (statement of Dr. Donald Kennedy, Comm'r, FDA) [hereinafter cited as *Business Record Hearings*]; *Freedom of Information Act: Hearings Before the Subcomm. on Admin. Practice and Procedure of the Senate Comm. on the Judiciary*, 95th Cong., 1st Sess. 4 (1977) (statement of Sherwin Gardner, Deputy Comm'r, FDA) [hereinafter cited as *FOIA Hearings*].

6. 5 U.S.C. § 552 (1982).

7. *See* Review Panel on New Drug Regulation, U. S. Dep't of Health, Educ. & Welfare, Final Report 33-34 (1977) (open decision-making process will increase public confidence; current policy prevents public access to decision-making process) [hereinafter cited as Final Report]. One of the major purposes of the FOIA is to

While the FOIA requires mandatory disclosure of most records requested by the public,[8] nine specific categories of records are exempt from these mandatory disclosure provisions.[9] One of these categories, the trade secret exemption, exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential."[10] In FOIA litigation, safety and efficacy data submitted to the FDA generally have been examined under the Restatement of Torts definition of trade secret which places great emphasis on the competitive advantage to be derived from specific information.[11] Because safety and efficacy data often have great com-

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educate the public and enhance public confidence in government. *See* Koch & Rubin, *A Proposal For A Comprehensive Restructuring of the Public Information System*, 1979 Duke L.J. 1, 30-31 (1979); McGarity & Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 Harv. L. Rev. 837, 844 (1980); Note, *FDA Disclosure of Safety and Effectiveness Data: A Legal and Policy Analysis*, 1979 Duke L.J. 286, 318 (1979) [hereinafter cited as *FDA Disclosure*].

8. 5 U.S.C. § 552(a)(3) (1982). The FOIA requires that the request reasonably describe the record and be made in accordance with published rules and procedures. *Id.*

9. 5 U.S.C. § 552(b) (1982). Because of the FOIA's emphasis on disclosure these exemptions are to be narrowly construed and the burden of proof is on the agency opposing disclosure. FBI v. Abramson, 456 U.S. 615, 630-31 (1982); *see* Ryan v. United States Dep't of Justice, 617 F.2d 781, 790 (D.C. Cir. 1980); Washington Research Project, Inc. v. United States Dep't of Health, Educ. & Welfare, 504 F.2d 238, 244 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 963 (1975).

10. 5 U.S.C. § 552(b)(4) (1982).

11. Restatement of Torts § 757 comment b (1939). The Restatement provides, in part, that "[a] trade secret may consist of 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." *Id.* This definition has been used to determine the scope of "trade secret" in the FOIA's trade secret exemption in all but one case examining the scope of "trade secret" in the trade secret exemption. *See* Union Oil Co. v. FPC, 542 F.2d 1036, 1044 (9th Cir. 1976) (natural gas reserves held to be a trade secret under Restatement definition); Public Citizen Health Research Group v. FDA, 539 F. Supp. 1320, 1325 (D.D.C. 1982) (applying Restatement definition to safety and efficacy data submitted to the FDA), *aff'd in part, rev'd in part and remanded*, 704 F.2d 1280 (D.C. Cir. 1983); Waelde v. Merck, Sharp & Dohme, 94 F.R.D. 27, 28-29 (E.D. Mich. 1981) (drug company had not shown all NDA data trade secret under the Restatement definition, not entitled to protective order); St. Paul's Benev. Educ. & Missionary Inst. v. United States, 506 F. Supp. 822, 830-31 app. (N.D. Ga. 1980) (applying Restatement definition to computer tape data); Martin Marietta Corp. v. FTC, 475 F. Supp. 338, 343 (D.D.C. 1979) (applying Restatement definition to deposition of executive); Ashland Oil, Inc. v. FTC, 409 F. Supp. 297, 303 (D.D.C.) (applying Restatement definition to natural gas reserve estimates), *aff'd*, 548 F.2d 977 (D.C. Cir. 1976) (per curiam). *But see* Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983) (holding Restatement definition inappropriately applied to trade secret exemption).

petitive significance, the FDA believes such data to be exempt from mandatory disclosure under the FOIA as a trade secret.[12]

Although information may be exempt from the FOIA's mandatory disclosure provisions, it may nonetheless be released at the discretion of the record-holding agency.[13] The Trade Secrets Act (TSA), however, prevents discretionary disclosure of trade secrets by the FDA to the extent not authorized by law.[14] Because properly-promulgated substantive FDA regulations have the force and effect of law,[15] discretionary disclosure pursuant to such a regulation would not violate the TSA.[16] Section 301(j) of the Act,[17] however, prohibits the FDA from

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12. *See Business Record Hearings*, *supra* note 5, at 70 (statement of Dr. Donald Kennedy, Comm'r, FDA) ("We have interpreted, since, 1938, the term 'method [or] process which as a trade secret is entitled to protection' under section 301(j) of our law as encompassing animal and human testing data." (quoting section 301(j) of the Act)); McGarity & Shapiro, *supra* note 7, at 862 & n.127 (citing cases holding safety and efficacy data to be trade secret); Final Report, *supra* note 7, at 33 (safety and efficacy data exempt from disclosure as trade secrets). In adopting the Restatement definition, the FDA stated in response to comments:

> The Commissioner concludes . . . that the Restatement definition of a trade secret should remain the basic guideline for application of [the trade secret exemption] from the Freedom of Information Act. . . . The Commissioner can 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. 44,602, 44,612 (1974) (citation omitted).

13. Chrysler Corp. v. Brown, 441 U.S. 281, 294 (1979); Mead Data Central, Inc. v. United States Dep't of the Air Force, 566 F.2d 242, 258 (D.C. Cir. 1977); Florida Medical Ass'n v. Department of Health, Educ. & Welfare, 479 F. Supp. 1291, 1301 (M.D. Fla. 1979); Martin Marietta Corp. v. FTC, 475 F. Supp. 338, 341 (D.D.C. 1979). This discretionary disclosure is subject to judicial review under § 10(e) of the Administrative Procedure Act, which provides that the agency's decision to disclose may be set aside if found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) (1982).

14. 18 U.S.C. § 1905 (1982). The Trade Secrets Act 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 . . . of any person, firm, partnership, corporation, or association . . . 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.

Id.

15. *See* National Assoc. of Pharmaceutical Mfrs. v. FDA, 637 F.2d 877, 879 (2d Cir. 1981); United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 246 (2d Cir. 1977); American Frozen Food Inst. v. Califano, 555 F.2d 1059, 1060 (D.C. Cir. 1977) (per curiam); National Nutritional Foods Assoc. v. Weinberger, 512 F.2d 688, 697 (2d Cir.), *cert. denied*, 423 U.S. 827 (1975); 2 K. Davis, Administrative Law Treatise § 7:8, at 42 (2d ed. 1979).

16. *See* Chrysler Corp. v. Brown, 441 U.S. 281, 295-96 (1979); St. Mary's Hosp., Inc. v. Harris, 604 F.2d 407, 409-10 (5th Cir. 1979); J.H. Lawrence Co. v. Smith, 545 F. Supp. 421, 424 (D. Md. 1982); Westchester Gen. Hosp. v. United States Dep't of Health, Educ. & Welfare, 464 F. Supp. 236, 251 (M.D. Fla. 1979).

17. 21 U.S.C. § 331(j) (1982).

releasing information to the public "concerning any method or process which as a trade secret is entitled to protection."[18] Although disclosure of safety and efficacy data may serve the public interest, the Agency believes that section 301(j) prevents it from issuing a substantive regulation providing for discretionary disclosure of safety and efficacy data.[19] Accordingly, "authorization by law" as required by the Trade Secrets Act for disclosure of such information is lacking.

The Court of Appeals for the District of Columbia, however, recently refused to apply the Restatement definition of trade secret to safety and efficacy data in the context of a FOIA request. In *Public Citizen Health Research Group v. FDA*,[20] the court held that a narrow, production-oriented definition of trade secret should be applied to the FOIA's trade secret exemption.[21] Applying this definition to the safety and efficacy data at issue, the court held the data not exempt from disclosure as trade secrets.[22]

After reviewing both mandatory and discretionary disclosure of information under the FOIA, this Note argues that the narrow *Citizen Health Research* definition of trade secret should be applied to the term as used in section 301(j) of the Act. The Note concludes that as a result the FDA is "authorized by law" to issue regulations that permit discretionary disclosure of safety and efficacy data.[23] In addition, several factors are proposed as guidelines for the FDA in exercising its discretion to release information pursuant to such regulations.

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18. *Id.*

19. The FDA's position is that § 301(j)'s prohibition against disclosure of a "method [or] process which as a trade secret is entitled to protection" encompasses safety and efficacy data. *See Business Record Hearings*, *supra* note 5, at 70 (testimony of Dr. Donald Kennedy, Comm'r, FDA); *FOIA Hearings*, *supra* note 5, at 6 (statement of Sherwin Gardner, Deputy Comm'r, FDA). In response to comments on proposed public information regulations, the FDA stated that there was no difference in scope between the Trade Secrets Act and § 301(j). "This [has] the effect of prohibiting any discretionary release of documents that fall within the trade secrets . . . exemption to the Freedom of Information Act." 39 Fed. Reg. 44,602, 44,612 (1974).

20. 704 F.2d 1280 (D.C. Cir. 1983).

21. *Id.* at 1288.

22. *Id.* at 1290.

23. The issue whether discretionary disclosure of safety and efficacy data constitutes a "taking" under the fifth amendment is beyond the scope of this Note. The issue has arisen in the context of EPA disclosure of data concerning pesticides. *Compare* Mobay Chem. Corp. v. Gorsuch, 682 F.2d 419, 422 (3d Cir.) (disclosure of safety and efficacy data by EPA held constitutional), *cert. denied*, 103 S. Ct. 343 (1982) *and* Chevron Chem. Co. v. Costle, 641 F.2d 104, 114 (3d Cir.) (same), *cert. denied*, 452 U.S. 961 (1981) *and* Petrolite Corp. v. United States EPA, 519 F. Supp. 966, 974 (D.D.C. 1981) (same) *with* Monsanto Co. v. Acting Adm'r United States EPA, 564 F. Supp. 552, 567 (E.D. Mo. 1983) (disclosure of safety and efficacy data by EPA held unconstitutional), *argued* Feb. 27, 1984, 52 U.S.L.W. 3649 (U.S. Mar. 6, 1984) (No. 83-196).

I. Disclosure Of Safety And Efficacy Data Under The FOIA

A. *Mandatory Disclosure of Safety and Efficacy Data*

The Federal Food, Drug, and Cosmetic Act requires new-drug manufacturers to submit to the FDA a New Drug Application (NDA),[24] containing the results of preclinical and clinical studies of the new drug's safety and effectiveness, as well as detailed descriptions of the drug's chemistry, composition and methods of manufacture.[25] This information is evaluated by the FDA as the basis for its decision whether to approve the drug's introduction into interstate commerce.[26]

The policy underlying the FOIA supports the disclosure of this safety and efficacy data. Congress' primary purpose in enacting the FOIA was to encourage openness in agency decision-making processes, thereby permitting public evaluation of how an agency is carrying out its statutory duties.[27] Disclosure of safety and efficacy data would allow the public to determine if the FDA is fulfilling its duty to protect the public from harmful or ineffective drugs.[28]

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24. 21 U.S.C. § 355(b) (1982).

25. *Id.* Prior to the submission of an NDA, a new-drug sponsor must obtain the approval of the FDA to test the safety and efficacy of new drugs. *See id.* § 355(i); 21 C.F.R. § 312.1 (1983); Final Report, *supra* note 7, at 19-20. The applicant must submit a Notice of Claimed Investigational Exemption for a New Drug (IND), which discloses the chemical name, a list of chemical components, a statement of quantitative composition, and the methods of manufacturing, processing, and packing of the new drug, in addition to any data already developed concerning the drug's safety and effectiveness. 21 C.F.R. § 312.1(a)(2) (1983). Approval of the IND allows the sponsor to ship the drug in interstate commerce in order to conduct clinical testing. *See id.* § 312.1(a). The NDA consists of the results of the clinical testing and the IND. *See id.* § 314.1(b).

26. *See* 21 U.S.C. § 355(d) (1982); Final Report, *supra* note 7, at 24-25.

27. H.R. Rep. No. 1497, 89th Cong., 2d Sess. 6 (1966), *reprinted in* Senate Comm. on the Judiciary, 93d Cong., 2d Sess., Freedom of Information Act Source Book 27 (Comm. Print 1974) [hereinafter cited as Source Book] *and in* 1966 U.S. Code Cong. & Ad. News 2418, 2423; S. Rep. No. 813, 89th Cong., 1st Sess. 3 (1965), *reprinted in* Source Book, *supra*, at 38; *see* United States Dep't of the Air Force v. Rose, 425 U.S. 352, 360-61 (1976); NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 152-53 (1975); Washington Post Co. v. United States Dep't of Health & Human Servs., 690 F.2d 252, 264 (D.C. Cir. 1982).

28. *See FOIA Hearings*, *supra* note 5, at 6 (statement of Sherwin Gardner, Deputy Comm'r, FDA); McGarity & Shapiro, *supra* note 7, at 843-44; *FDA Disclosure*, *supra* note 7, at 318. The purpose of the Act was to protect the consumer. *See* Kordel v. United States, 335 U.S. 345, 349 (1948); United States v. Sullivan, 332 U.S. 689, 696 (1948); United States v. Naremco, Inc., 553 F.2d 1138, 1141 (8th Cir. 1977); United States v. Diapulse Corp. of Am., 457 F.2d 25, 27-28 (2d Cir. 1972); United States v. Four Devices, 176 F.2d 652, 654 (10th Cir. 1949); United States v. Two Bags, 147 F.2d 123, 127 (6th Cir. 1945). The Act requires submission of safety data in order to "prevent the premature marketing of new drugs not properly tested for safety." H.R. Rep. No. 2139, 75th Cong., 3d Sess. 9 (1938), *reprinted in* 6 FDA, A Legislative History of the Federal Food Drug and Cosmetic Act and Its Amend-

In addition, factors peculiar to the FDA's responsibilities support disclosure. In deciding whether a new drug is safe and effective, the FDA must rely on the voluminous data submitted by the drug manufacturer.[29] It has been suggested that disclosure of NDA data would allow for more thorough review of the safety and efficacy data submitted by drug manufacturers.[30] Scientists and others would be able to evaluate independently the data submitted by manufacturers and provide further assurance that such data accurately reflect a drug's safety and effectiveness.[31] Additionally, such disclosure would minimize the waste of resources that occurs when tests on new drugs are duplicated by other new-drug manufacturers.[32]

Congress exempted trade secret and confidential commercial information from disclosure under the FOIA to protect against harm resulting from agency disclosure of valuable business information.[33] This exemption permits an agency to withhold "trade secrets and

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ments at 300, 308 (1982) [hereinafter cited as Legislative History]. The Act was amended in 1962 to require submission of efficacy data in order to assist the FDA in providing "a safer and more reliable drug supply for the Nation by requiring . . . a premarketing showing that all new drugs are effective—as well as safe—for their intended uses." S. Rep. No. 1744, 87th Cong., 2d Sess. 8 (1962), *reprinted in* 22 Legislative History, *supra*, at 94, 101.

29. *See* 21 U.S.C. § 355(b) (1982) (FDA requires submission of NDA by new-drug manufacturer). Data submitted in support of a NDA may total several hundred volumes. *See* Final Report, *supra* note 7, at 24. In addition, such data may not be totally reliable. The FDA has recognized that adverse data may be minimized and favorable data emphasized. In an effort to minimize manufacturer bias the FDA usually examines the raw safety and efficacy data developed by drug manufacturers. *See* 45 Fed. Reg. 82,052, 82,053 (1980).

30. *See* Final Report, *supra* note 7, at 34; McGarity & Shapiro, *supra* note 7, at 843.

31. *See* Final Report, *supra* note 7, at 34 (Current policy prevents scientists and the public from "examining and commenting on the facts which underlie agency decisions."); McGarity & Shapiro, *supra* note 7, at 843 (Public disclosure would provide assistance in assessing data and improve the quality of agency decisions.); *FDA Disclosure*, *supra* note 7, at 317-18 (Public disclosure would insure public participation in the FDA decision-making process.).

32. *See* Final Report, *supra* note 7, at 35; McGarity & Shapiro, *supra* note 7, at 845-46.

33. *See* 5 U.S.C. § 552(b)(4) (1982). The trade secret and confidential commercial information exemption of the FOIA was considered "necessary to protect the confidentiality of information which is obtained by the Government . . . but which would customarily not be released to the public by the person from whom it was obtained. This would include business sales statistics, inventories, customer lists, and manufacturing processes." S. Rep. No. 813, 89th Cong., 1st Sess. 9 (1965), *reprinted in* Source Book, *supra* note 27, at 44; *see* Shermco Indus. Inc. v. Secretary of Air Force, 613 F.2d 1314, 1317 (5th Cir. 1980); National Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 768 (D.C. Cir. 1974); Audio Technical Servs. Ltd. v. Department of Army, 487 F. Supp. 779, 781 (D.D.C. 1979); Clement, *The Rights of Submitters to Prevent Agency Disclosure of Confidential Business Information: The Reverse Freedom of Information Act Lawsuit*, 55 Tex. L. Rev. 587, 593-94 (1977).

commercial or financial information obtained from a person and privileged or confidential."[34] The courts, in interpreting this exemption, rely on the definition of trade secret provided by section 757 of the Restatement of Torts.[35] This definition focuses on competitive advantage, providing that a trade secret may consist of a "compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over his competitors who do not know or use it."[36] Under the Restatement definition, safety and efficacy data have been considered trade secrets by both the courts and the FDA.[37]

Safety and efficacy data submitted to the FDA provide a competitive advantage to the submitter. Accumulation of such data is costly,[38] however, and is often formulated at the expense of other research and development that a drug company might have conducted. Competitors must compile their own safety and efficacy data if they wish to submit an NDA for the same drug.[39] If the submitter's safety and

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34. 5 U.S.C. § 552(b)(4) (1982). The majority of litigation over the scope of this exemption concerns the second prong, which exempts confidential commercial information from disclosure under the FOIA. *See* United States Dep't of Justice, Freedom of Information Case List 213 (1983 ed.); O'Reilly, *Government Disclosure of Private Secrets Under the Freedom of Information Act*, 30 Bus. Law. 1125, 1126 (1975); *FDA Disclosure*, *supra* note 7, at 297. One commentator has noted that in "practically none of the reported reverse FOIA cases (or direct FOIA cases) have the courts treated the disputed material as trade secrets." Connelly, *Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosures of Business Data*, 1981 Wis. L. Rev. 207, 267. The confidential commercial information prong applies to data if its disclosure would be likely: "(1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." National Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974) (footnote omitted).

35. *E.g.*, Union Oil Co. v. FPC, 542 F.2d 1036, 1044 (9th Cir. 1976); Public Citizen Health Research Group v. FDA, 539 F. Supp. 1320, 1325 (D.D.C. 1982), *aff'd in part, rev'd in part and remanded*, 704 F.2d 1280 (D.C. Cir. 1983); St. Paul's Benevolent Educ. & Missionary Inst. v. United States, 506 F. Supp. 822, 830 (N.D. Ga. 1980); *see* J. O'Reilly, Federal Information Disclosure § 14.06, at 14-14 (1977); Connelly, *supra* note 34, at 230; O'Reilly, *supra* note 34, at 1126; *FDA Disclosure*, *supra* note 7, at 297-99.

36. Restatement of Torts § 757 comment b (1939).

37. See *supra* note 12 and accompanying text.

38. *See* 39 Fed. Reg. 44,601, 44,634 (1974) (FDA estimates cost of developing safety and efficacy data as "hundreds of thousands, and in some instances, millions of dollars"); McGarity & Shapiro, *supra* note 7, at 849 (average cost of testing estimated in 1980 to be between 2.7 and 4.7 million dollars).

39. *See* McGarity & Shapiro, *supra* note 7, at 849; Final Report, *supra* note 7, at 33. FDA regulations provide that data in FDA files may be incorporated by reference into an NDA "furnished by a person other than the applicant [only if] use of such information is authorized . . . by the person who submitted it." 21 C.F.R. § 314.1(b) (1983).

efficacy data were disclosed to a competitor, the competitor could incorporate the data into its own NDA. Disclosure would allow a competitor to determine the feasibility of developing similar drugs without the research and development costs incurred by the first manufacturer. A competitor might also incorporate the same data into an application in a foreign country for the manufacture and sale of the drug.

The FOIA, however, does not prohibit agencies from disclosing records that may be withheld pursuant to one of the FOIA's exemptions.[40] Thus, the FDA may decide to disclose safety and efficacy data even if the data are exempt from disclosure under the FOIA as a trade secret. Discretionary disclosure of exempt material, however, is subject to statutory restrictions.

B. *Discretionary Disclosure of Exemption Four Trade Secret Data*

When an agency attempts to release to the public data that the submitter considers to be a trade secret, the submitter may seek to enjoin disclosure.[41] This reverse-FOIA suit is brought under section 10(a) of the Administrative Procedure Act (APA),[42] which provides for

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40. See *supra* note 13 and accompanying text.

41. *E.g.*, Penzoil Co. v. FPC, 534 F.2d 627, 629 (5th Cir. 1976); Continental Oil Co. v. FPC, 519 F.2d 31, 32-33 (5th Cir. 1975), *cert. denied*, 425 U.S. 971 (1976); Brookwood Medical Center, Inc. v. Califano, 470 F. Supp. 1247, 1248 (N.D. Ga. 1979), *aff'd mem.*, 614 F.2d 1295 (5th Cir. 1980); Burroughs Corp. v. Schlesinger, 403 F. Supp. 633, 634 (E.D. Va. 1975); Westinghouse Elec. Corp. v. Schlesinger, 392 F. Supp. 1246, 1248 (E.D. Va. 1974), *aff'd*, 542 F.2d 1190 (4th Cir. 1976), *cert. denied*, 431 U.S. 924 (1977); McCoy v. Weinberger, 386 F. Supp. 504, 506 (W.D. Ky. 1974). The first such suit was Charles River Park "A", Inc. v. HUD, 360 F. Supp. 212, 213 (D.D.C. 1973), *remanded*, 519 F.2d 935 (D.C. Cir. 1975); *see* Clement, *supra* note 33, at 589-90. FDA regulations provide for notification to the submitter of data when the confidentiality of the data is uncertain. 21 C.F.R. § 20.45 (1983). If the Agency decides to release the data, the submitter has five days after notification to institute suit seeking to enjoin disclosure of the data. *Id.* § 20.46. As Professor Clement notes, most reverse-FOIA suits are brought by the submitter of the data upon receiving notification of pending disclosure, prior to actual release to the requester. Clement, *supra* note 33, at 590 n.8.

42. 5 U.S.C. § 702 (1982). Prior to Chrysler Corp. v. Brown, 441 U.S. 281 (1979), reverse-FOIA suits were brought under three legal theories. Under the first, submitters contended that the FOIA prohibited agencies from disclosing data that fell into any of the FOIA's exemptions and thus the FOIA provided an implied cause of action. *E.g.*, Brookwood Medical Center, Inc. v. Califano, 470 F. Supp. 1247, 1248 (N.D. Ga. 1979), *aff'd mem.*, 614 F.2d 1295 (5th Cir. 1980); Westinghouse Elec. Corp. v. Brown, 443 F. Supp. 1225, 1228 (E.D. Va. 1977); Westinghouse Elec. Corp. v. Schlesinger, 392 F. Supp. 1246, 1248 (E.D. Va. 1974), *aff'd*, 542 F.2d 1190 (4th. Cir. 1976), *cert. denied*, 431 U.S. 924 (1977). Second, submitters argued that a cause of action existed to prevent disclosure of trade secret data under the Trade Secrets Act. *E.g.*, *Brookwood Medical Center, Inc.*, 470 F. Supp. at 1249; *Brown*, 443 F. Supp. at 1228; *Schlesinger*, 392 F. Supp. at 1248. Finally, submitters claimed that the APA provided for review of an agency's decision to disclose material that was

judicial review of agency action.[43] A reverse-FOIA suit will prevent disclosure of trade secrets if the decision to disclose was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[44] Under section 10(e) of the APA, the Federal Trade Secrets Act may bar disclosure of safety and efficacy data as being "not in accordance with law."[45]

In *Chrysler Corp. v. Brown*,[46] the Supreme Court dealt with a challenge under the APA to discretionary disclosure of data pursuant to agency regulations.[47] The Court recognized that, "properly promulgated, substantive agency regulations have the 'force and effect of law,' "[48] and thus could provide the authorization to disclose data that otherwise would be prohibited by the TSA.[49] The Court

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either exempt from the FOIA or within the ambit of the Trade Secrets Act. *E.g.*, General Dynamics Corp. v. Marshall, 572 F.2d 1211, 1217-18 (8th Cir. 1978), *vacated and remanded*, 441 U.S. 919 (1979); Chrysler Corp. v. Schlesinger, 565 F.2d 1172, 1190-92 (3d Cir. 1977), *vacated and remanded sub nom.* Chrysler Corp. v. Brown, 441 U.S. 281 (1979). The Supreme Court in *Chrysler* held that only the APA provided judicial review of an agency's decision to disclose data exempt from the FOIA, thereby limiting reverse-FOIA suits to the third theory. *See Chrysler Corp.*, 441 U.S. at 294, 316, 318.

43. The APA provides: "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702 (1982). *See* Megapulse, Inc. v. Lewis, 672 F.2d 959, 965-66 (D.C. Cir. 1982); Humana of Va., Inc. v. Blue Cross, 622 F.2d 76, 78 (4th Cir. 1980); J. H. Lawrence Co. v. Smith, 545 F. Supp. 421, 423 (D. Md. 1982).

44. 5 U.S.C. § 706(2)(A) (1982); *see* Green v. IRS, 556 F. Supp. 79, 83 (N.D. Ind. 1982); Joseph Schlitz Brewing Co. v. SEC, 548 F. Supp. 6, 8 (D.D.C. 1982); St. Joseph's Hosp. v. Blue Cross, 489 F. Supp. 1052, 1062 (N.D.N.Y.), *aff'd mem.*, 614 F.2d 1290 (2d Cir. 1979); English, *Protecting the Stakeholder: Defense of the Government Agency's Interests During Reverse FOIA Lawsuits*, 31 Ad. L. Rev. 151, 169 (1979).

45. *See* Chrysler Corp. v. Brown, 441 U.S. 281, 318 (1979); Humana of Va., Inc. v. Blue Cross, 622 F.2d 76, 78 (4th Cir. 1980); Green v. IRS, 556 F. Supp. 79, 83 (N.D. Ind. 1982); Joseph Schlitz Brewing Co. v. SEC, 548 F. Supp. 6, 8 (D.D.C. 1982); 5 U.S.C. § 706(2)(A) (1982).

46. 441 U.S. 281 (1979).

47. *Id.* at 287. In *Chrysler*, the plaintiff was seeking to block the disclosure of employment data submitted to the Defense Logistics Agency (DLA). Pursuant to Executive Orders 11246 and 11375, the Secretary of Labor required government contractors to submit data concerning affirmative-action programs. *Id.* at 286. The Secretary had also promulgated regulations providing for the public disclosure of such records when in the public interest. *Id.* at 287. After Chrysler submitted the data, a FOIA request was received by the DLA and Chrysler was notified that the data was to be released pursuant to the regulations promulgated by the Secretary. Chrysler brought suit to block disclosure of the data. *Id.* at 287-88.

48. *Id.* at 295.

49. *See id.* at 315-16; Parkridge Hosp., Inc. v. Califano, 625 F.2d 719, 722-24 (6th Cir. 1980); St. Mary's Hosp., Inc. v. Harris, 604 F.2d 407, 409 (5th Cir. 1979); J.H. Lawrence Co. v. Smith, 545 F. Supp. 421, 424 (D. Md. 1982); 2 B. Mezines, J. Stein & J. Gruff, Administrative Law § 10A.04[3], at 10A-53 (1983).

held that such a regulation must be "reasonably within the contemplation of [the] grant of [rulemaking] authority" given the agency by Congress.[50] In addition, the regulation must affect "individual rights and obligations"[51] and be properly promulgated as required by section 4 of the APA.[52]

The Federal Food, Drug, and Cosmetic Act of 1938 contains a general grant of rulemaking authority, empowering the FDA to issue regulations "necessary for the efficient enforcement" of the Act.[53] This general grant of rulemaking authority has been held to authorize the FDA "to promulgate substantive regulations having the binding force of law."[54] Section 301(j) of the Act, however, prohibits the FDA from disclosing a "method or process which as a trade secret is entitled to protection."[55] This prohibition is applicable to information obtained from manufacturers that submit safety and efficacy data to the FDA for drug approval.[56]

The FDA has applied the Restatement definition of trade secret to section 301(j);[57] consequently, FDA regulations implementing section 301(j) prohibit the discretionary disclosure of safety and efficacy data.[58] A statement accompanying the publication of the regulations

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50. *Chrysler Corp.*, 441 U.S. at 306.

51. *Id.* at 302 (quoting Morton v. Ruiz, 415 U.S. 199, 232 (1974)).

52. The Court noted that "the promulgation of these regulations must conform with any procedural requirements imposed by Congress," and that these limitations are those imposed by the APA. *Id.* at 303. The Court held that regulations authorizing disclosure must be properly promulgated according to the "notice-and-comment" rulemaking provisions of § 4 of the APA. *Id.* at 313.

53. 21 U.S.C. § 371(a) (1982).

54. National Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688, 697 (2d Cir.), *cert. denied*, 423 U.S. 827 (1975); *see* National Ass'n. of Pharmaceutical Mfrs. v. FDA, 637 F.2d 877, 879 (2d Cir. 1981); United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 246 (2d Cir. 1977); American Frozen Food Inst. v. Califano, 555 F.2d 1059, 1060 (D.C. Cir. 1977) (per curiam); 2 K. Davis, *supra* note 15, § 7:8, at 42-43 (discussing 21 U.S.C. § 371(a)). To disclose safety and efficacy data, the FDA must promulgate a regulation which would satisfy the *Chrysler* tests. As in *Chrysler*, an FDA regulation authorizing disclosure of safety and efficacy data would affect individual rights and obligations. 441 U.S. at 302. If such a regulation were promulgated in accordance with § 4 of the APA, the regulation would conform to "any procedural requirements imposed by Congress." *Id.* at 303. As was the case in *Chrysler*, the focus of analysis would then be whether it was "reasonably within the contemplation" of § 701(a) of the Food Drug and Cosmetic Act. One commentator has noted that the FOIA itself empowers agencies to promulgate substantive regulations authorizing the disclosure of exempt data when in the public interest. *See* Clement, *supra* note 33, at 619-20.

55. 21 U.S.C. § 331(j) (1982).

56. *Id.* See *supra* notes 17-19 and accompanying text.

57. *See* 21 C.F.R. § 20.61(a) (1983).

58. FDA regulations provide that previously undisclosed safety and efficacy data will be disclosed only when certain circumstances are shown. These are: "(1) The NDA has been abandoned . . . [or] (2) A final determination is made that the NDA is

indicates that the FDA considers itself required by law to withhold such data.[59]

Implicit in this analysis of section 301(j)'s prohibition against disclosure of a "method or process which as a trade secret is entitled to protection" is the assumption that the Restatement definition was meant to apply to safety and efficacy data obtained from drug manufacturers.[60] A recent reexamination of the trade secret doctrine by the Court of Appeals for the District of Columbia, however, together with an analysis of the legislative history of section 301(j), suggest that the Restatement definition should not be applied to section 301(j).

II. *Citizen Health Research*'s Narrow Definition Of Trade Secret As Applied To Section 301(j)

A. Citizen Health Research—*A Narrow Definition of Trade Secret*

In *Public Citizen Health Research Group v. FDA*,[61] the Court of Appeals for the District of Columbia addressed the issue whether records produced during ongoing clinical studies of the safety and efficacy of intraocular lenses were exempt from disclosure under the FOIA.[62] The Court of Appeals stated that it was "far from clear that

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not approvable . . . [or] (3) Approval of the NDA is withdrawn . . . [or] (4) A final determination has been made that the drug is not a new drug [or] (5) A final determination has been made that the drug may be marketed without submission of such safety and/or effectiveness data and information." 21 C.F.R. § 314.14(f) (1983). Section 20.82 provides that the Commissioner may, in his discretion, disclose any data that are otherwise exempt when in the public interest, or when such disclosure will promote the objectives of the Act or agency, except "any record that is: (1) Exempt from public disclosure pursuant to § 20.61. . . . " *Id.* § 20.82. Section 20.61 exempts from disclosure any information that is a trade secret as defined by the Restatement. *See id.* § 20.61.

59. Responding to comments received concerning the FDA's public information regulations, the FDA stated: "The Commissioner advises . . . that he has no discretion to release trade secret information. All records subject to the trade secret exemption from the Freedom of Information Act are prohibited from public disclosure pursuant to 18 U.S.C. 1905 and 21 U.S.C. 331(j). . . . Accordingly, [§ 20.82] does not permit discretionary release of such material." 39 Fed. Reg. 44,602, 44,619 (1974).

60. 39 Fed. Reg. 44,602, 44,634 (1974). "Data that no longer provide a competitive advantage—because any competitor may lawfully market the product involved, or because the information has otherwise been made public, or for other reasons—no longer qualify as a trade secret under 18 U.S.C. 1905, 21 U.S.C. 331(j), or the Freedom of Information Act." *Id.*

61. 704 F.2d 1280 (D.C. Cir. 1983).

62. *Id.* at 1283. The records were submitted to the FDA by intraocular lens manufacturers and were subsequently requested by a public interest group. The FDA refused to disclose certain requested records, basing its decision on the FOIA's trade secret exemption and FDA regulations prohibiting the disclosure of trade secrets. Health Research Group brought suit challenging the FDA's application of the trade-

Congress intended [the Restatement definition of trade secret] to govern in FOIA cases,"[63] and held the broad Restatement definition inapplicable "as inconsistent with the language of the FOIA and its underlying policies."[64] The court asserted that "the term 'trade secrets' in Exemption 4 of the FOIA should be defined in its narrower common law sense, which incorporates a direct relationship between the information at issue and the productive process."[65]

The *Citizen Health Research* court defined trade secret, for the purposes of the exemption, as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort."[66] The court cited the only pre-FOIA case to define trade secrets under the TSA, which applied a similar definition.[67] Applying this restrictive definition, the court concluded that the safety and efficacy data at issue were not protected by the exemption's trade secret prong.[68] The court stated that "under no plausible reading of the phrase 'plan, formula, process or device' could the [data] sought by the [Health Research Group] be said to fall within its ambit."[69] The case was remanded for a determination whether the data was otherwise exempt from mandatory disclosure under the commercial information prong.[70]

Because release of safety and efficacy data may result in competitive harm, such data may be exempt from mandatory disclosure under the FOIA's commercial information prong. Nevertheless, the data may still be disclosed by the FDA unless such disclosure is prevented by section 301(j). If the Restatement definition is applied to section 301(j)'s prohibition against release of a "method or process" which is a trade secret, then the FDA is prohibited from discretionary disclosure of safety and efficacy data.[71] If, however, a narrow production-ori-

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secret exemption. *See id.* The lower court held much of the requested material to be trade secret, and therefore exempt from disclosure under the exemption. Public Citizen Health Research Group v. FDA, 539 F. Supp. 1320, 1328-30 (D.D.C. 1982), *aff'd in part, rev'd in part and remanded*, 704 F.2d 1280 (D.C. Cir. 1983).

63. *Citizen Health Research*, 704 F.2d. at 1286.

64. *Id.* at 1288.

65. *Id.*

66. *Id.*

67. United States *ex rel.* Norwegian Nitrogen Prods. Co. v. United States Tariff Comm., 6 F.2d 491, 495 (D.C. Cir. 1925), *vacated as moot*, 274 U.S. 106 (1927).

68. *Citizen Health Research*, 704 F.2d at 1290.

69. *Id.*

70. *Id.* at 1292.

71. See *supra* notes 98-110 and accompanying text. This is currently the FDA's position. See *supra* notes 57-59 and accompanying text.

ented approach is taken to section 301(j), the FDA may use its discretion to disclose safety and efficacy data.[72]

B. *Narrow Definition of Trade Secret Applied to Section 301(j)*

Section 301(j) of the Federal Food, Drug, and Cosmetic Act prohibits the FDA from disclosing any "method or process which as a trade secret is entitled to protection."[73] In the absence of a congressional definition of the terms of this prohibition, it is assumed that Congress intended their ordinary meanings to apply.[74] As the *Citizen Health Research* court found, the term 'trade secret' is both broadly and narrowly defined at common law.[75] The court opted for a narrow, production-oriented definition of trade secret.[76] In section 301(j), however, the scope of the term "trade secret," in addition to being subject to conflicting interpretations, is limited to any "*method or process* which as a trade secret is entitled to protection."[77] Therefore, by its terms section 301(j)'s prohibition is limited to information relating to the methods or processes of production.[78] This interpretation is

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72. Arguably, the only statutory bar to discretionary disclosure of such data by the FDA is § 301(j) of the Act. The Trade Secrets Act will not bar disclosure of data pursuant to valid substantive regulations. As the Court in *Chrysler* made clear, however, such a regulation must be related to the Congressional grant of rulemaking authority given the agency. *See* Chrysler Corp. v. Brown, 441 U.S. 281, 308 (1979). In the area of public information, the only possible limitation of the FDA's authority is § 301(j). If the scope of § 301(j) does not encompass safety and efficacy data, there is no limitation on the FDA's rulemaking authority which could prevent it from disclosure pursuant to such regulation.

73. 21 U.S.C. § 331(j) (1982).

74. *See* United States v. Clarke, 445 U.S. 253, 254 (1980); Caminetti v. United States, 242 U.S. 470, 485 (1917); T. L. Hunt, Inc. v. Commissioner, 562 F.2d 532, 535 (8th Cir. 1977); United States v. Hunter, 459 F.2d 205, 210 (4th Cir.), *cert. denied*, 409 U.S. 934 (1972); 2A C. Sands, Sutherland Statutory Construction § 46.01, at 48 (4th ed. 1973).

75. *Citizen Health Research*, 704 F.2d at 1286. The court noted that two definitions were applied in determining the scope of "trade secret," the narrow *Norwegian Nitrogen* definition and the broad Restatement definition. *See id. Compare* Restatement of Torts § 757 comment b (1939) (broad common-law definition) *with* United States *ex rel.* Norwegian Nitrogen Prods. Co. v. United States Tariff Comm'n, 6 F.2d 491, 495 (D.C. Cir. 1925) (narrow common-law definition), *vacated as moot*, 274 U.S. 106 (1927).

76. *See Citizen Health Research*, 704 F.2d at 1289. The court stated that application of the Restatement definition of trade secret, with its emphasis on competitive advantage, would render the confidential commercial information prong of the exemption meaningless. Material is exempt from disclosure under the exemption's second prong if its disclosure is likely to cause substantial competitive harm. *Id.* See *supra* note 34.

77. 21 U.S.C. § 331(j) (1982) (emphasis added).

78. A method is "a way of doing anything; mode; procedure; process; . . . regularity or orderliness in action." Webster's New Universal Unabridged Dictionary 1134 (2d ed. 1983). A process is "a continuing development involving many changes;

supported by examining the legislative history of the prohibition against disclosure.

1. History of Section 301(j)'s Prohibition Against Disclosure

The first draft of the Food, Drug, and Cosmetic Act, introduced in the Senate in 1933,[79] had no provision prohibiting disclosure of trade secrets.[80] The proposed Act required drug manufacturers to label all drugs with the drug's formula and composition by weight.[81] The bill also provided for government inspection of factories in order to issue factory permits and prevent the manufacture of illegal drugs.[82] Manufacturers were not required to submit formulas to the FDA, nor were there any special requirements for the approval of new drugs.[83]

During hearings on the proposed Act, manufacturers protested that the labeling requirements would force disclosure of secret formulas and methods of combining ingredients, and thus would destroy their

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. . . a particular method of doing something, generally involving a number of steps or operations." *Id.* at 1434. Safety and efficacy data are not methods or processes as defined here, because neither is a "mode" or "procedure" or a "method of doing something." By contrast, a secret type of manufacturing or packaging process or a newly-invented method of determining the efficiency of a manufacturing process would be a "method" or "process".

79. *See* S. 1944, 73d Cong., 1st Sess. (1933), *reprinted in* 1 Legislative History, *supra* note 28, at 1. The bill's introduction stated that its purpose was "[t]o prevent the manufacture, shipment, and sale of adulterated or misbranded food, drugs, and cosmetics, and to regulate traffic therein, . . . and for other purposes." *Id.*, *reprinted in* 1 Legislative History, *supra* note 28, at 1. The report of a later bill similar to S. 1944 described the Act as a remedy for the inadequacies of the Federal Food and Drug Act of 1906. *See* S. Rep. No. 493, 73d Cong., 2d Sess. 1 (1934), *reprinted in* 2 Legislative History, *supra* note 28, at 721.

80. *See* S. 1944, 73d Cong., 1st Sess. § 17 (1933), *reprinted in* 1 Legislative History, *supra* note 28, at 23-25.

81. *See id.* §§ 6(b), 8(e), *reprinted in* 1 Legislative History, *supra* note 28, at 7, 11.

82. *See id.* §§ 12, 13, *reprinted in* 1 Legislative History, *supra* note 28, at 16-18. Section 13 (factory inspection) gave the FDA authority to "enter upon the premises of manufacturers and dealers where . . . [adulterated or misbranded drugs] are being manufactured or held in storage . . . . Authority to inspect premises is usually regarded as an indispensable implement for the enforcement of statutes enacted for the protection of the public health." S. Rep. No. 493, 73d Cong., 2d Sess. 17, *reprinted in* 2 Legislative History, *supra* note 28, at 737.

83. Provisions regarding submission of data as a condition to marketing new drugs were not included in the proposed Act until after the Elixir Sulfanilamide disaster of 1937, in which over 70 people were killed as a result of using a newly-developed, untested drug. See *infra* notes 93-98 and accompanying text. Representative Chapman, who introduced the provision that subsequently became § 505 of the Act, stated in debate the there was nothing in the pre-Elixir bill that would have prevented the occurrence of the Elixir incident. *See* 82 Cong. Rec. 135 (1937); Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 Law & Contemp. Probs. 2, 20 (1939).

property interests.[84] The manufacturers claimed that the benefit accruing to the public by such labeling did not justify the disclosure of their formulae.[85]

Manufacturers also claimed that factory inspections would place them at a competitive disadvantage.[86] At the hearings, the General Counsel of the National Confectioners Association stated that an inspector's memory may "serve him in good stead . . . [because the] [p]rocesses with which he has become familiar . . . can be utilized unfairly in competing with the very manufacturer whom he has inspected. It must be remembered that time and money are expended by progressive manufacturers in establishing plant practices [and] developing equipment . . . ."[87]

In the next session, Senator Copeland introduced a new bill that prohibited disclosure of "any method or process which is entitled to protection in equity as a trade secret" and that was obtained as a result of factory permit or inspection procedures.[88] The Senate Report

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84. *See Food, Drugs, and Cosmetics: Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 154 (1933) (statement of Dr. John F. Anderson, Vice President, E.R. Squibb & Sons) (disclosure of formula on labels would damage property rights) [hereinafter cited as *Hearings on S. 1944*], *reprinted in* 1 Legislative History, *supra* note 28, at 245; *id.* at 312 (brief of United Medicine Mfrs.) (disclosure of ingredients and formulae will harm manufacturers), *reprinted in* 1 Legislative History, *supra* note 28, at 403; *id.* at 453 (brief of Delson Chem. Co.) (if forced to disclose formulae the manufacturer "may find his products in competition with cheap imitations" which will cause him competitive harm), *reprinted in* 1 Legislative History, *supra* note 28, at 544; *id.* at 484 (letter of Dec. 15, 1933 from Merrill Hutchinson to Sen. Shipstead) (same), *reprinted in* 1 Legislative History, *supra* note 28, at 575.

85. *See Hearings on S. 1944*, *supra* note 84, at 304 (statememt of Norman Dillingham) ("disclosure of any formula is absolutely unjustified by any possible benefits accruing to the public"), *reprinted in* 1 Legislative History, *supra* note 28, at 395; *id.* at 312 (brief of United Medicine Mfrs.) (disclosure will be to the "ultimate disadvantage of the purchasing public"), *reprinted in* 1 Legislative History, *supra* note 28, at 403.

86. *See Hearings on S. 1944*, *supra* note 84, at 137 (statement of Sebastian Mueller, Vice President, H.J. Heinz Co.) (objecting to goverment access to methods or processes), *reprinted in* 1 Legislative History, *supra* note 28, at 228; *id.* at 157 (statement of Dr. John F. Anderson, Vice President, E.R. Squibb & Sons) (the government's right to "inspect all equipment, methods, processes, materials, containers" not objectionable if access limited to government, but "eventually what is in the hands of the Government is in the hands of the competitor"), *reprinted in* 1 Legislative History, *supra* note 28, at 248; *id.* at 299 (statement of John S. Hall) (objecting to disclosure of "perfected methods and processes"), *reprinted in* 1 Legislative History, *supra* note 28, at 390.

87. *Hearings on S. 1944*, *supra* note 84, at 444 (statement of W. Parker Jones, General Counsel for Nat'l Confectioners' Ass'n), *reprinted in* 1 Legislative History, *supra* note 28, at 535.

88. S. 2800, 73d Cong., 2d Sess. § 17(g) (1934), *reprinted in* 1 Legislative History, *supra* note 28, at 787.

accompanying the bill explained that "[a]s a safeguard to manufacturers, [the disclosure prohibition] would penalize the improper use or disclosure of any information obtained by Government inspectors . . . concerning any secret method or process in use in any plant."[89]

A third bill, substantially identical to the second, was introduced in 1935.[90] When the Senate passed this bill, the text of the section prohibiting disclosure of trade secrets was identical to the current section 301(j), though it expressly applied only to information obtained through the Act's factory permit and inspection provisions.[91] When provisions requiring drug manufacturers to submit safety data to the FDA were included in the bill, section 301(j) was extended to include this information.[92] It is doubtful, however, that Congress intended to include all data required from drug manufacturers within the scope of the prohibition.

2. Inclusion of New Drug Data Within Section 301(j)'s Prohibition

In May of 1938, after the third bill had passed the Senate and was before the House, provisions were included requiring submission of data to the FDA before a manufacturer could market a new drug.[93] The Elixir Sulfanilamide disaster of late 1937 prompted the inclusion of these requirements.[94] Over seventy people died during September and October of 1937 because they used a newly-developed drug that had never been tested, despite the availability of simple clinical tests.[95]

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89. S. Rep. No. 493, 73d Cong., 2d Sess. 21 (1934), *reprinted in* 2 Legislative History, *supra* note 28, at 741. The prohibition as expressed in the Senate Report was limited to disclosure of information obtained by plant inspection and permit procedures and did not include the term "trade secret." *See id.* at 17-18, 21, *reprinted in* 2 Legislative History, *supra* note 28, at 737-38, 741.

90. S. 5, 74th Cong., 1st Sess. (1935), *reprinted in* 3 Legislative History, *supra* note 28, at 1.

91. S. 5, 74th Cong., 1st Sess. § 708(a)(9) (1935), *reprinted in* 4 Legislative History, *supra* note 28, at 216. The section prohibited "[t]he using by any person to his own advantage . . . any information acquired under authority of sections 305 [Emergency Permit Control] or 707 [Factory Inspection] concerning any method or process which as a trade secret is entitled to protection." *Id.*, *reprinted in* 4 Legislative History, *supra* note 28, at 216.

92. *See* S. 5, 74th Cong. 1st Sess. § 301(j) (1935), *reprinted in* 3 Legislative History, *supra* note 28, at 1. The Senate passed S. 5 on March 9, 1937. 81 Cong. Rec. 2019 (1937). As a result of the Elixir Sulfanilamide disaster, the House amended S. 5 to include § 505. *See* Cavers, *supra* note 83, at 20. There was no debate concerning the application of § 301(j) to information acquired under § 505.

93. Section 505 first appeared in the proposed Act, S. 5, on March 5, 1938, when the House Committee on Interstate and Foreign Commerce amended the bill. *See* S. 5, 75th Cong., 1st Sess. § 505 (Comm. Print No. 4 1938), *reprinted in* 6 Legislative History, *supra* note 28, at 46.

94. *See* 1 H. Toulmin, A Treatise on the Law of Foods, Drugs and Cosmetics § 1.5, at 13 (2d ed. 1963); Cavers, *supra* note 83, at 20.

95. *See* Elixir Sulfanilamide, S. Doc. No. 124, 75th Cong., 2d Sess. 3 (1937), *reprinted in* 5 Legislative History, *supra* note 28, at 883, 885-87.

Shortly thereafter bills were introduced in both the Senate and the House requiring manufacturers to submit data to the FDA to obtain approval before introducing a new drug.[96] The House bill subsequently became section 505 of the Act.[97] Section 505 requires manufacturers to submit full reports of investigations showing that the drug is safe and effective for use, a full list of the articles used as components of the drug, a full description of the methods used in the manufacturing, processing, and packing of the drug, and a full statement of the drug's composition.[98]

The purpose of section 301(j), together with the submission requirements of section 505 of the Act, suggests that not all the data required under section 505 should be included within the scope of "any method or process which as a trade secret is entitled to protection."[99] The drug industry had two complaints concerning disclosure of safety and efficacy data required under section 505 of the earliest draft of the Act. These were the proposed labeling requirements,[100] that required disclosure of formulae and the composition, and disclosure of methods or processes used in factories.[101] In response to these industry complaints,

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96. *See* H.R. 9341, 75th Cong., 3d Sess. 1-2 (1938), *reprinted in* 6 Legislative History, *supra* note 28, at 1; S. 3073, 75th Cong., 3d Sess. 1-2 (1938), *reprinted in* 6 Legislative History, *supra* note 28, at 10.

97. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052-53 (1938) (codified as amended at 21 U.S.C. § 355 (1982); *see* 1 H. Toulmin, *supra* note 94, § 1.5, at 13; Cavers, *supra* note 84, at 13. *Compare* H.R. 9341, 75th Cong., 3d Sess. 2 (1938) (House bill requiring submission of safety data on new drugs), *reprinted in* 6 Legislative History, *supra* note 28, at 2 *with* 21 U.S.C. § 355 (1982) (§ 505 of the Act as codified and amended).

98. *See* 21 U.S.C. § 355(b) (1982). Efficacy data were not required under the Act of 1938. This requirement was added by Pub. L. No. 87-781, §§ 103, 104, 76 Stat. 780, 782-85 (1962). In 1962, the House passed a bill which would have required all data acquired by the FDA to be held confidential. The bill omitted the phrase "concerning any method or process which as a trade secret is entitled to protection" from § 301(j). *See* H.R. 11,581, 87th Cong., 2d Sess. § 202(2) (1962), *reprinted in* 22 Legislative History, *supra* note 28, at 980. The Senate did not agree to the amendment, and the Drug Amendments of 1962 did not omit the phrase from § 301(j). *See* Drug Amendments of 1962, H.R. Rep. No. 2526, 87th Cong., 2d Sess. 26 (1962), *reprinted in* 1962 U.S. Code Cong. & Ad. News 2927, 2935 *and in* 23 Legislative History, *supra* note 28, at 161, 186. In any event, the enlarged scope of the proposed prohibition was directed towards production data. The House report accompanying H.R. 11,581 stated: "[I]n view of the broadened factory inspection authority contained in the bill, the . . . amendments to section 301(j) extend the prohibitions of this section. . . . " Drug Amendments of 1962, H.R. Rep. No. 2464, 87th Cong., 2d Sess. 15 (1962), *reprinted in* 22 Legislative History, *supra* note 28, at 984, 998.

99. 21 U.S.C. § 331(j) (1982).

100. S. 1944, 73d Cong., 1st Sess. §§ 6(b), 8(e), *reprinted in* 1 Legislative History, *supra* note 28, at 7, 11.

101. See *supra* notes 84-87 and accompanying text. Manufacturers may have been more wary of the factory inspection provision. As Walter G. Campbell, Chief of the FDA stated at the hearings on S. 1944: "I have had manufacturers of drug products

subsequent bills did not require such explicit labeling,[102] and prohibited disclosure of secret methods or processes that were obtained through factory permit or inspection procedures.[103]

Section 505 requires drug manufacturers to submit for FDA approval formulae, composition, and components used in a new drug, in addition to a description of the methods used in the drug's manufacturing, processing and packing.[104] Section 301(j) applies to the methods of manufacture, processing and packing obtained by virtue of section 505. It is arguable that section 301(j) was also meant to protect new-drug formulae and composition.[105] Although the earlier drafts subjected formulae to the labeling requirements,[106] these requirements were omitted, in response to industry complaints,[107] by the time the bill became law.[108] This omission supports the argument for including formulae and composition within section 301(j). It is unlikely that Congress intended to allow the FDA to disclose such data to the public when Congress decided against requiring the manufacturer to provide formula and composition on drug labels.

The safety and efficacy data required by section 505,[109] however, were unlikely to be discovered through factory permit or inspection

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tell me repeatedly that there was no objection to [the labeling] requirement; that it was not the ingredients or the composition of the article which constitute the secret, but rather the method of combining the various ingredients." *Hearings on S. 1944*, *supra* note 84, at 59, *reprinted in* 1 Legislative History, *supra* 28, at 151.

102. *See* S. 5, 74th Cong., 1st Sess. § 402(b) (1935) (requiring quantity disclosure in package labeling), *reprinted in* 3 Legislative History, *supra* note 28, at 13; S. 2800, 73d Cong., 2d Sess. § 6(b) (1934) (same), *reprinted in* 1 Legislative History, *supra* note 28, at 765; S. 2000, 73d Cong., 2d Sess. § 6(b) (1934) (same), *reprinted in* 1 Legislative History, *supra* note 28, at 603.

103. *See* S. 5, 74th Cong., 1st Sess. § 708(g) (1935), *reprinted in* 3 Legislative History, *supra* note 28, at 33; S. 2000, 73d Cong., 2d Sess. § 17(g) (1934), *reprinted in* 1 Legislative History, *supra* note 28, at 623; S. 2800, 73d Cong., 2d Sess. § 17(g) (1934), *reprinted in* 1 Legislative History, *supra* note 28, at 787.

104. 21 U.S.C. § 355(b) (1982).

105. In light of the vehement opposition expressed at the hearings on S. 1944 to the labeling requirements of the bill, the watering down of the provisions in subsequent bills must have been in response to the statements made at the hearings. See *supra* notes 84-87 and accompanying text. Disclosure of formulae and composition would result in at least as much competitive injury as would disclosure of a method or process of production. In this instance at least, the Restatement definition of trade secret applied to the scope of § 301(j) would accomplish the result Congress intended.

106. *See* S. 1944, 73d Cong., 1st Sess. §§ 6(b), 8(b) (1934), *reprinted in* 1 Legislative History, *supra* note 28, at 7, 10.

107. After the hearings on S. 1944, the Subcommittee's Statement With Reference to Revised Bill, S. 2800, stated that the changes retained the earlier aim of consumer protection "but they remove[d] the causes for apprehension so generally felt by reputable manufacturers . . . ." *Hearings on S. 1944*, *supra* note 84, at 494, *reprinted in* 1 Legislative History, *supra* note 28, at 585.

108. See *supra* notes 84-91 and accompanying text.

109. 21 U.S.C. § 355(b) (1982).

procedures. Accordingly, Congress could not have intended to protect this data by section 301(j)'s prohibition against disclosure.

The common-law definition of trade secret adopted by the court in *Citizen Health Research* appropriately delimits the scope of section 301(j)'s prohibition against disclosure of a "method or process which as a trade secret is entitled to protection."[110] Section 301(j) was intended to protect secret methods or processes used in the manufacturing process, not to prohibit disclosure of data, such as safety and efficacy data, that are unrelated to the production process.[111] A narrow, production-oriented definition of trade secret would protect data in the manner intended by Congress and thus should be adopted by the FDA in interpreting section 301(j). This approach would permit the FDA to issue substantive regulations authorizing disclosure of safety and efficacy data.[112] These regulations would advance the public welfare and afford more efficient enforcement of the Act by providing safer and more effective drugs.[113] Consequently, such regulations would furnish the authorization by law required by the Trade Secrets Act.[114]

These regulations should take into consideration the legitimate needs of the manufacturer, in addition to the public benefits accruing from disclosure of safety and efficacy data. To accomplish this, the regulation should take advantage of the benefits of discretionary disclosure, as opposed to mandatory disclosure under the FOIA. The FOIA requires disclosure to any member of the requesting public, including competitors.[115] Discretionary disclosure, on the other hand, would permit the FDA to release information when it determines that to do so is in the public interest.[116] Several factors may guide the FDA

110. 21 U.S.C. § 331(j) (1982).

111. See *supra* notes 79-92 and accompanying text.

112. Under the Restatement definition of trade secret, as applied to § 301(j), the FDA is prohibited by § 301(j) from releasing safety and efficacy data. If § 301(j) is read so as to not include safety and efficacy data, then the FDA is not prevented from disclosing safety and efficacy data. See *supra* notes 53-60 and accompanying text.

113. *See* 21 U.S.C. § 371(a) (1982) (providing that the FDA may "promulgate regulations for the efficient enforcement of [the Food, Drug, and Cosmetic Act]"). Because disclosure of safety and efficacy data would help ensure thorough review of manufacturer-submitted data, and hence further the Act's purpose of providing safer and more effective drugs for the public, disclosure of safety and efficacy data is "reasonably within the contemplation of [the] grant of [rulemaking] authority" given the the FDA in § 371(a). *See* Chrysler Corp. v. Brown, 441 U.S. 281, 306 (1979).

114. See *supra* notes 41-52 and accompanying text.

115. *See* 5 U.S.C. § 552(a)(3), (b) (1982).

116. In Westinghouse Elec. Corp. v. NRC, 555 F.2d 82 (3d Cir. 1977), the court held that a grant of authority similar to that given the FDA authorized the Nuclear Regulatory Commission (NRC) to disclose proprietary material exempt from the FOIA as trade secret when the NRC determined that the benefits of public appraisal of agency action outweigh the "demonstrated concern for protection of competitive position." *Id.* at 88, 93. The court noted that the regulations had been subject to extensive public comment. *Id.* at 86.

in exercising its discretion to release safety and efficacy data. The agency should consider whether release of the data will: 1) facilitate public evaluation of the data; 2) increase public awareness of internal FDA procedures; and 3) reduce the need for duplicative testing of the new drug.

Additionally, the FDA must protect the legitimate needs of the new-drug manufacturer by minimizing the disincentive to future research and development that may result from disclosure. Current FDA regulations, which state that once information is in the public domain it may be released to anyone requesting it,[117] should be revised to exclude safety and efficacy data released by the FDA pursuant to such "discretionary" regulation. The FDA should also explicitly prohibit the use of disclosed safety and efficacy data by drug manufacturers seeking to use such data in support of their own NDA. The FDA has suggested that a five-year period in which other manufacturers could not use such data would be adequate to protect the submitting manufacturer.[118]

Conclusion

Adoption of the *Citizen Health Research* definition of trade secret by the FDA is appropriate in light of the legislative history of section 301(j) of the Act. If this definition is applied, the FDA may, and should, issue regulations promoting discretionary disclosure of safety and efficacy data.

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117. 21 C.F.R. § 20.81(a) (1983).

118. *See Drug Regulation Reform Act of 1979: Hearings on S. 1075 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Labor and Human Resources*, 96th Cong., 1st. Sess. 378 (1979) (testimony of Donald Kennedy, Comm'r, FDA); Final Report, *supra* note 7, at A-3.