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Private Litigation under the Federal Food, Drug and Cosmetic Act: Should the Right to Sue Be Implied?

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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land: the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis contributions and comments are invited.

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TO THE READER

The question of whether a person injured by violation of a federal statute is entitled to a private right of action is a debated and troublesome subject. *Richard Cole* and *Marc Shapiro* discuss this topic in relation to the Federal Food, Drug and Cosmetic Act in their joint article "Private Litigation under the Federal Food, Drug and Cosmetic Act: Should the Right to Sue Be Implied?" In analyzing the issue, the authors refer to case history both under the Act and under other federal statutes. They identify the factors important to courts in deciding whether to accord a private right of action and apply them to the Act. They consider the importance of implying private rights of action and suggest the types of cases in which such rights might be utilized under the Federal Food, Drug and Cosmetic Act. Since the wording of the Act does not expressly preclude implication of private rights of action, the legislative history of the Act is analyzed. The authors explore the possibiltiy of alternative remedies, pointing out both the advantages and disadvantages of different state and federal administrative and common law remedies. In their conclusion, Cole and Shapiro suggest some possible solutions to this question. Mr. Cole is a member of the Virginia bar and is currently serving as a legal specialist with the United States Coast Guard. Mr. Shapiro is an associate of the law firm of Kleinfeld, Kaplan and Becker. Their article begins on page 576.

"Drug and Device Establishment Inspections" is a discussion of the Food and Drug Administration's constitutional and statutory authority to inspect establishments which manufacture, process, pack or hold drugs and medical devices. Written by *Thomas O. Henteleff*, a partner with the law firm of Kleinfeld, Kaplan and Becker, the article contains an analysis of several Supreme Court cases which concern the right of owners to refuse administrative searches in the absence of a search warrant. Mr. Henteleff also details the differences between the Agency's inspection authority of drugs and its authority over devices. The article, which begins on page 613, ends with a description of two Congressional bills which would substantially increase the Agency's power in relation to devices.

"Lawyers of the FDA—Yesterday and Today" is the title and the subject of an article by *Francis E. McKay*. Mr. McKay, Chief of the Pleadings Branch in the Food and Drug Division of the Department of Health, Education and Welfare Office of the General Counsel, writes about the beginnings of the Food and Drug Administration as the Food and Drug Section of the Solicitor's Office of the Department of Agriculture. He recounts the history of the Agency and the lawyers who did and still do work for it. The article begins on page 621.

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Journal

Private Litigation under the Federal Food, Drug and Cosmetic Act: Should the Right to Sue Be Implied?

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I. Introduction

A. Scope of Article.

WHEN AN INDIVIDUAL IS INJURED by conduct which constitutes a violation of a federal regulatory statute, should that person be able to sue for relief under the statute? If the statute is the Federal Food, Drug and Cosmetic Act,[1] the individual will search its

* The authors wish to thank Richard A. Merrill, who as a Professor at the University of Virginia School of Law, graciously offered helpful comments and suggestions during the preparation of this article. The authors also wish to state that the views and opinions expressed here are solely their own.

[1] The Federal Food, Drug and Cosmetic Act, as amended in 1971, appears at 21 U. S. C. Secs. 301-392. It will hereinafter be referred to as "the Act" or "the Food and Drug Act." Sections of the Act will be referred to in text by the numbers in the Act itself, rather than by those in the United States Code.

The Act establishes two broad categories of violations—those which are defined as adulteration and those defined as misbranding. The adulteration con-

(Continued on next page.)

provisions in vain, for no section authorizes a private individual harmed by conduct that violates the Act to recover damages for an injury. Nor is there a provision for a private individual to attempt to enjoin actions that are in violation of the Act. Statutory silence concerning such private actions, however, does not preclude a court from implying these rights of action. This article will examine the possible implication of such private rights of action under the Food and Drug Act.[2]

The question whether a court should imply a private cause of action for persons injured by violation of a federal regulatory statute is one which has often been raised where the statute contains no express provision for private enforcement.[3] The first Supreme Court case recogniz-

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(Footnote 1 continued.)
cept focuses on the physical condition of foods and drugs. Sec. 402 deals with the presence of contamination in food in the form of poisonous or deleterious substances (physical adulteration) or such economic adulteration as the addition of ingredients to foods to make them appear better than they are or the removal of valuable constituents. The concept of misbranding in Sec. 403 deals with representation, such as whether the labeling or containers are false or misleading, whether food is falsely represented as a food for which standards of identity have been set, and whether there is proper label disclosure of ingredients. The application of these basic concepts in the drug area in Secs. 501 and 502 is analogous to that in the food area.

[2] These private rights of action could, of course, be explicitly provided for by Congress. This possibility will be discussed in the conclusion.

[3] The United States Supreme Court has implied private rights of action, for example, in *Allen v. State Board of Electors*, 393 U. S. 544 (1969) (Voting Rights Act of 1965); *Wyandotte Transp. Co. v. United States*, 389 U. S. 191 (1967) (Rivers and Harbors Appropriation Act of 1899); *Textile Workers v. Lincoln Mills*, 353 U. S. 448 (1957) (Labor Management Relations Act); and *Tunstall v. Brotherhood of Locomotive Firemen and Enginemen*, 323 U. S. 210 (1944) (Railway Labor Act). It has denied private rights of action in *Cort v. Ash*, 43 U. S. L. W. 4773 (June 17, 1975) (Federal Election Campaign Act of 1971); *National Railroad Passenger Corp. v. National Association of Railroad Passengers*, 414 U. S. 453 (1974) (Rail Passenger Service Act of 1970); and *Montana-Dakota Util. Co. v. Northwestern Public Service Co.*, 341 U. S. 246 (1951) (Federal Power Act). Circuit and district court decisions implying private rights of action include: *Burke v. Compania Mexicana de Aviacion, S. A.*, 433 F. 2d 1031 (CA-9 1970) (National Railway Labor Act); *Gomez v. Florida State Employment Service*, 417 F. 2d 569 (CA-5 1969) (Wagner-Peyser Act of 1933); *Fitzgerald v. Pan American World Airways, Inc.*, 229 F. 2d 499 (CA-2 1956) (Civil Aeronautics Act of 1938); *Reitmeister v. Reitmeister*, 162 F. 2d 691 (CA-2 1947) (Communications Act of 1934); *Farmland Indus., Inc. v. Kansas-Nebraska Natural Gas Co.*, 349 F. Supp. 670 (DC Neb. 1972) (Natural Gas Act); *Common Cause v. Democratic Nat'l Comm.*, 333 F. Supp. 803 (DC D of C 1971) (Corrupt Practices Act); *Fagot v. Flintkote Co.*, 305 F. Supp. 407 (DC ED La. 1969) (Fair Labor Standards Act); and *Wills v. Trans World Airlines*, 200 F. Supp. 360 (DC SD Cal. 1961) (Federal Aviation Act). Lower federal decisions denying implied private rights of action include: *Intracoastal Transp., Inc. v. Decatur County*, 482 F. 2d 361 (CA-5 1973) (Bridge Act of 1906); *McCord v. Dixie Aviation Corp.*, 450 F. 2d 1129 (CA-10 1971) (Federal

(Continued on next page.)

ing an implied federal right of action for violation of a federal regulatory statute was *Texas v. Rigsby*.[4] In that case, an employee of a railroad company had been injured in a fall caused by a defective grab iron. He was suing for damages based on a violation of the Federal Safety Appliance Act. In holding that the employee had an implied right under the statute to sue for its violation, the court offered what was to become a much-quoted formulation of the rationale for implication:

"A disregard of the command of a statute is a wrongful act, and where it results in damage to one of a class for whose especial benefit the statute was enacted, the right to recover damages from the party in default is implied . . . ."[5]

Since that case, judicial decisions concerning whether or not to imply a private right of action have been based on many more sophisticated and complicated factors. It is no longer sufficient merely to show that the plaintiff was meant to be protected by the statute and that the harm suffered was of the kind the statute was meant to prevent.

In approaching the question of whether a private right of action should be implied for violations of the Federal Food, Drug and Cosmetic Act, the first considerations will be the importance of according private rights of action and the types of cases in which such private rights might be utilized under the Act. The focus will then shift to a consideration of the Act itself—its present enforcement provisions, its legislative history, and the adverse decisions of courts that have considered implication of private rights of action for its violation. After briefly considering the role of the court as a lawmaker when it engages in implication, those factors important to courts in deciding whether to imply private rights of action under other federal statutes will be identified and applied to the Act. Finally, a judgment will be made as to whether a court should imply a private right of action under the Food and Drug Act and, if so, what limits might be appropriate in defining the cause of action.

B. Value of Implied Private Remedy.

The failure of the Food and Drug Act to provide remedies to the injured consumer does not mean that the consumer is without recourse. There may be remedies available under state common or statutory law for conduct that would constitute a violation of the Act. The case

(Footnote 3 continued.)
Aviation Act of 1958); *Royal Serv., Inc. v. Maintenance, Inc.*, 361 F. 2d 86 (CA-5 1966) (Small Business Act); and *Acorn Iron and Supply Co. v. Bethlehem Steel Co.*, 96 F. Supp. 481 (DC ED Pa. 1951) (Defense Production Act of 1950).

[4] 241 U. S. 33 (1916).

[5] *Id.* at 39.

for implying a federal remedy is, of course, strongest where no common law or statutory remedy exists.[6]

However, even where a state remedy exists, there may be reasons why an implied federal private action would be advantageous for a plaintiff. One reason is that diversity of citizenship would not be required for use of the federal courts, since the right would "arise under" a federal statute and, thus, would support jurisdiction in the federal courts.[7] Alternatively, the court might base its jurisdiction on 28 U. S. C. Sec. 1337, as the Act is both a statute of the United States and an act of Congress regulating interstate commerce.[8] In either case, the consumer would gain the advantage of being able to choose between state and federal courts.

A federal right of action may lead to substantive advantages for the plaintiff in proving his case. The common law defenses of contributory negligence and assumption of risk in negligence actions may be eliminated or narrowed by a federal court defining the cause of action, which would be a distinct advantage to plaintiff consumers.[9] It is also possible that difficulties in proving intent and reliance in common law fraud actions may be reduced in a federal action for violation

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[6] See *Colonial Realty Corp. v. Bache & Co.*, 358 F. 2d 178, 182 (CA-2 1966), cert. denied 358 U. S. 817 (1966); *Mounger v. Brandt*, 250 F. Supp. 445 (DC WD Wis. 1966). See generally Note, "Implying Civil Remedies from Federal Regulatory Statutes," 77 *Harvard Law Review* 285, 290 (1963).

[7] Implication would therefore provide an individual with the opportunity to use the federal courts under their federal question jurisdiction to redress harm caused by violation of the Act. This jurisdiction is granted in 28 U. S. C. Sec. 1331(a), which reads: "The district courts shall have original jurisdiction of all civil actions wherein the matter in controversy exceeds the sum or value of $10,000, exclusive of interest and costs, and arises under the Constitution, laws, or treaties of the United States."

[8] The section reads: "The district courts shall have original jurisdiction of any civil action or proceeding arising under Act of Congress regulating commerce. . . ." Use of this section as a basis for jurisdiction would afford the consumer the advantage of not having to meet the $10,000 jurisdictional amount required under 28 U. S. C. Sec. 1331(a).

[9] In discussing statutes under which courts have abolished defenses of contributory negligence or assumption of risk, Prosser describes them as ". . . statutes . . . which clearly are intended to protect the plaintiff against his own inability to protect himself, including his own lack of judgment or inability to resist various pressures." W. Prosser, *Handbook of the Law of Torts* Secs. 65, 68 at 425, 453 (4th ed. 1971). This description would seem also to apply to the Act, in its provisions concerning both foods and drugs. In relation to the possible elimination of such defenses under the Act, see Note, "Developments in the Law: The Federal Food, Drug, and Cosmetic Act," 67 *Harvard Law Review* 632, 722 (1954).

of the Act.[10] In short, the burden of proving his case may be lighter for the consumer in the federal courts under the federal statute than in the state courts under state law.

There are also possible procedural advantages in having a federal action available. In many cases it would afford the individual a broader range of discovery devices than would be available in many state courts, an advantage which seems critical in the food and drug area where the alleged violator will often possess the best information as to the existence of a violation.[11] Where the plaintiff has the choice of suing in federal or state court, he will be able to include as factors in his decision the more advantageous of their respective statutes of limitations, venue requirements, and security for costs requirements. Finally, the use of the federal courts rather than state courts should lead to more uniform results.

C. Instances Where Private Remedy Might Be Sought.

The above considerations apply generally to implication of private rights of action under any federal regulatory statute. But how might private individuals seek to exercise a private right of action under the Food and Drug Act? The most common way would be in those instances where an individual, who sustained a physical injury proximately caused by a violation of the Act, attempts to sue for damages. For example, it would be possible that the ingestion of a misbranded drug, taken in reliance on the misleading label would cause physical injury to the individual. That individual could then sue the offending drug company on the basis of the alleged violation of the Act, arguing that such violation would create a federal cause of action arising under federal law.[12]

Plaintiffs might also invoke an implied cause of action for damages stemming from economic, as well as physical, injury. Where, for example, a person sustains economic injury resulting from the deaths of his horses after they were fed adulterated food, he might seek to assert a right of action arising from violation of federal law,[13] predicating jurisdiction on either the existence of a federal question under 28 U. S. C.

[10] On the difficulties facing the consumer in common law actions for misrepresentation and deceit, see Note, "Private Remedies Under the Consumer Fraud Acts: The Judicial Approaches of Statutory Interpretation and Implication," 67 *Northwestern University Law Review* 413, 417 (1972).

[11] This would be so at least in those states which do not have procedure codes modeled after the Federal Rules of Civil Procedure. Note, "Developments in the Law—Discovery," 74 *Harvard Law Review* 940, 950 (1961).

[12] See *Powell v. Kull*, 329 F. Supp. 193 (DC MD Pa. 1971).

[13] See *Wells v. Wells*, 240 F. Supp. 283 (DC WD Ky. 1965).

Sec. 1331(a) or on the fact that the action arises under an act of Congress regulating commerce under 28 U. S. C. Sec. 1337.

Further, individuals may seek to enforce the Act through injunctive actions. For instance, a peanut butter manufacturer might discover that a competitor's product is not complying with the FDA standard of identity for peanut butter and, thereby, is in violation of the Act. The manufacturer might reasonably want to obtain an injunction to prevent this violation from continuing. By asserting this violation of the Act, the manufacturer could argue that a private cause of action is impliedly created by the Act which allows him to seek equitable relief. Likewise, a public interest group, alleging that a product being manufactured in violation of the Act is injuring consumers, economically or physically, might also seek an injunction to end the violation. These are a few examples of situations in which private parties might seek to compel compliance with the Act or to recover damages for injuries resulting from its violation.

II. Previous Interpretation of the Federal Food, Drug and Cosmetic Act on the Implication Issue

A. Statutory Language.

The Act currently provides three basic mechanisms of governmental enforcement: criminal prosecution;[14] injunction;[15] and seizure.[16] Thus the Food and Drug Administration (FDA), upon finding a violation of the Act, can turn to any of these court enforcement tools. In addition, the Agency has utilized non-statutory methods of enforcement (voluntary recall,[17] publicity,[18] and warning or "regulatory" letters[19]) under threat of the statutory enforcement techniques. The fact remains, however, that all of these enforcement mechanisms can be instituted only by the government, not by private individuals or groups. This seems implicit in Section 307 of the Act, which provides, in part, that, "All such proceedings for the enforcement, or to restrain violations of this Act shall be by and in the name of the United States."

It may be that the purpose of Section 307 was not aimed at demanding government, as opposed to private, enforcement of the Act, but rather

[14] The Act, Sec. 303, 21 U. S. C. Sec. 333 (1970).

[15] The Act, Sec. 302, 21 U. S. C. Sec. 332 (1970).

[16] The Act, Sec. 304, 21 U. S. C. Sec. 334 (1970).

[17] *Symposium on Recalls*, 27 Food Drug Cosmetic Law Journal 332-354 (June 1972); Gellhorn, "Adverse Publicity by Administrative Agencies," 88 *Harvard Law Review* 1380, 1407-16 (1973).

[18] Gellhorn, "Adverse Publicity by Administrative Agencies," *supra* note 17.

[19] FDA Regulatory Procedure Manual, Ch. 8-10, Regulatory Letters.

its purpose was to require court enforcement by the Justice Department, as opposed to the FDA. It is the Justice Department, in the name of the United States, which brings the actions into court. An examination of legislative history shows a lack of debate on the meaning of Section 307. Furthermore, if the word "such" is interpreted as referring to the enforcement proceedings explicitly provided for in the Act—as seems logical— then Section 307 would not foreclose implied private remedies.

Nonetheless, the language of the statute appears to preclude any input by private parties into the statutory enforcement scheme as there are no formal, statutory methods for instigation of citizens' complaints or for intervention by private parties. Although a first reading of the statute would indicate that its inforcement lies solely in the hands of the government, Section 307 also can be read as not precluding implied private actions. Since there was a lack of any Congressional debate on the topic, the language of the Act alone should not bar a private right of action.

B. Legislative History.

If the wording of the Act does not expressly preclude implied private rights of action, it is appropriate here to consider the legislative history of the Act. If an examination of the legislative history revealed an unambiguous intent by Congress that private rights of action are or are not to be recognized, then there is no reason to delve into various policy considerations as to whether such a right should be implied.

In 1933, while Congress was considering a revision and update of the 1906 Pure Food and Drug Act, Section 24 in Senate Bill 1944 was proposed for inclusion in the new law. This section provided for a private right of action for damages and read: "LIABILITY FOR PERSONAL INJURIES—A right of action for damages shall accrue to any person for injury or death proximately caused by violation of this Act."[20] The fact that this proposed section was eventually dropped in later versions of the new Act has led one commentator to conclude that Congress had shown its intent that there not be a private right of action under the Act.[21]

There was scant attention paid to this provision at the Senate hearings. Probably the most significant exchange occurred between the subcommittee Chairman, Senator Copeland, and a representative

[20] Hearings on S. B. 1944 before a subcommittee of the Senate Committee on Commerce, 73rd Congress, 2nd Session, at 10 (1933).

[21] Sales, "Does the FDC Act Create a Private Right of Action?," 28 Food Drug Cosmetic Law Journal 501, 505-508 (August 1973).

of the Department of Agriculture, which was to be responsible for enforcing the Act.

> Senator Copeland: "Let me ask you about section 24 on page 31. Is that a little gratuitous?"
>
> Mr. Campbell: "That is a statement of legal rights."
>
> Senator Copeland: "They have that power now, if they ever will get it?"
>
> Mr. Campbell: "Right."[22]

There is no recorded debate on this proposed section among members of the subcommittee.[23] Statements made by industry representatives concurred in the assessment that the section was unnecessary.[24] Although a conclusion that the subcommittee did not want to go beyond common law rights is a permissible one to draw from the exchange quoted above and the subsequent deletion of the provision, it has also been read as arguably showing that Congress intended a private right of action without Section 24.[25]

Extension of Common Law Rights

Although there were objections raised to this section based on its possible extension of common law rights,[26] the basic criticism was that it was unnecessary and would only serve to call consumers' attention to rights they already had. This would lead consumers to assert those rights more frequently, and the section would thus serve as "an embarrassment to honest manufacturers. . . ."[27] Thus, the legislative history simply does not provide an answer as to what Congress intended in 1933. There was no debate or consideration given to the merits of having a private right of action, and the reasons for deletion of Section 24 are unclear.

Finally, it should be pointed out that if Section 24 did embody a new private right of action, then the forerunner of the present enforcement provision of the Act, Section 307 (providing for enforcement in the name of the United States), could not have been seen by the drafters to be exclusive, for the two provisions appear in the same Act. This juxtaposition lends further credence to reading the "All such actions

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[22] Hearings, *supra* note 20, at 81.

[23] See generally Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record* (1938).

[24] Hearings, *supra* note 20, at 20-21.

[25] Note, "Developments in the Law: The Federal Food, Drug, and Cosmetic Act," 67 *Harvard Law Review* 632, 722 (1954).

[26] Hearings, *supra* note 20, at 114.

[27] *Id.* at 161, 219.

. . ." language in Section 307 as limited only to those enforcement actions previously explicitly authorized.

In 1934, another proposed section of the new Act declared certain violations of the Act to be public nuisances.

"Section 19.(a) Each of the following acts is hereby declared a public nuisance: (1) The repetitious introduction into interstate commerce of any adulterated or misbranded food, drug, or cosmetic. (2) The repetitious dissemination of any false advertisement for radio broadcast, United States mails, or interstate commerce for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics. (3) The repetitious dissemination of a false advertisement by any means for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics in interstate commerce. . . ."[28]

The conclusion has been drawn from this provision that "[s]ince a public nuisance may be enforced by a private party when he can show special injury, we must conclude, once again, that an attempt was made to extend the common law rights of private citizens under the act."[29] The fact is that not once did any member of Congress mention the effect of this provision on private rights.[30] One analysis of this provision suggests that the nuisance language was probably intended only to place the section in a familiar judicial framework to justify the injunction remedy, thereby eliminating any risk of the section being invalidated.[31] In a statement on this provision, the FDA made clear that it thought of this provision only as a means of avoiding a multiplicity of suits where a manufacturer indulged in repeated and frequent violations.[32]

Thus, the legislative history of the 1938 Act, while certainly not indicating an unambiguous intent by Congress that there be private rights of action under the Act, should not be read to preclude the implication of such rights of action. Rather, this examination of the Act's legislative history is inconclusive concerning any intent regarding private rights of action. That question never seems to have been a topic of debate among members of a Congressional subcommittee or on the floor of either house. This examination of legislative history supports the judgment of one writer that,

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[28] 78 *Congressional Record* 4567, 4570 (1934).

[29] Sales, "Does the FDC Act Create a Private Right of Action?," *supra* note 21, at 507-508.

[30] See generally Dunn, *Legislative Record*, *supra* note 23.

[31] Fisher, "The Proposed Food and Drugs Act: A Legal Critique," 1 *Law and Contemporary Problems* 74, 113 (1933).

[32] Dunn, *Legislative Record*, *supra* note 23, at 130.

"With the exception of rare cases, the process of deciding whether to imply a cause of action is more likely to be hindered than helped when placed in the narrow context of a search for tokens of legislative intent."[33]

C. Case Development.

To see how the legislative history and language of the statute have been operative in case law, consider the following presentation of cases that have dealt with the issue of implication of private rights of action. Among the cases which have indirectly considered the issue is *Orthopedic Equipment Co. v. Eutsler.*[34] In that case, the plaintiff charged negligence in the misbranding of a surgical nail which had been inserted in his leg. Markings on the nail had indicated that a certain size hole should be drilled in a bone in the patient's leg before the nail's insertion. The nail, however, proved too large for the hole drilled of that size. Forcing of the nail into the hole led to a condition where amputation of the leg was necessary.

The Fourth Circuit said that although

"... the Food and Drug Act does not expressly provide a civil remedy for injured consumers, it imposes an absolute duty on manufacturers not to misbrand their products and the breach of such duty may give rise to civil liability."[35]

But such liability referred to liability as it might exist under state law, and was not a liability that arose as a federal cause of action. Federal jurisdiction was based in this case on diversity of citizenship, but the right of action arose under state law. The case stands for the proposition that violation of the federal Act might establish negligence as a matter of law in a state cause of action. As the Court noted:

"The majority of American courts which have passed on this question, in cases arising under state laws resembling the Federal Act, have held violations to be negligence per se."[36]

In *Wells v. Wells,*[37] the plaintiff sought damages in the amount of $225,000 because of the defendant's sale of contaminated oats which caused the deaths of plaintiff's horses. The federal district court dismissed for lack of jurisdiction, holding that this was a common law action and not an action arising under the laws of the United States, the Food and Drug Act in particular. The Court's opinion can be described as conclusionary at best.

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[33] Note, "Implying Civil Remedies from Federal Regulatory Statutes," 77 *Harvard Law Review* 285, 291 (1963).

[34] 276 F. 2d 455 (CA-4 1960).

[35] *Id.* at 460.

[36] *Id.* at 460 and cases cited therein.

[37] 240 F. Supp. 283 (DC WD Ky. 1965).

In a case which met the issue of implication more squarely than the previous ones, *Clairol, Inc. v. Suburban Cosmetics and Beauty Supply,*[38] the plaintiff sought an injunction to prevent the defendant from selling to the general public the plaintiff's product, a coal tar dye which had been specifically packaged, labeled and distributed by the plaintiff for professional use only. Such sale of the product by the defendant could subject the product to seizure by the FDA since sale to the general public would be in violation of the federal Act. The defendant sought to remove the case to federal court arguing that the plaintiff's complaint raised a federal question under the Federal Food, Drug and Cosmetic Act.

The federal district court disagreed with this assertion, viewing the action as one based on the state law of unfair business practices. In fact, the court, relying on the statutory language indicating that suits were to be brought in the name of the United States, stated that it did not appear that a suit could be brought under the Act by a private individual. Plaintiff's reference to the Act in his complaint was seen as simply a means of showing that irreparable harm would occur (seizure of his products), thus entitling him to relief at common law for unfair competition. The Court went on to note:

"The defendant argues that the fact that § 337 of Title 21 (§ 307) provides for enforcement by the United States Government does not preclude a civil action for damages by private parties. It bases this contention on the theory that a civil remedy will be implied from a criminal statute where the public welfare involved or the personal interest invaded is one which the criminal statute is intended to protect. Defendant points to *Orthopedic Equipment Co. v. Eutsler* . . . . in support of its contention that the Federal Food, Drug, and Cosmetic Act creates such a private, federally based cause of action. The jurisdiction of the court in *Eutsler*, however, was based on diversity of citizenship and the court's decision as to the defendant's liability was based on its interpretation of the law of Virginia . . . . That decision therefore does not stand for the proposition that a private civil remedy exists under the Federal Food, Drug, and Cosmetic Act. Indeed, there does not seem to be any case in which such a remedy has been recognized."[39]

In *Cross v. Board of Supervisors of San Mateo County,*[40] the plaintiff sought to enjoin defendants who manufactured, distributed and used air freshener devices, which were alleged to be falsely labeled concerning chemical makeup and effect and, thereby, detrimental to

[38] 278 F. Supp. 859 (DC ND Ill. 1968).

[39] *Id.* at 861. See also *Powell v. Kull,* 329 F. Supp. 364 (DC SD Fla. 1971), where plaintiff's action for damages for death of plaintiff's decedent, allegedly caused by the prescription of misbranded drugs, was dismissed. The court concluded on the authority of *Eutsler* and *Clairol* that there was no federal question raised and, therefore, no federal jurisdiction under 28 U. S. C. Sec. 1331(a).

[40] 326 F. Supp. 634 (DC ND Cal. 1968), affirmed, 442 F. 2d 362 (CA-9 1971).

people's health and welfare. The district court made short shrift of an attempt to base this action on the Food and Drug Act.

"Congress has established the procedural means through which the Secretary of Health, Education, and Welfare may enforce the provisions of this Act. It is further provided in this Act that .... [The Court refers to Section 307]. The mere allegation that this act has been violated is not a statement of a claim for relief in favor of a private individual. *Clairol, Inc. v. Suburban Cosmetics and Beauty Supply*, 278 F. Supp. 859 (N. D. Ill., 1968)."[41]

While the Court in *Cross* relied upon Section 307 to deny a federal right of action, a federal district court, in *State of Florida v. Eli Lilly Co.*,[42] cited the legislative history in addition. It was the Court's view that:

"The legislative history of the Act indicates that an express provision for a private right of action for damages was included in an early version of the bill but was omitted from all later versions after being attacked on the ground that it would create an unnecessary federal action duplicative of state remedies. Thus, the terms and legislative history of the statute compel the conclusion that Congress did not intend to allow private rights of action for damages under the statute."[43]

The district court distinguished the case from others in which private rights of action had been recognized.

"Plaintiff's reliance upon cases arising under other federal regulatory statutes is misplaced .... First, the federal statutes involved in those cases had [no] provisions requiring all actions to be brought by the United States .... Secondly, those decisions did not deal with legislative history like that of the Food, Drug, and Cosmetic Act, showing explicit rejections by Congress of a provision for private actions. Finally such decisions typically involved claims for which no corresponding civil remedies are available in state courts."[44]

An analysis of these cases suggests that it is Section 307 and what the courts have felt to be negative legislative history that have deterred the courts from implying a private right of action. As suggested earlier, however, Section 307 should not necessarily be a bar to a private right of action, and the legislative history can hardly be seen as conclusive on the issue.

III. Ability of Federal Courts to Exercise a Lawmaking Function

While federal courts have not implied a private right of action arising from the Act, that does not put the question to rest. Such an action could be created on those policy grounds that courts have traditionally considered in implication cases, notwithstanding the

[41] *Id.* at 638.
[42] 329 F. Supp. 364 (DC SD Fla. 1971).
[43] *Id.* at 365.
[44] *Id.* at 366.

prior adverse decisions, which we submit rest on shaky assumptions. Clearly Congress could create a right of action on behalf of private individuals as it sees fit. In fact, a bill providing for the institution of citizen suits in a particular situation is before the 94th Congress.[45]

[45] S. B. 641, the Consumer Food Act of 1975, sponsored by Senators Moss, Magnuson and Hart, provides for "Citizens' Civil Suits." However, this provision is in itself very limited. It provides in Section 410:

"(g)(1) Except as provided in paragraph (2) of this subsection, any person may commence a civil action for mandatory or prohibitive injunctive relief, including interim equitable relief, on his own behalf, whenever such action constitutes a case or controversy—

(A) against any person (including the Secretary) who is alleged to be in violation of any regulation promulgated under subsection (c)(1) of this section or

(B) against the Secretary where there is alleged a failure of the Secretary to comply with the safety assurance plan established under subsection (b) of this section or to perform any act or duty under this section which is not discretionary with the Secretary.

The district courts of the United States shall have jurisdiction over actions brought under this section, without regard to the amount in controversy or the citizenship of the parties.

(2) No civil action may be commenced—

(A) under paragraph (1)(A) of this subsection—

(i) prior to 60 days after the plaintiff has given notice of the alleged violation to the Secretary and to any alleged violator in such manner as the Secretary may by regulation require; or

(ii) if the Attorney General or the Secretary has commenced and is diligently prosecuting proceedings with respect to such alleged violation.

(B) under paragraph (1)(B) of this subsection, prior to 60 days after the plaintiff has given notice to the Secretary of such alleged failure to comply with the plan or to perform an act or duty.

(3) In any action under this subsection the Attorney General or the Secretary may intervene as a matter of right.

(4) The court, in issuing any final order in any action brought pursuant to paragraph (1) of this subsection, may award costs of litigation (including reasonable attorney and expert witness fees) to any party, whenever the court determines such an award is appropriate.

(5) Nothing in this subsection shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of any regulation or order or to seek any other relief.

(6) For purposes of this subsection, the term 'person' means an individual, corporation, partnership, association, State, municipality, or political subdivision of a State."

Thus, there is a limitation in the relief that would be available under this section, the section providing only for injunctive relief. No provision is made for damages. Further, this relief could only be sought in limited instances, only where there is alleged to be a violation of any regulation promulgated under Subsection (c)(1) of the same section. Regulations promulgated under (c)(1) establish safety assurance standards to reduce the risk of adulteration by food processors. The "citizen suit" provisions in no way provide for other types of relief or relief in other situations. (Discussion will not be made here of suits to require the Secretary to perform nondiscretionary acts or duties under the section.)

(Continued on next page.)

Absent Congressional action, however, and assuming there are sufficient policy grounds in favor of a private right of action, one must still establish that it is within the proper role of the federal courts to create such rights of action. For if it is not, then consideration of those grounds becomes a purely academic exercise.

The following discussion will consider a court's power to imply rights of action, or its lawmaking authority, and not the separate issue of a court's ability to administer rights of action. That latter issue is one of the distinct policy questions in considering whether a private right of action should be created.

In considering courts' powers to make law, it has been said:

"... beyond Congressional intent lies federal common law, or at least a concept of inherent judicial power, and the doctrine of implied remedies has limited proper application unless it is conceded that federal courts have some role as coordinate lawmakers.

Uncertainty as to the courts' lawmaking power is peculiar to the federal courts where, at least since *Erie R.R. v. Tompkins*, judges have been regarded as a questionable source of new law outside a statutory or constitutional framework. Even so, it seems clear that federal courts do perform a lawmaking function in some areas and that one of these lies in the penumbra of federal legislation."[46]

The argument against the role of federal courts as lawmakers is that the exercise of such authority is a violation of the doctrine of separation of powers, as the lawmaking power is intended to lie with the legislature, not the judiciary. The capability to resolve the policy

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(Footnote 45 continued.)

However, while the possibility of passage of S. B. 641 remains slim, one must address the question of what effect subsequent passage of this provision might have on the ability of courts to imply private rights of action for violations of the Act other than under Subsection (c)(1) or to provide relief for violations of Subsection (c)(1) other than injunctive relief. It might be argued that under the doctrine *expressio unius est exclusio alterius*, Congress intended that, by expressly providing here for this particular right of citizen relief, other forms of private rights of action or relief were to be excluded. However, that argument can be diminished by the very words of the "citizen suit" provision itself. Paragraph (5) provides, "Nothing in this subsection shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of any regulation or order or to seek any other relief."

Surely, one meaning of paragraph (5) is that pre-existing state or common law remedies are not to be foreclosed by the federal provision. More than that, however, paragraph (5) would make it difficult for any court to read the citizen suit provision as precluding other private rights of action, when private rights of action, if they exist and whatever they are, are preserved in paragraph (5). While paragraph (5) may not be an affirmative direction to allow or encourage courts to create private rights of action, it clearly means that Section 410(g) is not meant to preclude them, without stating one way or the other whether Congress intended in 1938 for private rights of action to exist.

[46] Note, "Implying Civil Remedies from Federal Regulatory Statutes," *supra* note 33.

conflicts regarding what types of relief should be provided and in what instances is to repose in the legislature. The courts do not have the capability to engage in the extensive debates and hearings necessary to resolve large policy questions. Further, there may be an inherent unfairness in the retroactive effect of a court's solution. And finally, there can be no public mandate vindicating the court's decision.

However, such problems are greatly diminished where the conduct involved has already been proscribed by the legislature and all that the court is doing is providing an additional remedy. As has been said:

"...making its decision in relation to an existing and functioning statute, the court may be in an even better position to assess the need for supplemental civil relief than was the legislature at the time of enactment."[47]

This seems especially so where, after the statute has been in operation over a period of time, the court can determine whether additional modes of relief are necessary to enable the staute tc achieve its aims. In sum, there is a strong argument for allowing federal courts a role as lawmakers, especially when the court is merely supplying a remedy for conduct already proscribed by the legislature. Further, this position has become recognized doctrine. Courts, in a number of instances, have implied private rights of action, and these decisions have been sustained, even by the Supreme Court.[48]

IV. Generally Recognized Criteria for Implication as Applied to the Federal Food, Drug and Cosmetic Act

Working on the assumption that it would be within the authority of a federal court to imply a private right of action for violations of the Food and Drug Act, the following questions remain: Should courts imply these remedies? What are the criteria by which this decision is to be made? Does the Food and Drug Act meet these criteria? Several general criteria have been identified for implication over a range of federal statutes. They are:

(1) *Protected class:* Are the plaintiffs within the class of persons intended to be protected by the statute?

(2) *General statutory considerations:* Does the presence or absence of any language in the statute itself help in determining whether a private action may arise?

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[47] *Id.* at 291.

[48] For example, *J. I. Case v. Borak*, 377 U. S. 426 (1964); *Allen v. State Board of Electors*, 393 U. S. 544 (1969).

(3) *Alternative administrative remedies:* Are there remedies available through the agency which would make the implication of a private right of action superfluous?

(4) *Alternative state remedies:* Are there remedies available under state law which would make the implication of a federal private right of action superfluous?

(5) *Role of the court:* Would a federal court have the ability or expertise to administer a private right of action?

(6) *Effect on regulatory scheme:* Would a private right of action upset a delicate administrative enforcement balance? Would a private right of action effectively supplement agency enforcement and further serve the purpose of the statute?

Each of these criteria will be discussed in turn and applied to the implication of private rights of action under the Food and Drug Act. The results of this analysis will provide an effective guide for determining whether and when a court should imply a private right of action.

A. Protected Class.

It has often been said that when a person in the class for whose benefit a statute was enacted suffers a harm which the statute was designed to prevent, that person ought to have a remedy against the violator.[49] The food and drug consuming public constitutes the class to be protected by the Act, and their physical and economic losses are the harms the statute is intended to prevent.

The case is not so easily made that the statute was designed to protect competitors in the food and drug market from one another, as in the case of a soup manufacturer whose competitor is not complying with the prescribed good manufacturing practices, and thereby is lowering costs. However, since enforcement of the statute would necessarily protect such competitors from what otherwise would be an unfair competitive practice, competitors are impliedly within the class protected. Further, these practices are within the harms

[49] See *Cort v. Ash*, 43 U. S. L. W. 4773 (June 17, 1975); *Wyandotte Transportation Co. v. U.S.*, 389 U. S. 191 (1967); *J. I. Case v. Borak*, 377 U. S. 426 (1964); *Bruce's Juices v. American Can Co.*, 330 U. S. 743 (1947); *Texas & Pacific Ry. v. Rigsby*, 241 U. S. 33 (1916); *Guthrie v. Alabama By-Products Co.*, 328 F. Supp. 1140 (DC ND Ala. 1971), affirmed 456 F. 2d 1294 (CA-5 1972); *Fitzgerald v. Pan American World Airways*, 229 F. 2d 499 (CA-2 1956); *Reitmeister v. Reitmeister*, 162 F. 2d 691 (CA-2 1947); *Fagot v. Flintkote Co.*, 305 F. Supp. 407 (DC ED La. 1969); *Kardon v. National Gypsum Co.*, 69 F. Supp. 512 (DC ED Pa. 1946); *Gorris v. Scott*, 9 L. R. 125 (Exch. 1874).

the statute means to prevent. In short, the class protected by the Act is so broad, and the harms protected against by the Act so varied, that it is difficult to conceive of a plaintiff in a private action who could not meet this criteria.

B. General Statutory Considerations.

Obviously, the first place to turn in considering whether a private right of action might be implied is the statute itself. Is there any language in it which expressly extinguishes or creates the private remedy? As we have already discussed, the Food and Drug Act does not directly address the problem, nor does its legislative history resolve the question of the Congressional intent.

Several theories can be forwarded to explain Congressional silence about private remedies. Professor O'Neil comments:

"The possibility of mere inadvertence must be rejected; it is inconceivable that the legislature simply overlooked so important a matter as private remedies. It is quite possible though, that the draftsmen considered the existing common law remedies so effective that new private sanctions simply were not needed. This theory would invite the continued recognition of prior remedies that do not impair the regulatory scheme, and would not clearly preclude the implication of new private claims against statutory violations. On the other hand, the legislature might well have intended to immunize a regulated industry from the heavy burdens of private damage suits, at least during the early years of regulation. Or the draftsmen might have designed so delicate or intricate a regulatory framework that no room remained for the courts to supplement the agency's superintendence of the regulated sector. It is clear that no private lawsuits would be permitted under either of the last two theories."[50]

What Professor O'Neil is suggesting is that when statutory considerations are inconclusive, as is the case under the Food and Drug Act, the decision-maker must then move on to other criteria such as pre-existing remedies or the effect on the regulatory scheme. This approach seems consistent with two very recent Supreme Court cases on implication, *Cort v. Ash*[51] and *National Railroad Passenger Corp. v. National Association of Railroad Passengers.*[52]

[50] O'Neil, "Public Regulation and Private Rights of Action," 52 *California Law Review* 231, 233 (1964).

[51] 43 U. S. L. W. 4773 (June 17, 1975), in which a stockholder sued corporate directors of Bethlehem Steel Corporation, on behalf of himself and the corporation, for damages and injunctive relief because of advertisements in connection with the 1972 Presidential election. The advertisements had been paid for with corporate funds in alleged violation of 18 U. S. C. Sec. 610, which prohibits corporations from making contributions or expenditures in connection with specified federal elections.

[52] 414 U. S. 453 (1974).

Justice Brennan, writing for the Court in *Cort v. Ash* said:

"In determining whether a private remedy is implicit in a statute not expressly providing one, several factors are relevant. First, is the plaintiff 'one of the class for whose *especial* benefit the statute was enacted'...? Second, is there any indication of legislative intent, explicit, or implicit, either to create such a remedy or to deny one? See *e.g., National Railroad Passenger Corp. v. National Association of Railroad Passengers*, 414 U. S. 453, 458, 460 (1974) (*Amtrak*). Third, is it consistent with the underlying purposes of the legislative scheme to imply such a remedy for the plaintiff? And finally, is the cause of action one traditionally relegated to state law, in an area basically the concern of the States, so that it would be inappropriate to infer a cause of action based solely on federal law?"[53]

In speaking of the second factor listed above, the opinion recognizes that inconclusive legislative intent would not preclude the implication of a private right of action. "In situations in which it is clear that federal law has granted a class of persons certain rights, it is not necessary to show an intention to *create* a private cause of action, although an explicit purpose to *deny* such a cause of action would be controlling."[54] Obviously, given an absence of either a clear intention to create or to deny the private action, the other factors must become relevant.

This is confirmed by an examination of *National Railroad Passenger Corp.*, cited by Justice Brennan above. There the Supreme Court refused to imply a private right of action to enjoin Amtrak from discontinuing certain passenger trains pursuant to its powers under the Rail Passenger Service Act of 1970 (Amtrak Act).[55] The plaintiff argued that the discontinuances were not authorized by, and, in fact, were prohibited by, the Amtrak Act. Justice Stewart, writing for the Court, stated two grounds that must exist in order to infer a private cause of action: (1) such inference must be consistent with evident legislative intent; and (2) it must effectuate the purposes intended to be served by the statute.[56] Justice Stewart found that neither ground was met in that case. An examination of the legislative history of Section 307(a) of the Amtrak Act, wherein the means of enforcement are provided, showed a clear rejection of a clause which would have explicitly permitted suits to enforce that Act's provisions by "any person adversely affected or aggrieved." The House Committee on Interstate and Foreign Commerce understood when it rejected the provision that it would have allowed a private right of action to enforce the Act. Justice Stewart also explained how

[53] 43 U. S. L. W. 4773, at 4776.

[54] 43 U. S. L. W. 4773, at 4778.

[55] 45 U. S. C. Sec. 501 *et seq.*

[56] This is a criterion which will be discussed in our treatment of effect on regulatory scheme, *infra*.

implication of the private action would be inconsistent with the purposes of the Act.[57]

Evident Legislative Intent

The *National Railroad Passenger Corp.* case means that where *there is evident* legislative intent regarding a private right of action, the court decision must be consistent with that intent, whether it be affirmative or negative. Justice Stewart said, "A private cause of action not otherwise authorized by the statute must be consistent with the evident legislative intent."[58] However, where there is no evident legislative intent, as in the Federal Food, Drug and Cosmetic Act, the issue remains to be resolved by the other criteria for implication as the Court again implied in *Cort v. Ash.*

A second statutory language problem concerns those instances where, under some statutes, courts have put weight on cryptic statutory language which might suggest an intent of Congress to create private remedies. To the extent that this has been done, such reliance on statutory language diminishes the importance of reliance on other criteria. To particularize, in one of the leading cases on the implication of private remedies, *J. I. Case v. Borak*,[59] the Supreme Court framed the issue before them as:

"Whether section 27 of the Act[60] *authorizes a federal cause of action* for rescission or damages to a corporate stockholder with respect to a consummated merger which was authorized pursuant to the use of a proxy statement alleged to contain false and misleading statements violative of section 14(a) of the Act." (Emphasis supplied.)[61]

The Court goes on to note:

"It appears clear that private parties have a right *under* section 27 to bring suit for violation of section 14(a) of the Act. Indeed this section specifically grants the appropriate District Courts' jurisdiction over 'all suits in equity and actions at law brought to enforce any liability or duty created' under the Act."[62] (Emphasis supplied.)

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[57] This is discussed in our treatment of the role of the court, *infra.*

[58] 414 U. S. at 458.

[59] 377 U. S. 426 (1964). See also *Fitzgerald v. Pan American World Airways*, 229 F. 2d 499 (CA-2 1956); *Kardon v. National Gypsum Co.*, 69 F. Supp. 512 (DC ED Pa. 1946).

[60] Securities and Exchange Act of 1934, Sec. 27, 15 U. S. C. Sec. 78aa (1970), which provides, "The district courts of the United States, the Superior Court of the District of Columbia, and the United States courts of any Territory or other place subject to the jurisdiction of the United States shall have exclusive jurisdiction of violations of this title or the rules and regulations thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty created by this title or the rules and regulations thereunder."

[61] 377 U. S. at 428.

[62] *Id.* at 430.

However, the opinion of the Court seems to posit an alternative basis for implying a private right of action. Considering that a policy of Section 14 is the protection of investors, the Court noted that "Private enforcement provides a necessary supplement to Commission action";[63] and that "the possibility of civil damages or injunctive relief serves as a most effective weapon in the enforcement of the proxy requirements";[64] and finally that "under the circumstances here it is the duty of the courts to be alert to provide such remedies as are necessary to make effective the Congressional purpose."[65]

Thus the debate is joined as to whether Section 27 standing alone without the companion enforcement policy basis under Section 14 would have been sufficient to imply the private right of action, or whether those grounds would be sufficient standing alone without Section 27. The resolution of this debate is important, for courts in looking to *Borak* for guidance when dealing with other statutes may be slow to imply a private right of action on the basis of enforcement policy alone without an accompanying statutory basis.[66]

However, subsequent decisions have not viewed Section 27 as essential for the implication of a private remedy. Justice Harlan, speaking of *Borak* in a concurring opinion in *Bivens v. Six Unknown Federal Narcotics Agents*,[67] said:

"The exercise of judicial power involved in *Borak* simply cannot be justified in terms of statutory construction; nor did the *Borak* court purport to do so. The notion of 'implying' a remedy, therefore, as applied to cases like *Borak* can only refer to a process whereby the federal judiciary exercises a choice among traditionally available judicial remedies according to reasons related to the substantive social policy embodied in an act of positive law."[68]

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[63] *Id.* at 432.

[64] *Id.*

[65] *Id.* at 433.

[66] In *Holloway v. Bristol-Myers*, 485 F. 2d 986, 1001 (DC DofC 1973), a class action suit on behalf of the consuming public, the Court considered allegations that the manufacturer of Excedrin had engaged in false advertising. Plaintiffs sought declaratory, injunctive, compensatory and punitive relief for this alleged violation of the Federal Trade Commission (FTC) Act. In considering whether to imply such a private right of action, the Court noted that, in *Borak*, Sec. 27 "reduced the degree of judicial implication brought to bear in developing a private remedy since it provided a firm basis from which to begin the process of extrapolation." Unlike the Securities Exchange Act of 1934, Sec. 27, 15 U. S. C. Sec. 78aa (1970), the FTC Act did not contain any express grant of jurisdiction to the federal courts for actions brought under it which grant might provide an indication of Congressional intent to allow private parties to enforce the substantive provisions of the FTC Act. For this and other reasons, the Court refused to imply the remedy.

[67] 403 U. S. 388 (1971).

[68] *Id.* at 402, note 4.

Other examination into the debate of the importance of Section 27 versus the importance of the policy reasons for implication in *Borak* has also concluded that the real key to the implication was the latter.[69] Thus, the absence of a comparable jurisdictional section in the Food and Drug Act should not preclude a private remedy, and other cases have found private actions without such language.

Despite the use of Section 27 in *Borak,* and in light of *National Railroad Passenger Corp.* and *Cort v. Ash,* there remains nothing in the Food and Drug Act itself or in its legislative history to prevent a court from implying a private right of action from it. Resolution of the issue of implication must rest on other criteria.

C. Alternative Administrative Remedies.

Where an agency has power to grant relief sought by the plaintiff against conduct violative of regulatory requirements, a court-created remedy might be unnecessary. And in those situations where the agency refused to grant relief, for the court to then create a remedy would, in effect, be a circumvention of the regular procedure and judicial review of the agency's decision.[70] Where, however, the agency lacks power to grant the relief, the argument becomes stronger for the implication of the private remedy. The Second Circuit supported this fact in *Fitzgerald v. Pan American World Airways.*[71] In that case, singer Ella Fitzgerald claimed to have been bumped from her commercial flight because of racial prejudices. Such conduct, she alleged, constituted unjust discrimination and undue and unreasonable prejudice and disadvantage in violation of the Civil Aeronautics Act of 1938.[72] Noting that the Civil Aeronautics Board could not grant reparations, the Second Circuit allowed a private action for damages arising from violation of the federal statute.[73]

We have already noted that the court enforcement mechanisms under the Food and Drug Act are seizure, injunction and criminal penalties, in addition to various non-statutory mechanisms. The fact that the Food and Drug Act provides no mechanism for compensation to consumers injured by violation of the Act argues for implication. The closest that the FDA has come to seeking any compensation for

[69] Note, "Private Rights from Federal Statutes: Toward a Rational Use of Borak," 63 *Northwestern University Law Review* 454 (1968).

[70] See *T. I. M. E., Inc. v. U. S.,* 359 U. S. 464, 474 (1958).

[71] 229 F. 2d 499 (CA-2 1956).

[72] 49 U. S. C. Sec. 484(b), (repealed by P. L. 85-726 (1958)).

[73] See also *Wills v. Trans World Airlines, Inc.,* 200 F. Supp. 360 (DC SD Cal. 1961).

injured consumers was in the case of *United States v. Mytinger & Casselberry, Inc.*,[74] in which it sought restitution of the purchase price to consumers who had bought a misbranded food supplement. The case, however, was settled without mention of restitution, so there has been no judicial determination on the availability of such relief. Even if restitution were available, it would often fall far short of actual damages based on injury. Moreover, recoveries would be very small (cost of product) and it would be difficult to locate all of the purchasers.[75]

Court Relief

Where the relief sought is injunctive, rather than compensatory, the question is not as easily resolved. While the FDA can seek injunctive relief, there is no formal mechanism for a complaining party to request such action by the FDA. Therefore, the only recourse remaining to a private party is to seek court relief. It is true that by one method or another, its own investigation or informal complaint, the FDA might be made aware of alleged violations but decide to take no action. Court-provided relief in these instances might be inconsistent with FDA policy. However, this problem comes under a different criteria—the effect on the regulatory scheme. The fact still remains that the individual seeking the injunction cannot formally be provided such relief by the FDA and is left to court action.

This is in contrast to the Federal Election Campaign Act Amendments of 1974,[76] discussed in *Cort v. Ash*.[77] In that case, the respondent sought an implied right of action for injunctive relief to prevent further violation of the Act. Such relief was denied because the Act provided an administrative procedure whereby any person believing that a violation had occurred could file a complaint with the Federal Election Committee. The Committee could investigate the complaint, and, if warranted, request the Attorney General to institute a civil action for relief, including injunctive relief.[78] The Food and Drug Act, lacking a similar express means for citizen complaint, should not then preclude a private right of action for injunction.

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[74] Cited in Note, "Restitution in Food and Drug Enforcement," 4 *Stanford Law Review* 519 (1952).

[75] See Note, "Developments in the Law: The Federal Food, Drug, and Cosmetic Act," 67 *Harvard Law Review* 632, 718-20 (1954); Note, "Restitution in Food and Drug Enforcement," 4 *Stanford Law Review* 519 (1952); and Rayne, "Penalty Through Publicity: FDA's Restitution Gambit," 7 FOOD DRUG COSMETIC LAW JOURNAL 666 (1952).

[76] P. L. 93-943 (1974).

[77] 43 U. S. L. W. 4773 (June 17, 1975).

[78] 18 U. S. C. Secs. 310 and 314(a), as amended by P. L. 93-943 (1974).

D. Alternative State Remedies.

Where a plaintiff has available *effective* state remedies (through statute or common law), there is less incentive for a federal court to imply a cause of action.[79] Conversely, the strongest case for implication exists where the federal statute has created new duties, violation of which would (or might) not provide a basis for relief under state law.

For many of the acts, such as negligence, strict liability, warranty, fraud and deceit, which constitute violations of the Food and Drug Act, state common law affords theories of relief.[80]

A state court may treat violation of the federal Act as negligence per se under state law. This is what the Fourth Circuit did in *Orthopedic Equipment Co. v. Eutsler,*[81] but this case appears to stand alone. Most of the cases which have relied on the negligence per se approach in the food and drug area have used state statutes as defining the standard of care. One commentator states that:

"The majority of jurisdictions have adopted the view that such a violation is 'negligence per se.' In these states a plaintiff need only prove that the defendant has violated a statute and that, as a result, the plaintiff was harmed in a manner which the statute was intended to prevent. Defendant's knowledge of the defect in his product is immaterial and his only defenses are proof of plaintiff's contributory negligence and disproof of causation."[82]

In those states which have food and drug laws which impose at least as strict a standard as the federal Act, this approach would seem to adequately protect the consumer. However, not all states have such statutes,[83] and there is no guarantee that even a state standard which

[79] See generally Note, "Implying Civil Remedies from Federal Regulatory Statutes," 77 *Harvard Law Review* 285, 292-294 (1961); O'Neil, "Public Regulation and Private Rights of Action," 52 *California Law Review* 231 (1964).

[80] The difficulties associated with establishing fraud and deceit stem from the requirements of proving intent and reliance. These difficulties are discussed in Note, "Private Remedies Under the Consumer Fraud Acts: The Judicial Approaches of Statutory Interpretation and Implication," 67 *Northwestern University Law Review* 413, 417 (1972). The obstacles to common law recovery were crucial to decisions granting implied remedies in the securities area. See 3 Loss, *Securities Regulation*, 1683 (2nd ed. 1961).

[81] 276 F. 2d 455 (CA-4 1960), *supra* note 34.

[82] Woods, "The Effect of the Food, Drug, and Cosmetic Act on Private Litigation," 8 FOOD DRUG COSMETIC LAW JOURNAL 511, 513 (1963), and cases cited therein.

[83] At the present time, the food and drug laws of 13 states do not cover medical devices, 10 states have no provisions on cosmetics, and Wisconsin has no drug law. Less than half of the states regulate food additives and color additives. Ten states have food labeling requirements less stringent than the Act, and sixteen have less stringent drug labeling requirements (Mississippi has none at all). A breakdown of the coverage of the various states' laws can be found in CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 10-005–10-061.

appears to be as strict as the federal standard will be interpreted and applied that way by a state court. Finally, an interest in granting similar relief to similar violations of the Act[84] would be better served by allowing the consumer to seek redress in the federal courts, than by restriction to common law remedies which may vary greatly from state to state.[85]

A further difficulty facing the consumer in a state negligence action is the existence of such defenses as assumption of risk or contributory negligence which will bar recovery if granted. Since a court which decides to grant a federal cause of action will also need to decide what defenses will be available, it is possible that these defenses may be scuttled under a new federal cause of action.[86]

Uniform Sales Act

Another possible common avenue for relief under state law is the warranty action, either by a purchaser who resells the product or the ultimate consumer.[87] Warranties of merchantability or fitness of goods are imposed by a large majority of states through adoption of either the Uniform Sales Act or the Uniform Commercial Code.[88] In *Herman v. Smith, Kline, and French Laboratories*,[89] the Food and Drug

[84] See generally Depew, "The Need For Uniformity in Food Legislation," 16 FOOD DRUG COSMETIC LAW JOURNAL 169 (1961); Goodrich, "Uniformity in Federal-State Food Regulations," 17 FOOD DRUG COSMETIC LAW JOURNAL 305 (1962).

[85] See *Fitzgerald v. Pan American World Airways*, 229 F. 2d 499 (CA-2 1956), where the Second Circuit, in creating a right under a federal statute to vindicate alleged racial discrimination by an air carrier, said that "although we regard it as not controlling, we note also the following: Congress sought uniformity in the practices of those subject to this Act." The Second Circuit was concerned that the action involved might not be unlawful under the common law of many states, thereby creating a checkered enforcement pattern. See also *Mortimer v. Delta Air Lines*, 302 F. Supp. 276, 279 (DC ND Ill. 1969) where the Court says, "It is equally important to note the considerations of federal interest which contribute to the desirability of implying a federal remedy from this regulatory statute. The basic setting for civil rights and anti-discrimination legislation and enforcement has been federal to guarantee uniform application and enforcement of those rights and to avoid adverse effects of local interest or absence of state remedy. In addition, we have here the substantially interstate character of the activity which contributes to the need for federal cognizance and the importance of uniformity in result." And to the extent the existence of a wholly satisfactory state forum and the lack of an interest in uniformity mitigate against implication, see *Mounger v. Brandt*, 250 F. Supp. 445 (DC WD Wis. 1966).

[86] The rationale for abolishing such defenses in food and drug cases is discussed *supra* note 9.

[87] See generally Woods, "The Effect of the Food, Drug, and Cosmetic Act on Private Litigation," *supra* note 82, at 514-526.

[88] Prosser, *Handbook of the Law of Torts*, Sec. 97, at 655 (4th ed. 1971).

[89] 286 F. Supp. 694 (DC ED Wis. 1968).

Act was specifically held not to preempt the applicability of the Wisconsin Uniform Sales Act to a breach of warranty action arising from the plaintiff's use of a drug marketed by the defendant. In jurisdictions that have adopted such acts, it has been held that a warranty of merchantability means that a product that does not satisfy the warranty cannot be resold by a retailer without the retailer violating the law,[90] and that the warranty of fitness means fitness for consumption.[91] Most actions contemplated under warranty theories are for economic injury. While, in theory, an individual consumer may have a right of action under a warranty, the measure of the economic loss will probably be too small to cause a resort to legal action. Furthermore, there is no guarantee that violation of the federal statute will constitute a breach of warranty.

Even before the Uniform Commercial Code or Uniform Sales Act, the common law had historically recognized an implied warranty in the food area, holding a seller strictly liable as an insurer of the product sold.[92] Or a seller could be held strictly liable under a theory of misrepresentation where statements made on the labels of goods proved to be false.[93] However, numerous difficulties with implied warranty theory have caused many jurisdictions to jettison warranty actions in favor of tort actions, so that recovery under theories of warranty remain spotty and uncertain at best.[94]

The theory of strict liability in tort is accepted by at least two-thirds of the states. The restatement formulation is as follows:

"(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller."[95]

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[90] See *Myers v. Malone and Hyde*, 173 F. 2d 291 (CA-2 1949).

[91] See generally Woods, "The Effect of the Food, Drug, and Cosmetic Act on Private Litigation," *supra* note 82.

[92] Prosser, *Handbook of the Law of Torts*, *supra* note 88, Sec. 97.

[93] *Id.*

[94] *Id.*

[95] *Id.*, Sec. 98, at 657.

However, there are violations of the Act, especially in the economic area, that would not be covered by strict liability. For example, peanut butter which does not contain the percentage of peanuts prescribed by the standard of identity promulgated by the FDA under Section 401 of the Act would surely not be seen as "unreasonably dangerous" so as to create a strict tort liability.[96]

Thus, from the standpoint of the consumer, it appears that there are serious deficiencies with all of the possible common law approaches.[97] In addition to the problems mentioned, it may be that certain portions of the Act will be seen as creating duties that are not similar to any recognized at common law and are, therefore, not enforceable by the common law.[98] In the absence of a right of action under the Act, violations of these provisions will cause damage to consumers for which they will have no remedy.

Moreover, it does not appear that the consumer can rely on state agencies for full protection, since state consumer fraud agencies have instituted relatively few injunctive proceedings and few states can seek restitution for injured consumers.[99]

So, even with the wide variety of state remedies available, the effectiveness of each remains subject to question. The problems with relying on common law remedies, the need for available means of redress in the area of economic injury to the consumer, and an interest in uniform remedies should lead a court to conclude that a federal implied right of action should be recognized under the Act.

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[96] The standards of identity for peanut butter may be found in 33 *F. R.* 10506 (1968).

[97] For the difficulties in recovering under common law theories in the area of prescription drug cases, see Merrill, "Compensation for Prescription Drug Injuries," 59 *Virginia Law Review* 1, 29-68 (1973).

[98] The area of standards of identity is one example. Under Section 401 of the Act, regulations may be promulgated setting minimum, maximum or exact percentages of a constituent in a product so that it will conform to consumer expectations. The standards of identity concept stems from the "economic adulteration" concept, which is designed to protect consumers from paying prices for products calculated to lead them into thinking they are buying something better than they actually are. See Forte, "Definitions and Standards of Identity for Foods," 14 *U. C. L. A. Law Review* 796 (1967). A consumer would have a difficult time persuading a court that there is a common law right to a given percentage of constituent in a product. Again, there is the problem of individual injury being slight, approaching *de minimis,* and, therefore, discouraging the seeking of redress absent the availability of the class action.

[99] See generally Eovaldi & Gestrim, "Justice for Consumers: The Mechanisms of Redress," 66 *Northwestern University Law Review* 281 (1971).

E. Role of the Court.

Even if one concluded that private remedies under the Act would be desirable, there would remain the question whether a court could properly provide such remedies. This question has three aspects: the role of the judiciary in the regulatory scheme fashioned by Congress; the competence of courts to decide the substantive questions which would arise; and the ability of the court to define and fashion the attributes of a federal cause of action.

The Supreme Court considered the role of the judiciary in denying a private right of action in *National Railroad Passenger Corp. v. National Association of Railway Passengers.*[100] The Court stressed the fact that the railway corporation set up by Congress was meant to be able to quickly implement its decisions to discontinue routes, without having to go through some intermediate regulatory body such as the Interstate Commerce Commission. The Court believed that the allowance of private suits would interpose courts into just such a position and thereby frustrate Congress' intent. Nothing in the Food and Drug Act, however, indicates that private suits under it would thrust courts into a role which Congress had decided would be detrimental to achieving its legislative purpose.

In *Holloway v. Bristol-Myers Corp.*,[101] Judge Leventhal was concerned with the role of the court in the regulatory scheme established by the Federal Trade Commission (FTC) Act. Under the Act, the FTC operates as a quasi-judicial tribunal with court review limited to appeals from Commission decisions. Judge Leventhal held that the role of the courts under that Act was not one of direct enforcement, but, rather, one of supervision *after* the administrative processes of the Commission had been completed. The courts lacked the expertise and knowledge possessed by the Commission, as evidenced by the role assigned to them by Congress. In short, authority and competence to decide what constituted an "unfair or deceptive act or practice" or an "unfair method of competition" within the meaning of the FTC Act lay primarily with the Commission, which should resolve the issue in an Agency hearing.

In contrast, there are no adjudicatory tribunals within the FDA, and courts have long been involved in dealing with questions of both law and fact concerning violations of the Act. Proceedings for seizures, injunctions or criminal violations are brought in the federal district

[100] 414 U. S. 453 (1974).
[101] 485 F. 2d 986 (CA DofC 1973).

courts or in the United States Courts of the Territories.[102] Courts have decided whether food was contaminated,[103] whether labels on dietary supplements were misleading,[104] what the proper standard is for economic adulteration,[105] and whether the American diet is deficient in vitamins and would be helped by a particular type of sugar product.[106] In short, the courts have been at the center of action on questions affecting all areas of the Act, often deciding the types of technical questions that the FTC Act committed to Agency expertise.[107] Clearly, if Congress thought that federal judges were competent to decide the issues involved in these contexts, they should also be viewed as competent to decide the same issues in the context of a private suit for damages or injunction.

Finally, the question of the court's ability to create the attributes of a federal right of action still remains. The courts would have to decide what defenses would be available, what statutes of limitations would apply, and what limits on the cause of action such as security requirements, venue, and the questions of similar nature. The development of such a body of rules would have to follow recognition of a private right of action. There are many sources from which to draw these attributes, among them state common law of tort, federal statutes of general application (venue, for example),[108] and the Act itself,[109] in addition to the plain good sense of the courts. While this problem poses some difficulties, that fact alone should not prevent implication.[110]

F. Effect on Regulatory Scheme.

The most important and difficult inquiry is whether a private right of action would upset a delicate administrative enforcement

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[102] The Act, Secs. 302(a) and 304(a)(1), 21 U. S. C. Secs. 332(a) and 334(a)(1)(1970).

[103] *United States v. Capitol City Foods, Inc.*, 345 F. Supp. 277 (DC ND 1972).

[104] *United States v. An Article of Food . . . Nuclomin*, 482 F. 2d 581 (CA-8 1973).

[105] *United States v. 88 Cases . . . Bireley's Orange Beverages*, 187 F. 2d 967 (CA-3 1951).

[106] *United States v. 119 Cases . . . New Dextra Brand Fortified Sugar*, 231 F. Supp. 551 (DC SD Fla. 1963).

[107] However, there appears to be a growing tendency on the part of the FDA to avoid going to court by handling these issues administratively. Examples include the over-the-counter drug review, and the common or usual name requirements for food labeling.

[108] 28 U. S. C. Secs. 1391–1392 (1970).

[109] The Act, Sec. 303(c), 21 U. S. C. Sec. 333(c) (1970), which establishes certain good faith defenses to criminal prosecution under the Act.

[110] See *Moragne v. States Marine Lines*, 398 U. S. 375, 405–408 (1969), in which the Supreme Court discusses the process of defining a cause of action for wrongful death under federal maritime law.

balance or whether it would effectively supplement agency enforcement and further serve the purpose of the statute. On the one hand it can be argued that where an agency has taken action or can provide no remedy, a private right of action can be an effective enforcement mechanism to help effectuate the policy of the statute in question—it provides a remedy to administrative inability or failure to act. The contrary argument is that failure to act is or may be an exercise of discretion on the part of the agency, which is charged with maintaining a delicate balance of regulation and resolving enforcement policy questions. In short, where there is a regulatory law delegating broad discretionary responsibilities to a specialized administrative agency, one must weigh the "practical effect" of implying a right of action on the regulatory scheme.[111]

"The private remedy must be judged by its practical effect upon the regulatory machinery and the functions of the agency. Generally speaking, the broader and more detailed the agency's powers and responsibilities, the more reluctant the courts are to take interstitial action in the regulated sector. It is rare that the terms of the statute give the agency an exclusive enforcement power. More often, the regulatory scheme is so pervasive, or the balance struck between the regulated sector and the rest of the economy so delicate, that the agency must by implication be given certain exclusive powers. In these instances private grievances must be redressed through the agency or not at all, even though the agency may be powerless to award damages or reparation."[112]

A private remedy could interfere with an agency's enforcement in several ways. Among these are: possible lack of uniform results; production of results at variance with the aims of the agency; a tendency to dull the incentive to exhaust administrative remedies; and the deleterious economic effect on the regulated industry subjected to increased financial liability.[113] Finally, the agency may find itself handcuffed by a result in a privately initiated suit which had been poorly tried and which created unfavorable precedent.

The practical effect on the regulatory scheme was a key consideration in *Holloway v. Bristol-Myers*.[114] Holding that a private right of action should not be recognized under the FTC Act, the Court was concerned with the possible incompatibility of private and public

[111] See generally *Hewitt-Robins, Inc. v. Eastern Freight-Ways, Inc.*, 371 U. S. 84 (1962); *Holloway v. Bristol-Myers*, 485 F. 2d 986 (CA DofC 1973); *Fagot v. Flintkote Co.*, 305 F. Supp. 407 (DC ED La. 1969); Note, "Judicial Refusal To Imply a Private Right of Action Under the FTCA," 1974 *Duke Law Journal* 506; O'Neil, "Public Regulation and Private Rights of Action," 52 *California Law Review* 231 (1964).

[112] O'Neil, "Public Regulation and Private Rights of Action," *supra* note 111, at 263, 264.

[113] *Id.* at 264–267.

[114] 485 F. 2d 986 (CA DofC 1973).

enforcement. Private litigants would not be subject to the same constraints as the Commission, and the need for constant intervention in these suits would cause a drain on the Commission's resources, making it a "hostage" of private concerns.[115]

Private Enforcement

Judge Leventhal discounted the notion that private enforcement was a necessary supplement to agency action in providing consumer protection. He concluded that the legislature, in concocting the enforcement scheme, surely considered consumer protection as part of the balance, but it also considered the interests of business, with particular concern for tempered enforcement, the orderly development of commercial standards, and freedom from multiplicious litigation as part of that enforcement balance. Further, the FTC, in exercising its enforcement discretion, considered many factors, including the relative seriousness of the departure from accepted trade practices, the effect on public welfare, the disruption to settled commercial relations, the precedential value of the rule of law sought to be established, and whether the action should be against a single party or industry-wide. The Court rightly feared that piecemeal actions would not be brought with these considerations in mind. Nor would this approach allow for the orderly development of precedent, which the Commission could provide.[116] In short, the Court's main concern was that private suits would replace a coordinated enforcement program based upon the sound discretion and expert judgment of the Agency.

Several of the above points relate to the "in-house" nature of the FTC operation, since it has its own administrative courts. This, as discussed earlier, differs sharply with the FDA scheme in which formal enforcement of the Act takes place primarily in the judicial system. Equally important in *Holloway,* however, was the enforcement philosophy associated with the FTC, one expressed by Representative Lea, one of the co-sponsors of the Wheeler-Lea Amendments of 1938 to the FTC Act:

> "The great majority of people who advertise want to do the right thing, and if the Government points out to them where they are making a mistake and are in violation of the law, they are willing to conform to the law.... [T]he principal virtue of the Federal Trade Commission procedure . . . is to give the honest businessman a chance to adjust his differences without harassing him or bringing him into court. . . ."[117]

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[115] *Id.* at 997.

[116] *Id.* at 997–999.

[117] 83 *Congressional Record* 392, 406 (1938).

This philosophy sounds quite similar to that embraced by the FDA; namely, that industry will want to do what is best for consumers. A former FDA Commissioner put it this way:

"[Most] manufacturers recognize that consumer interest and producer interest are inseparable, and that practices adverse to consumer interest are likewise adverse to the interest of industry; . . . most manufacturers make sincere efforts to meet all legal requirements not only because they are the law . . . but because it is the right thing to do."[118]

This philosophy of industry good faith has led to an enforcement policy of cooperation with representatives of industry in such areas as the setting of standards of identity, development of acceptable labeling, and the increasing use of the voluntary recall of contaminated products (rather than a court-ordered injunction or seizure).

A recent FDA program based on this philosophy is one of issuing detailed regulations to fully inform industry of what it needs to do to comply with the law.[119]

"In the past 20 years there has been a gradual realization both that the government has a duty to inform those it regulates of the precise requirements that they are expected to fulfill under the law, and that promulgation of regulations specifying in detail those legal requirements is the most effective and efficient means by which industry-wide regulation can be achieved. . . . Litigation in many instances represents the failure of effective regulation."[120]

Taking this philosophy into account, many of the objections raised to implication in *Holloway* seem equally applicable here. Namely, private suits could lead to conflicting results, establish unfavorable precedent, and frustrate an agency enforcement policy based on agency discretion.

If examination of the effect of a private right of action on the regulatory scheme ended here, then such a right would be seen as one not calculated to further the purposes of the Act, since it might be at variance with the basic FDA philosophy of enforcement and could severely hamper the implementation of that philosophy. However, other factors mitigate the apparent seriousness of this interference; namely evidence of Agency ineffectiveness, the effect of limited resources on the formulation of FDA's enforcement policy, and the fact that citizen suits may supplement the enforcement ef-

[118] Turner, *The Chemical Feast*, p. 82, quoting former FDA Commissioner Paul Dunbar.

[119] See, for example, 21 CFR Sec. 1.17 on nutrition labeling of food and 21 CFR Sec. 100.1-5 on nutritional quality guidelines for food.

[120] Hutt, "Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act," 28 FOOD DRUG COSMETIC JOURNAL 177, 183 (March 1973).

forts of the FDA without being at odds with the Congressional purpose in the Act.

To the extent that an agency is ineffective in enforcing the law it was meant to administer, private suits could be a helpful addition to the total enforcement program. A court seeking to assess the effectiveness of the FDA in enforcing the Act would not have to look far for help. In a statement before a subcommittee of the House of Representatives in 1972 on the FDA's food inspection program, the FDA Commissioner Charles C. Edwards stated that ". . . we do not have in our field forces anywhere near the reasonable number of people to carry out our program."[121] A study conducted by a committee set up to review and evaluate the scientific efforts of the FDA found that:

"The responsibilities handled by the District laboratories are literally overwhelming. At the present time, for example, Districts have no possibility of analyzing the large number of samples which might accompany any sustained, systematic sampling of the food supply. Similarly, they can do no more than spot check the supply of drugs entering interstate commerce.

. . .

"[The FDA] currently faces enormous responsibility for consumer protection and the public health, but with limited resources, constricted perspective and little solid constituency in the public or medical and scientific establishments."[122]

In a speech delivered by former FDA General Counsel Peter B. Hutt, he asserted that:

"It is outside the realm of possibility, either now or in the foreseeable future, for the Food and Drug Administration fully to enforce every provision of the Act. One simply cannot achieve optimal regulation of a highly inventive $135 billion a year group of industries on a budget of $164 million."[123]

The factor of agency limitations was a crucial one in *J. I. Case v. Borak*.[124] The Supreme Court noted that resource problems greatly

[121] FDA Oversight-Food Inspection, Hearings Before the Subcommittee on Public Health and Environment of the House Committee on Interstate and Foreign Commerce, 92nd Congress, 1st Session, p. 6 (1972).

[122] Ritts Committee Report 22, 53 (1971).

[123] Hutt, "Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act," *supra* note 120, at 180, 181.

[124] 377 U. S. 426, 432. 433 (1964). The Court was aided by the filing of an *amicus curiae* brief by the SEC urging implication. Where the agency takes a position favorable to implication, it should influence the Court toward that result. The failure to so urge the Court should not block implication, however, as it may be due as much to an agency jealous of its powers and not wanting to admit ineffectiveness as to a perception of individual suits as unnecessary or harmful. A previous General Counsel of the FDA stated that, at the time, there was no official FDA position regarding private remedies. Conversation with Peter Hutt, December 6, 1974, Charlottesville, Va. But see *Holloway v. Bristol-Myers, supra* note 101, at 1001, where the court brushed aside substantial evidence of FTC ineffectiveness with the statement that ". . . Congress has not seen fit to alter the statutory plan established in 1938."

limited the effectiveness of the Securities and Exchange Commission (SEC):

"The Commission advises that it examines over 2,000 proxy statements annually and each one of them must necessarily be expedited. Time does not permit an independent examination of the facts set out in the proxy material and this results in the Commission's acceptance of the representations contained therein at their face value, unless contrary to other materials on file with it. Indeed, on the allegations of respondent's complaint, the proxy material failed to disclose alleged unlawful market manipulation of the stock of ATC, and this unlawful manipulation would not have been apparent to the Commission until after the merger.

"We, therefore, believe that under the circumstances here it is the duty of the courts to be alert to provide such remedies as are necessary to make effective the Congressional purpose."[125]

It would be an encroachment by the judiciary on the Agency's powers, if it were to imply a private right of action where the failure of the FDA to act was simply an exercise of discretion by the Agency. The problem with this analysis is that the FDA does not, in fact, have anywhere near the resources to be able to exercise its enforcement discretion unfettered by monetary considerations. Rather, the FDA's enforcement policy must be shaped in the face of insufficient funds to enforce fully. Consumers utilizing a private right of action could be seen as taking up where the FDA's funds leave off, if they sued where FDA would like to but cannot.

Insufficiency of Funds

One commentator has suggested that using insufficiency of funds to fully enforce as an argument for implication may not be proper.[126] Insufficency of funds should, in his view, be considered an indication that Congress has exercised its judgment that a certain level of enforcement is desirable and has appropriated an amount of funds commensurate with the enforcement level it deems correct. This seems to simply move the whole argument back one step, for it assumes that Congress has unlimited funds to disburse and can thus decide how much enforcement it wants and appropriate the funds necessary, no matter what the cost. However, any amount appropriated to the FDA for enforcement will be the result of a balancing process, with all of the multifarious programs funded by Congress being weighed against each other for their respective shares of scarce funds. A more realistic approach to this whole question is that utilized in *Borak*, where the

[125] 377 U. S. 426, at 432, 433, note 14.

[126] Note, "The Phenomenon of Implied Private Actions Under Federal Statutes: Judicial Insight, Legislative Oversight or Legislation by the Judiciary?," 43 *Fordham Law Review* 441, 448 (1974).

Court looked at the purpose of the Securities and Exchange Act (the protection of investors in securities), measured the SEC's enforcement effort against that necessary to carry out this purpose, found that it was insufficient (due to lack of resources), and saw the availability of private rights of action as a means to "fill in the gap" and better enforce the Act.

Assuming that inadequate resources restrict the FDA to a policy of limited enforcement, it still is not an inevitable conclusion that allowing private rights of action is the proper response. A court must still be persuaded that such actions are actually an effective supplement to the enforcement program of the FDA. One facet of this is that allowing private actions could result in a further encroachment upon those limited funds which are presently used for enforcement. This could occur through the need of the FDA to monitor private suits and to intervene where necessary to protect its interests.

It could also occur if a court decides to use the primary jurisdiction approach of referring questions raised in court to the FDA for exercise of its expertise. For example, in a case where it is alleged that certain labeling is "false and misleading," a court may feel that the FDA should initially define such a broad statutory proscription.[127] The need to provide responses to issues referred by courts could result in a substantial drain on Agency resources, especially if the courts expanded the exercise of this approach to areas where the statutory proscriptions are more clearly defined than in Section 403(a) of the Act, which deals with false and misleading labeling of food.

While recognizing these problems, it must be remembered that the Act is meant to protect many consumers from many violations occurring all over the country. Even if the FDA could be informed of all these violations, the limits of its resources would prevent full enforcement. Granting private rights to individuals to sue for these violations could still prove to be a valuable supplement to the FDA's enforcement program.[128]

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[127] See *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U. S. 645 (1973), in which the Supreme Court held that the question of the "new drug" status of individual drugs or classes of drugs was properly referred to the FDA by the District Court, since it was a threshold question within the peculiar expertise of the Agency. The manufacturers had contended that their drugs were generally recognized as safe and therefore not subject to the statutory requirements applicable to "new drugs" under the 1962 amendments to the Food and Drug Act.

[128] However, there is some doubt as to the ability of consumers to evaluate some violations, such as unsanitary manufacturing conditions, which do not result in observable physical or economic injury, because of lack of authority or resources to investigate. See Note, "Developments in the Law: The Federal Food, Drug, and Cosmetic Act," 67 *Harvard Law Review* 632, 633 (1954).

V. Conclusion

Having analyzed the issue of private remedies from many perspectives, the task of making concrete suggestions remains. Action can be taken by two entities, the federal courts or the Congress. Should Congress direct itself to the issue, its clear expression of intent would foreclose judicial recognition of implied rights of action.

Without Congressional action, however, what should a federal court hold when presented with the issue? It is tempting to suggest that a court adopt a uniform approach in all instances—that private rights of action should be denied or allowed across the board. By making the same determination in each case, the court can avoid having to weigh the relative merits of implying a private right of action on an *ad hoc* basis. If case-by-case determination appears necessary, then it would be preferable to deny private remedies altogether. To allow the issue to remain open in every case invites baseless suits, uncertainty, confusion, and waste of judicial resources. Having concluded that implication of a private remedy would be acceptable in some situations, but not in others, it is tempting to suggest that, rather than thrashing the issue out in case after case, the private remedy simply not be allowed.

The only other alternative is to suggest where a clear line might be drawn between those instances where a private remedy should or should not be implied. We believe such a line falls between suits where the remedy prayed for is damages rather than an injunction. If a plaintiff can prove to a court that the defendant's violation of the Act proximately caused him physical or economic harm, a court should imply a remedy on his behalf. We believe that our discussion has shown that there is nothing in the Act or its history to prevent a court from doing this. The policies of the Act would be served with little harmful effect upon the regulatory scheme.

Consequences of Injunctions

The same cannot be said where the relief sought is an injunction. Since the FDA itself has the power to seek injunctions but does not have the power to grant reparations, it becomes more likely that a court-issued injunction in a private right of action might interfere with the FDA enforcement scheme. Also, the consequences of an injunction on the defendant could be severe, ranging from stopping a line of production to shutting down a plant. Such a result could have repercussions throughout the industry if a large manufacturer is involved. The

decision to seek such an action would seem to rest more logically with the Agency designated to regulate the entire industry. There may be instances where the issuance of an injunction in a private suit would effectively supplement FDA enforcement. However, there are instances where a court-awarded injunction would be directly counter to Agency enforcement policy.[129] To allow a court to imply an injunctive remedy would be to allow the court to substitute its judgment for that of the FDA. Perhaps this substitution would, in some instances, be warranted but if the Agency made no judgment, there would be no substitution. But there remains the danger that a court would not be able always to distinguish those situations warranting substitution and those not warranting it. The safest and best course is simply to deny that power altogether. Citizens would be left to informally express their concern to the FDA. The Agency then would take whatever action it deems appropriate.

Ideally, Congress should settle the issue It can extend rights to private citizens while at the same time creating mechanisms that would provide some measure of protection to Agency prerogatives. Certainly since there is policy in favor of implying a damage remedy by the courts, then it follows that it would be wise for Congress to cement this right by expressly providing for it. The drafting of such a provision creating a federal right of action for damages arising from violations of the Act should present no problem. In light of the uncertainty of state remedies and the benefits of a federal forum, there can be little argument against this remedy.

In the interest of consumer protection, Congress would also seem to be justified in allowing for citizen suits for enforcement of the Act, *as long as some form of notice and right to intervene are given to the Agency.* Such "citizen suits" provisions appear in the Clean Air Act,[130] the Federal Water Pollution Control Act,[131] and the Consumer Product Safety Act.[132] A similar provision was introduced in the Congress as an amendment to the Food and Drug Act, Section 410(g) of the proposed Consumer Food Act of 1975.[133] This latter provision and those above could serve as excellent models. In addition to providing federal court

[129] A private injunction seeking to remove an ineffective drug from the market would be at odds with Agency policy where, for instance, the FDA made a decision to allow an ineffective drug to remain on the market, feeling its use as a placebo was preferable to having no product available at all.

[130] 42 U. S. C. Sec. 1857h-2 (1970).

[131] 33 U. S. C. Sec. 1365 (1970).

[132] 15 U. S. C. Sec. 2073 (1970).

[133] *Infra* note 45.

jurisdiction for citizen suits to enforce the Act, the interests of the Agency could be given some protection. For example, Congress could provide that no civil action could be commenced prior to sixty days after the plaintiff has given notice of the alleged violation to the Secretary of Health, Education and Welfare. Further, civil actions for injunctions might be denied if the government had already begun action with respect to the alleged violation. And it would be essential in any citizen suit to allow the government to intervene as a matter of right. Other sensible requirements might be the awarding of costs of litigation as appropriate and/or the requirement of security by the plaintiff. With these safeguards to protect the interests of the government and to provide disincentives to frivolous suits, such a "citizen suits" provision would provide an extra measure of protection to the consumer. [The End]

HEARINGS ON FOOD FOR SPECIAL DIETARY PURPOSES TO REOPEN

Hearings will be reopened on regulations for food for special dietary purposes, the Food and Drug Administration (FDA) has announced. The hearings will begin November 10, 1975, for the specific purpose of permitting the reasonable cross-examination of Dr. Alfred E. Harper, Chairman of the Committee on Dietary Allowances of the Food and Nutrition Board, National Academy of Sciences-National Research Council (NAS-NRC). The NAS-NRC published the eighth edition of "Recommended Dietary Allowances," one of the fundamental sources relied upon in the development of the FDA's regulations to govern the labeling of foods for special dietary purposes. During the hearings Dr. Harper may be examined on the issues of methodology, appropriateness, and bias of the NAS-NRC's recommended dietary allowances. Written notices of appearances at the hearing must be filed with the FDA not later than October 30, 1975.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,472

Drug and Device Establishment Inspections

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THE FOOD AND DRUG ADMINISTRATION's (FDA's) AUTHORITY to enter and inspect establishments where drugs or devices are manufactured, processed, packed or held is limited by the affirmative requirements contained in Section 704 of the Federal Food, Drug and Cosmetic Act and the constitutional prohibition against "unreasonable" searches and seizures. The question as to what constitutes an "unreasonable" search and seizure within the context of the enforcement of a regulatory statute, such as the Federal Food, Drug and Cosmetic Act, is a surprisingly difficult one to resolve and one upon which the U. S. Supreme Court has vacillated over the years. In *Frank v. Maryland,*[1] the Supreme Court upheld, by a five to four vote, a state court conviction of a homeowner who refused to permit a municipal health inspector to enter and inspect his premises without a search warrant. However, in the 1967 companion decisions of *Camara v. Municipal Court*[2] and *See v. City of Seattle,*[3] the Supreme Court held that, in the absence of informed consent, an inspection of a private or commercial establishment pursuant to municipal health, housing or fire codes is, at least in the absence of an emergency situation, "unreasonable," unless it had been authorized by a valid search warrant. Thereby, the Court effectively overruled its decision in *Frank v. Maryland.* In *Camara,* the Court stated that "We hold that administrative searches of the kind at issue . . . are significant intrusions upon the interests protected by the Fourth Amendment [and] that such searches when authorized and conducted without a warrant

[1] 359 U. S. 360, 79 S. Ct. 804, — L. Ed. 2d 877 (1959).

[2] 387 U. S. 523, 87 S. Ct. 1727, 18 L. Ed. 2d 930 (1967).

[3] 387 U. S. 541, 87 S. Ct. 1737, 18 L. Ed. 2d 319 (1967).

procedure lack the traditional safeguards which the Fourth Amendment guarantees to the individual."[4] And in *See*, the Court said "that administrative entry, without consent, upon the portions of commercial premises which are not open to the public may only be compelled through prosecution or physical force within the framework of a warrant procedure."[5] The effect of these two 1967 Supreme Court decisions was to prevent the prosecution of individuals for exercising their constitutional right of refusing to allow administrative inspectors to enter and inspect their premises in the absence of a valid search warrant. Further, under the so-called exclusionary rule (or "fruit of a poisonous tree" doctrine), these two decisions had the added effect of severely restricting the government's use, in subsequent judicial proceedings, of evidence obtained in a warrantless administrative inspection, except where the inspection was preceded by voluntary informed consent.

Valid Search Warrant

The constitutional right of an owner or operator of an establishment to refuse entry in administrative inspections in the absence of a valid search warrant established by the decisions in *See* and *Camara* was subsequently recognized by Congress and most government agencies. It appeared that it would become a firmly established doctrine of constitutional law. However, by the end of 1970, both the climate of the country and the makeup of the Court significantly changed, and this "firmly" established doctrine turned out to be nothing more than a fleeting concept. The Warren Court had been largely replaced by the Nixon/Burger Court and the country's desire to establish safeguards to assure the privacy and security of an individual against unwarranted invasion by government officials was significantly weakened by the country's growing desire for "law and order" at any cost.

The Supreme Court's movement away from the constitutional doctrine laid down in *See* and *Camara*, and its movement back toward the doctrine established in *Frank v. Maryland*, blossomed in the year 1970 in a case entitled *Colonnade Catering Corp. v. U. S.*[6] The Court held that, in view of the government's historically broad authority to regulate the liquor industry, the general rule laid down in *See* and *Camara* against the prosecution of individuals for failing to allow a warrantless inspection should not apply to the government's regulation of the liquor industry. However, the Court went on to hold that, in the absence of a valid search warrant, the government could not physically force

[4] *Supra* note 2, at 534.
[5] *Supra* note 3, at 545.
[6] 397 U. S. 72, 90 S. Ct. 774, 25 L. Ed. 60 (1970).

entry. The remedy for refusal to permit entry and inspection was the imposition of the statutory fine of $500.00.

Exception to General Rule

This exception to the general rule laid down in *See* and *Camara* which the Court carved out in *Colonnade Catering Corp.*, was significantly extended by the Court by its decision in *United States v. Biswell.*[7] The Court, in *Biswell,* held that "where . . . regulatory inspections further urgent federal interest, and the possibilities of abuse and the threat to privacy are not of impressive dimensions, the inspection may proceed without a warrant where specifically authorized by statute."[8] According to the Court, "[i]n the context of a regulatory inspection system of business premises which is carefully limited in time, place and scope, the legality of the search depends not on consent but on authority of a valid statute."[9] It is important to note that this decision did not exempt administrative inspections from the constitutional prohibition against "unreasonable" searches and seizures but instead defined "unreasonable" in such a manner as to allow warrantless inspection of business premises, provided they are carefully limited in time, place, scope and manner. Moreover, the Court in *Biswell* did not overrule its holding in *Colonnade Catering Corp.*, which precludes the use of forcible entry in the absence of a search warrant or a clearly defined statutory provision authorizing such forced entry. Rather, the decision enables government agencies to enforce compliance by making it possible for the courts to impose civil and criminal penalties upon individuals who refuse to allow inspectors to enter and conduct an administrative inspection authorized by a statute. Thus, it seems that, in the absence of a valid search warrant, an FDA inspector is not entitled to use physical force to gain entry into establishments where drugs or devices are being manufactured, packaged or held. However, the owner or operator of such an establishment could be criminally prosecuted under the Federal Food, Drug and Cosmetic Act for refusal to allow an FDA inspector, upon showing appropriate credentials and a written notice of inspection, to enter the establishment at reasonable times and in a reasonable manner for the purpose of conducting an inspection authorized by the Act.

The Court in *Biswell* tried, in my opinion unsuccessfully, to distinguish its decisions in *See* and *Camara* on the basis that, in those cases, the mission of the inspection system was to discover and correct vio-

[7] 406 U. S. 311, 92 S. Ct. 1593, 32 L. Ed. 2d 87 (1972).

[8] *Supra*, at 317.

[9] *Supra*, at 315.

lations of conditions that were relatively difficult to conceal or to correct in a short time. Accordingly, the Court reasoned, the effectiveness of the regulatory inspection system did not require frequent and unannounced inspections. However, even assuming that this distinction may be applied in a meaningful way, it apparently cannot be used successfully to challenge the validity of warrantless inspection under the Federal Food, Drug and Cosmetic Act. In *United States v. Del Campo Baking Mfg. Company,*[10] the United States District Court for the Delaware District found that "if the [Federal] Food, Drug, and Cosmetic Act is to be effectively enforced to protect an urgent federal interest, 'unannounced' inspections are unquestionably of the utmost importance."[11] Thus, according to this district court, the FDA's inspection authority should be governed by the principle laid down in *Biswell,* as opposed to those laid down in *See* and *Camara,* that is, the lawfulness of an FDA inspection is not dependent upon consent or a search warrant but, rather, upon the adherence to the statutory requirements and limitations contained in the Federal Food, Drug and Cosmetic Act.

FDA's Inspection Authority

The scope and limitations of the FDA's inspection authority under the Federal Food, Drug and Cosmetic Act is dependent upon whether the establishment manufactures, packages or holds products subject to "device," or "drug" and "new drug" classifications. If the product subject to inspection is classified as a device, the FDA's inspection authority is limited to the authority contained in Sections 703 and 704 of the Act. Under Section 703 of the Act,[12] officials or employees designated by the FDA are entitled, upon written demand, to have access to and to copy shipping records in the possession of carriers engaged in interstate commerce or of persons receiving or holding drugs or devices in interstate commerce. The refusal to permit access to or copying of shipping records requested by the FDA in writing pursuant to Section 703 is a prohibited act, subjecting responsible persons to potential criminal liability (Sections 301(e) and 303 of the Act). However, any shipping records obtained pursuant to a written request for inspection under Section 703, and any evidence which is directly or indirectly derived from the shipping records, cannot be used in a criminal prosecution of the person[s] who made the records available to the FDA. This immunity from prosecution may be lost if the records are made available without first insisting upon and receiving a written

[10] 345 F. Supp. 1371 (DC Del. 1972).
[11] *Supra,* at 1376, footnote 12.
[12] 21 U. S. C. 373.

request for the records. It is because of this grant of immunity that the FDA only infrequently makes inspections of interstate shipments pursuant to Section 703.

Under Section 704 of the Act,[13] officials and employees designated by the FDA are authorized, upon presenting appropriate credentials and a written notice of inspection to the owner or operator, to enter at all reasonable times any factory, warehouse or establishment in which drugs or devices, shipped or to be shipped in interstate commerce, are manufactured, processed, packed or held. Within reasonable limits and in a reasonable manner, such officials and employees may examine and inspect the premises, equipment, finished and unfinished material, containers and labeling found on the premises. In addition, the inspector is entitled, upon providing a written receipt and, if requested, just compensation, to take samples of raw materials, goods-in-process, finished goods, and packaging and labeling found on the premises. If the inspector takes samples during an inspection, I strongly recommend that the owner or operator establish the routine of taking and retaining duplicate samples in case any question arises as to the accuracy of the FDA's analysis of the sample.

Reasonable Explanation

Where a device, as opposed to a new drug or a prescription drug, is the subject of inspection, the FDA is not entitled, as a matter of law, to any additional information. Manufacturers and distributors of devices are not required to give the inspector access to shipping and manufacturing records, complaint or personnel files, or product defect reports. However, if the inspector offers a reasonable explanation as to why access to these records is desired, it usually pays to cooperate with the Agency and make the information available. Conversely, if the inspector refuses to offer any reasonable explanation as to why he desires access to records to which he is not legally entitled and it appears that he is engaged in a mere fishing expedition, there are sound practical, as well as legal, reasons for respectfully declining to provide the requested information.

If, in the judgment of the inspector, the inspection of the premises and equipment reveals any conditions or practices which indicate that a device or drug contains filthy, putrid or decomposed substances or has been manufactured, packaged or held under insanitary conditions whereby it may have become contaminated with filth or rendered in-

[13] 21 U. S. C. 374.

jurious to health, the inspector, before leaving the premises, is required to provide the owner or operator with a written report specifying these conditions. In addition, at the completion of an inspection, it is the practice of some inspectors to request the owner or operator to sign an affidavit attesting to the findings of the inspector. The inspector has no legal right to require the execution of an affidavit and I recommend against signing an affidavit, since ordinarily the only purpose of the affidavit is to ease the FDA's burden in any subsequent litigation.

New Drug Application

If a product subject to inspection is classified as a drug or new drug, the FDA, in addition to the general factory inspection authority contained in Section 704 of the Act, has the authority, under Section 505(j)(1),[14] to require the holder of an approved new drug application (NDA) to establish and maintain such records and to make such reports relating to the safety and efficacy of the new drug as the Commissioner by regulation finds necessary to facilitate a determination as to whether grounds exist for instituting proceedings to revoke the NDA. Every person required to maintain records under Section 505(j)(1) is required, by Section 505(j)(2), to permit, at all reasonable times, a duly designated officer and employee of the FDA to have access to and to copy or verify such records. Pursuant to the authority contained in Section 505(j)(1), the FDA has promulgated detailed regulations.[15] Among other things, these regulations require the maintenance of records and the filing of reports on the published and unpublished reports of studies and investigations with the drug, on the clinical experience with the drug and on information relating to the quantity of drug distributed over a specific time period. Moreover, if a drug is subject to prescription drug classification, the inspector is entitled, under Section 704, to inspect essentially all records, data and information contained in the establishment (including any manufacturing, distribution and clinical experience records) which bear upon whether the prescription drug is adulterated, misbranded or otherwise in violation of the Act. The only exceptions to this broad inspection authority with respect to prescription drugs are certain data relating to finances, sales, pricing practices and research activities.

Congressional Bills

This discussion has been limited to the FDA's inspection authority under the existing statutory and regulatory scheme. However, there

[14] 21 U. S. C. 355(j).

[15] 21 CFR 310.300.

are two bills presently pending before Congress, either of which would substantially expand the FDA's inspection authority with respect to devices. One of the bills, H. 5545, was introduced by Congressman Rogers in the House of Representatives in March of 1975 and has been referred to the Committee on Interstate and Foreign Commerce and its Subcommittee on Public Health and the Environment, where it is still awaiting action. The other bill, S. 510, was introduced by Senator Kennedy in January and was passed by the Senate in April of this year. Under both H. 5545 and S. 510, the FDA is authorized to promulgate regulations requiring the maintenance of records and the filing of reports and information with the Agency bearing upon the safety and efficacy of devices or reasonably required to assure that a device is not adulterated or misbranded. Under H. 5545, the requirement concerning the maintenance of records and the filing of reports is intended to apply to all manufacturers, distributors and importers of devices. It is intended to cover all categories of devices including, with certain limitations, the devices subject to general controls, that is, those generally recognized as safe and effective. The record and reporting requirements under S. 510 are intended to apply to manufacturers, distributors and *sellers* of devices which are subject to "scientific review" (which is Congress' euphemism for premarket clearance) or "performance standards." In other words, the record and reporting requirements are more expansive (or restrictive depending upon one's viewpoint) under S. 510 than under H. 5545 insofar as the requirements are intended to apply to all sellers of devices, as well as manufacturers and distributors, but less expansive insofar as the requirements are not intended to extend to devices which are subject only to the general controls, as opposed to scientific review or performance standards.

Access to Records

Under both S. 510 and H. 5545, upon the request of a duly authorized official or employee of the FDA, every person who is required to maintain records and every person who is in charge of or has custody of the records is required to permit, at all reasonable times, the designated FDA official or employee to have access to and to copy and verify such records.

Based upon the present practices of the Agency, one can be assured that the FDA will use its authority to promulgate regulations requiring the maintenance of records to require manufacturers, distributors and [sellers] of all important devices to maintain records of the published and unpublished reports relating to the safety or

efficacy of the devices, of all consumer complaints, and of manufacturing processes and controls used in the production of the devices and the quantity of the devices distributed over a specified time. In addition, it is anticipated that the FDA would use the authority to require reports as the basis for requiring manufacturers, distributors and sellers of devices to promptly report to the Agency all significant adverse reactions and any significant manufacturing failure or product defect.

In addition to the authority which these bills would vest in the FDA to require the maintenance of records and to obtain access to such records, both bills would amend Section 704 of the Act so as to significantly expand the Agency's authority to inspect and obtain data and information relating to prescription devices. As discussed earlier, under existing Section 704 of the Act, the FDA's inspection authority with respect to both over-the-counter and prescription devices is limited to entering any factory, warehouse or establishment in which devices are manufactured, processed, packed, or held for introduction into interstate commerce or held after such introduction. In addition, the Agency may inspect such premises and the pertinent equipment, finished and unfinished materials, containers and labeling found therein. The FDA is not entitled under Section 704 to inspect manufacturing or distribution records for devices or to obtain access to any complaint files with respect to devices. The contemplated amendments to Section 704, however, would explicitly authorize the Agency to inspect essentially all things, including manufacturing and quality control records, complaint files, shipping records, internal memoranda, etc. in any establishment in which prescription devices are manufactured, processed, packed or held, which bear on whether the prescription devices are adulterated, misbranded, or otherwise manufactured, processed, packed, transported or held in violation of any provision of the Act. The only data and information relating to prescription devices which would not be subject to inspection under amended Section 704 is: (1) financial data; (2) sales data, other than shipping data; (3) personnel data, other than that relating to qualifications; and (4) research data, other than data required to be maintained under the general records and reporting provisions discussed above or under the specific records and reporting requirements made applicable by regulation to devices subject to scientific review. This amendment to Section 704 would make the FDA's inspection authority with respect to prescription devices coextensive with its existing authority with respect to prescription drugs.

[The End]

Lawyers of the FDA—Yesterday and Today

By FRANCIS E. McKAY

Mr. McKay Is Chief of the Pleadings Branch in the Food and Drug Division of the Department of Health, Education and Welfare Office of the General Counsel.

IT WAS IN 1906 that it all began. With the signing of the Food and Drug Act of 1906 by President Theodore Roosevelt on June 30, 1906, a new responsibility was thrust upon the Solicitor's Office of the United States Department of Agriculture (USDA). This involved the performance of legal services in connection with the review and prosecution of seizure and criminal cases under the Act, as recommended by the Department's Bureau of Chemistry, then headed by Dr. Harvey W. Wiley.

At that time George McCabe was the Department's Solicitor. He selected Willie Parker Jones, one of the Department's senior attorneys, to be responsible initially for handling food and drug cases and to head the new Food and Drug Section in the Solicitor's Office. Mr. Jones continued as head of the Section until about 1912, when he was appointed to another position in the Office of the Solicitor.

In 1908, a young attorney by the name of Patrick D. Cronin, who had entered government employment in the Forest Service in 1906, transferred to the Solicitor's Office, where he was assigned to food and drug law work. P. D. Cronin, as he preferred to sign his official correspondence, was born in South Boston, Massachusetts, on March 15, 1878 and obtained his legal schooling at Harvard and the Columbia Law School.

During his early years in the Solicitor's Office, Mr. Cronin was selected to act for the Solicitor in personally assisting the United States Attorneys and their assistants in the expeditious handling of the food and drug cases which had been referred to them. With his

knowledge of food and drug law, Mr. Cronin was able to familiarize the attorneys with the requirements of the new law and to provide legal advice on many of the novel questions of interpretation and application that arose. Mr. Cronin was appointed, in 1912, to succeed Willie Parker Jones, as Chief of the Food and Drug Section in the Solicitor's Office. He continued in this position until 1945. During his tenure, the Federal Food, Drug and Cosmetic Act of 1938 was enacted. His section and the Food and Drug Administration (FDA) were transferred to the Federal Security Agency pursuant to President Franklin D. Roosevelt's 1940 Reorganization Plan No. IV. Following this transfer, the Food and Drug Section was designated as the Food and Drug Division of the General Counsel's Office of the Federal Security Agency and Mr. Cronin was designated as Assistant General Counsel for the Division.

Administrative Hearings

In addition to Mr. Cronin, a small staff of lawyers was employed in the Food and Drug Section and in the Division which he headed. Some of the lawyers were directly involved in assisting United States Attorneys in the trial of food and drug cases while other lawyers were engaged in preparing the pleadings, in drafting regulations and in participating in administrative hearings. Among such lawyers who were on the staff in the last years at Agriculture and the early years at the Federal Security Agency were Daniel P. Willis, Edward Brown Williams, Michael Markel, John Murphy, William W. Goodrich and John V. O'Donnell, the Assistant Chief. Edward Brown Williams became Assistant Chief after John O'Donnell, and, upon Williams' resignation to enter private practice, Daniel Willis was appointed as Assistant Chief.

P. D. Cronin died on April 21, 1945, while still Assistant General Counsel. As Dr. Paul D. Dunbar, Commissioner of Food and Drugs then said:

"Pat Cronin will be remembered by his many friends in the Food and Drug Administration as one who shared their own convictions about the public-service value of food and drug law enforcement. Never interpreting the law in a narrow, technical sense, his constant endeavor was to apply its terms in such a way as to insure the greatest public protection. As a legal counsellor his wide experience and technical knowledge were always at the service of officers of the Food and Drug Administration. We took our problems to him in full knowledge that he would give them painstaking and sympathetic consideration."

It was also said of P. D. Cronin by Jack Tate, the General Counsel of the Federal Security Agency, that:

"He was the finest type of public official. We admired the high standard that he set and we tried to follow his example. He truly devoted his life to the welfare of his country. I am sure that the administration of the Food and Drug Act would not be as highly respected and as effective in the public good if P. D. had not been one of the small group who started it on its way and who carried on with it through the years. His intelligence, his high sense of integrity, his good humor and his unfailing sense of right and justice were foundation stones."

Daniel P. Willis was appointed Assistant General Counsel of the Food and Drug Division in 1945, after the death of Mr. Cronin. Mr. Willis was born at Church Creek in Dorchester County, Maryland, and attended law school at the University of Maryland before studying law in the office of the State Attorney in Dorchester County. He practiced law for ten years in Cambridge, Maryland, and was a United States Commissioner for three years before he began his government career in 1930 in the Solicitor's Office of USDA. In the mid-thirties he was assigned to assist in the trials of food and drug cases.

When Dan Willis became Assistant General Counsel, the Division was still small, with the following lawyers on its staff: Joseph Maguire; Ed Turkel; James Goding; Bernard Levinson; Arthur Dickerman; John Murphy; William Goodrich (on military leave); George Shaw; Benjamin Frauwirth; Francis McKay and Al Loverud (subsequently chosen to be Assistant Chief of the Division).

Branch Office

During Willis' years as Assistant General Counsel, the workload of the office steadily increased, requiring the employment of additional lawyers. A branch office, headed by Arthur Dickerman, was established in Los Angeles in 1947 to handle food and drug litigation in the far west area of the United States. In 1949, the office suffered a severe loss from the death of its Assistant Chief Al Loverud who, only a few months before, had completed his service as chief trial attorney in the second Koch trial involving Glyoxylide, a drug represented as a cancer remedy.

During this period, the Division gained the services of a number of young talented lawyers, including Alvin Gottlieb, Paul Steffy, William Risteau, Leonard Hardy, Selma Levine, Al Meissner, Ed Adelsheim and Lester Uretz. With these additional lawyers and with the appointment of William W. Goodrich as Assistant Chief, the Food and Drug Division continued to perform effectively the legal services required by the FDA in connection not only with the litigation of cases under the Federal Food, Drug and Cosmetic Act but also under various recent amendments to the Act, such as the Oleo-

margarine Act and the Durham-Humphrey Act relating to prescription drugs.

During this time a gradual but steady deterioration occurred in the health of Dan Willis, which resulted in his early retirement in 1952. At that time the Commissioner of Food and Drugs, Charles W. Crawfore, spoke of Willis in these words:

"With his all-too-early retirement, Dan Willis closes a record of distinguished service that will stand in the annals of Food and Drug law enforcement in a lasting tribute. He was the Food and Drug Administration's attorney in the development and trial of a long list of the toughest and most crucial cases—cases we remember by the names *Alberty, Marmola, Merlek, Nue-Ozo, Warm Springs,* to mention only a few. The intensity of his effort in preparing and trying his cases was a never-ending source of wonder to his associates. When a trial was in prospect nothing could stand in the way of his thorough preparation; and when the trial began he took but little time to eat and sleep. The first Koch case, which dragged out for 5 months, was a prodigious strain from which I do not believe he ever fully recovered.

"In developing legal plans and procedures he showed unusual resourcefulness and ingenuity. In cases involving many unexplored areas of law created by the passage of the Federal Food, Drug, and Cosmetic Act of 1938, his theories were fully accepted by the courts. His legal skill, his sound judgment, his fine sense of justice, his genuine concern for public welfare have contributed greatly to the success of food and drug law enforcement throughout his years of service."

After Dan Willis' retirement in early 1952, "Billy" Goodrich, as he was known at the General Counsel's office and at the FDA, was appointed Assistant General Counsel of the Food and Drug Division, and Joseph L. Maguire was chosen as Assistant Chief of the Division. Billy Goodrich was born in Marlin, Texas, on June 24, 1915, and graduated from the University of Texas and the University of Texas Law School. Following a period of private practice, he came to work with the Office of the Solicitor in USDA and was assigned to FDA matters. Through this appointment, the career tradition of promoting lawyers from within the Division was continued.

RIF Program

Shortly afterwards, the Food and Drug Division was confronted with a situation that had not previously arisen. Due to a cut in appropriations by the Congress, the institution of a RIF (reduction in force) program became necessary. Therefore, with much regret, several of the Division's most promising younger lawyers had to be released. A period of gradual attrition of staff personnel then ensued for several years, resulting in a decrease from a high of about 20 attorneys prior to the RIF to a low of 12 attorneys in 1955.

Following the depressing RIF experience and the change of the Federal Security Agency to the Department of Health, Education and Welfare (HEW), morale gradually improved in the office. In the middle and late fifties, as some of the attorneys on the staff moved on to other government positions and into private practice, a few additional attorneys were hired including Joanne Sisk, Robert Becker, William Brennan, Alan Kaplan, Rodney Munsey, and Warren Whyte. In May 1957, the position of Assistant Chief (which later was designated as Deputy Assistant General Counsel) became vacant due to the death of Joe Maguire and was subsequently filled by the promotion of Alvin Gottlieb to this position.

After Billy Goodrich became Assistant General Counsel, the office experienced a continued growth in its work. Additional amendments to the Federal Food, Drug and Cosmetic Act, consisting of the Pesticide Chemical Amendment and the Food Additives Amendment, were enacted. Significant cases involving the expenditure of much time and money were successfully concluded against Mytinger and Casselberry (relating to a vitamin and mineral product known as Nutrilite), Dinshah Ghadiali (Spectrochrome device), Wilhelm Reich (orgone energy accumulator device), and Hoxsey Cancer Clinic (a cancer treatment). Multiple seizures were made of many shipments of cranberries which were contaminated with the pesticide chemical aminothiazole. A decision in the *Dyestuffs and Chemicals* case was handed down by the Court of Appeals for the 8th Circuit in 1959 in favor of the government which established an important precedent in food and drug law concerning circumstances when objections to an administrative order would not justify an administrative hearing.

Most Important Amendments

The 1960's witnessed the enactment of the Color Additive Amendments, the Drug Abuse Control Amendments, the New Animal Drug Amendments and, what are probably the most important amendments that have yet been made to the Act, the Drug Amendments of 1962. The 1962 Drug Amendments require, among other things, that new drugs be approved by the FDA for effectiveness as well as for safety before they can be marketed. This new legislation substantially increased the workload of the Food and Drug Division. A heavy burden of litigation also developed in this period in connection with a large number of cases including Krebiozen (offered as a treatment for cancer), the Ellis Micro-Dynameter (a device for use in the diagnosis of disease), the Toilet Goods Association's cases (concerning the

timeliness or ripeness for judicial review of a challenge to the color additive regulations) and the Panalba drug case (relating to the right to an administrative hearing). The Division therefore found it necessary to employ additional attorneys. Among the attorneys who came to the office at that time were Robert Anderson, Bruce Brennan, Walter (Ed) Byerley, Edgar Cardwell, Harris Cutler, Joseph D'Erasmo, John Eldred, Michael Foley, Salvatore Franchino, Mary Goggin, Howard Harrison, William Herlihy, Paul Hyman, Axel Kleiboemer, Charles Marr, Nick Onychuk, Forrest Patterson, William Pendergast, Eugene Pfeifer, James Phelps, T. Gorman Reilly, Jeffrey Springer, Gary Yingling and John Young.

Some of these attorneys, after a few years, left the Division for opportunities elsewhere. Also, a longtime member of the staff, John Murphy, decided to retire in early 1962 after approximately 50 years of government service. Nevertheless, at the end of the 1960's, eighteen attorneys remained on the staff of the Division.

The decade of the 1970's began with the movement, about March 1970, of the Division from the HEW headquarters, North Building, on Independence Avenue, Washington, D. C. to the Parklawn Building on Fishers Lane in Rockville, Maryland. This move was made so that the Division could continue to serve effectively the FDA, whose headquarters was also moved to the Parklawn Building.

Surprise Retirement

On May 31, 1971, Billy Goodrich retired from his position as Assistant General Counsel after nearly 32 years of government service, during which he received the Superior Service Award and the Distinguished Service Award from HEW. The announcement of his retirement came as a surprise and with a real sense of loss by those in the Division and in the FDA who had been associated with him for so many years. FDA Commissioner Charles C. Edwards summed up this feeling very well in stating in a letter that "More than any single individual I can name, you have played a crucial role in shaping the development of this entire program." HEW Secretary Elliot Richardson called Goodrich "the Department expert" in food and drug matters, and said, "Your leaving is a great loss to the Department." "The Pink Sheet" stated, "Respected by friend and foe as a true pro—an effective and creative advocate of FDA's legal position —Goodrich expanded his influence beyond the role of general counsel to emerge as the major influence in determining FDA regulatory policy."

After the retirement of Billy Goodrich, Peter Barton Hutt was appointed as Assistant General Counsel for the Food and Drug Division, effective September 1, 1971. Hutt was born in Buffalo, New York, on November 16, 1934 and graduated from Yale University and Harvard Law School. He obtained his masters in law from N.Y.U. Law School under a fellowship from the Food and Drug Law Institute. Before his appointment, he had been active in the practice of food and drug law at the law firm of Covington & Burling in Washington, D. C. for approximately eleven years, and was a partner in the firm during the last three of those years.

Promulgation of Regulations

In accepting the appointment, Mr. Hutt said, "My philosophy is literally to do the best job conceivable for my client. The client will be the public through the FDA." Pursuant to this philosophy, Hutt emphasized the promulgation of regulations to implement the provisions of the Act, the most significant of which are probably those relating to food and nutrition labeling, GRAS food ingredients, new drug hearings, over-the-counter drugs, diagnostic products, biologics review, new "Freedom of Information" Act regulations, and regulations governing the Agency's practices and procedures.

This emphasis did not, however, result in any neglect in the enforcement of the Act through litigation. In 1973 alone, four landmark cases involving USV Pharmaceutical Corp., Ciba Corp., Bentex Pharmaceuticals, and Hynson, Westcott & Dunning, Inc., were decided by the Supreme Court. In these cases, the Court clarified and greatly strengthened the FDA's jurisdiction in new drug matters, the "grandfather" exemption from the new drug provisions of the Act, and the circumstances under which administrative hearings may be denied. In 1974, the litigation which began in 1971, involving in excess of 100 seizure actions against "Bon Vivant" soups alleged to be adulterated because of their preparation under insanitary conditions which may have rendered them injurious to health, was successfully concluded in favor of the government.

During Peter Hutt's tenure, the office expanded from a staff of 18 attorneys to 38, with an anticipated additional seven attorneys in pending appropriations. A system of bureau liaison attorneys was instituted, the result being greater daily contact by all Division staff with the FDA. In October 1974, the position of Assistant General Counsel was for the first time given the title of Chief Counsel of the Food and Drug Administration.

In December 1974, Peter Hutt announced that he would be leaving government service in May.* In the short time that he was with the Division, he received the Secretary's Special Citation, the FDA's Award of Merit, the Department's Distinguished Service Award, and the Arthur S. Fleming Award as one of the ten outstanding young men and women in the federal government. In accepting his resignation, John Rhinelander, the Department's General Counsel, said that "in my years of government service, I have never worked with an attorney who matched your legal skills, extraordinary work hours and talent for getting done well what should be done."

Multitude of Tasks

The end of the year 1974 saw the Division busy with a multitude of tasks relating to food and drug seizure, injunction and criminal actions instituted by the government, the defense of declaratory judgment and injunction actions brought against the FDA, the drafting of regulations, holding of administrative hearings, and counseling and advising the FDA on legal matters. The attorneys then serving the Division numbered 30 and consisted of Peter Hutt, Alvin Gottlieb, Edward Allera, Ken Baumgartner, Alan Bennett, Eric Blumberg, Fletcher Campbell, Edgar Cardwell, Terry Coleman, Anne Davidson, Ruth Edelson, John Eldred, Jay Geller, Howard Holstein, Arthur Levine, Francis McKay, Stephen McNamara, Stuart Pape, Forrest Patterson, Paul Ragan, Charles Raubicheck, Thomas Scarlett, Richard Silverman, Joanne Sisk, Robert Spiller, Jeffrey Springer, William Vodra, Jack Wohlreich, Gary Yingling and John Young.

In conclusion, it should be noted that in 68 years of federal food and drug law enforcement there has been no instance in which the integrity of any lawyer for the FDA has been questioned or any suspicion of corruptness of any such lawyer arisen. It is with justifiable pride that each lawyer who has served and is serving in the Food and Drug Division can look to the accomplishments of the Division under the leadership of Pat Cronin, Dan Willis, Billy Goodrich, Peter Hutt and Richard Merrill. **[The End]**

* On June 2, 1975, Richard A. Merrill, former Associate Dean of the University of Virginia Law School, was sworn in as Assistant General Counsel.

FOOD DRUG COSMETIC
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