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Food Drug Cosmetic Law JOURNAL

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG LAW INSTITUTE, INC.

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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Twenty-Third Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association.—The introduction and succeeding papers in this issue of the JOURNAL were presented at this meeting, which took place in New York City on January 23, 1968. Additional papers read at the meeting will be published in a later issue.

The "Introductory Statement" on page 69 is by *Franklin M. Depew,* President of the Food and Drug Law Institute and Chairman of the Meeting. It includes comments on the new regulations under the Fair Packaging and Labeling Act and the efforts of the Food and Drug Administration toward the achievement of voluntary compliance under this Act.

In his article, "Counsel's Role in Current Good Manufacturing Practice," which begins on page 71, *Richard E. Williams* discusses the failure of the Federal Food, Drug and Cosmetic Act to establish definitive standards for drug manufacturing. He stresses the fact that the law is too vaguely worded for precise evaluation of manufacturing processes. However, the author, who is Food and Drug Coordinator for Richardson-Merrell, Inc., points out that the most effective tool for the implementation of the statute is the diligent self-evaluation of the manufacturers. Their efforts will insure maximum compliance with a statute the standards of which can, perhaps, never be totally achieved.

Esther O. Kegan, who is a member of the law firm of Kegan, Kegan & Berkman, discusses the impact of "Federal Pre-emption in Consumer Laws" on the responsibilities of state governments in the field of consumer protection. The article begins on page 79.

"Some Applications of Drug, Device and Narcotic Laws for Health Science Practitioners," by *Sidney H. Willig,* is a thorough exploration of drug laws and regulations as they affect the pharmacist and physician, particularly in the use of the so-called "dangerous drugs" and narcotics. Mr. Willig, who is Professor of Law at Temple Law School, points out the moral and legal responsibilities of those who dispense drugs, and discusses the vulnerability of a physician who prescribes drugs for experimental purposes. The article, which begins on page 89, also deals with the question of dispensing narcotic drugs, and emphasizes the fact that physicians must be completely aware of all federal and state drug provisions in order to protect themselves and the public from damaging illegal procedures.

Correction.—The January issue of the JOURNAL incorrectly described *M. L. Yakowitz* as Director of the Division of Case Supervision, Bureau of Regulatory Compliance, FDA. Mr. Yakowitz is currently with Smith, Kline and French Laboratories in Philadelphia.

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Search Warrants and Sanitation Inspections— The New Look in Enforcement

By SIDNEY EDELMAN

The Following Article Was Presented at the 95th Annual Meeting of the American Public Health Association, Inc. at Miami, Florida, Housing and Health Session, October 25, 1967. Mr. Edelman Is the Chief of the Environmental Health Branch, Public Health Division, Office of the General Counsel, Department of Health, Education, and Welfare.

THE RECENT DECISIONS of the Supreme Court of the United States in *Camara v. Municipal Court of the City and County of San Francisco*[1] and *See v. City of Seattle*[2] call for a thorough reexamination and revision of the concepts and procedures which have previously guided the conduct of housing, sanitation and safety inspection programs in this country.

The *Camara* case arose out of the refusal of Camara, the lessee of the ground floor of an apartment building, to permit a housing inspector access to a part of the leased premises used by Camara as a personal residence. This residential use was alleged to be in violation of the occupancy permit for the building. Camara was advised that section 503 of the San Francisco Housing Code authorized the entry of housing inspectors into any building, structure or premises in the City, but he persisted in refusing the inspectors access to his apartment without a search warrant. Thereafter he was arrested and charged under section 507 of the Code[3] with refusing to permit a

[1] 87 S. Ct. 1727 (1967).
[2] 87 S. Ct. 1737 (1967).
[3] Under section 507, such refusal is a misdemeanor punishable by a fine of not more than $500 or by imprisonment for not more than 6 months or by both such fine and imprisonment.

lawful inspection. Contending that section 503 was contrary to the Fourth and Fourteenth Amendments, Camara sought a writ of prohibition in the Supreme Court against his trial on the charge of violating that section.

Upholding Camara's contention and overruling *Frank v. Maryland*[4], Mr. Justice White, writing for the Supreme Court, held that administrative searches for housing violations are significant intrusions on the privacy and security of individuals—interests which are protected by the Fourth Amendment[5] against arbitrary invasions by government officials and enforceable against the states under the Fourteenth Amendment.[6] The Court declared that such searches when authorized and conducted without a warrant procedure lack the traditional safeguards which the Fourth Amendment guarantees to the individual.

This is true, Mr. Justice White noted, whether the discovery of a violation on the initial inspection leads to a criminal conviction or results only in an administrative compliance order. In the latter case, he pointed out, refusal to comply is a criminal offense, with the fact of compliance verified by a second inspection, again without a warrant, and the refusal to permit the inspection is itself a crime.

Having concluded that a search warrant was necessary to support the inspection at issue, Mr. Justice White turned to the Fourth Amendment requirement that "no warrants shall issue but upon probable cause." Recognizing that "the only effective way to seek universal compliance with the minimum standards required by municipal codes is through routine periodic inspections of all structures,"[7] he declared that the area inspection approach was a reasonable search of private property within the meaning of the Fourth Amendment[8], and provided the following guidelines for the determination of "probable cause" to issue a warrant[9]:

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[4] 359 U. S. 360 (1959). This case held that sanitation and housing inspections not seeking evidence for criminal prosecution were not unreasonable searches within the Fourth Amendment and did not require search warrants.

[5] The Fourth Amendment (U. S. Constitution) provides:

"The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized."

[6] *Ker v. California*, 374 U. S. 23, 30 (1963); *Wolf v. Colorado*, 338 U. S. 25, 27 (1949); *Mapp v. Ohio*, 367 U. S. 643 (1961).

[7] *Camara v. Municipal Court of the City and County of San Francisco*, 87 S. Ct. 1727 (1967) at 1734.

[8] See footnote 7; p. 1735.

[9] See footnote 7; p. 1735.

. . . it is obvious that probable cause to issue a warrant to inspect must exist if reasonable legislative or administrative standards for conducting an area inspection are satisfied with respect to a particular dwelling. Such standards, which will vary with the municipal program being enforced, may be based upon the passage of time, the nature of the building (e.g., a multi-family apartment house) or the condition of the entire area, but they will not necessarily depend upon specific knowledge of the condition of the particular dwelling.

The Court noted three significant reservations to its general holding:[10]

1. Nothing in the opinion is intended to foreclose prompt inspections, even without a warrant, that the law has traditionally upheld in emergency situations.[11]

2. In the light of the Fourth Amendment's requirement that a warrant specify the property to be searched, "it seems likely that warrants should normally be sought only after entry is refused, unless there has been a citizen complaint or there is other satisfactory reason for securing immediate entry."

3. ". . . [T]he requirement of a warrant procedure does not suggest any change in what seems to be the prevailing local policy in most situations, of authorizing entry, but not entry by force, to inspect."

In *See,* the owner of a locked warehouse refused to permit a representative of the City of Seattle Fire Department to enter and inspect the warehouse without a warrant. Such inspection was part of a routine, periodic city-wide canvas to compel compliance with Seattle's Fire Code and was authorized by § 8.01.050 of the Code. That section authorized entry into buildings and inspections without a search warrant. See, who was convicted and given a suspended fine of $100 for violation of the section, contended that the warrantless inspection authorized by the Code would violate his rights under the Fourth and Fourteenth Amendments.

Mr. Justice White, speaking for the Court in this case also, declared that there was no justification for distinguishing between private houses and commercial premises insofar as the protection of the Fourth Amendment was concerned, saying:[12]

As we explained in *Camara,* a search of private houses is presumptively unreasonable if conducted without a warrant. The businessman, like the oc-

[10] See footnote 7; p. 1736.

[11] The opinion cites *North American Cold Storage Co. v. City of Chicago,* 211 U. S. 306 (seizure of unwholesome foods); *Jacobson v. Massachusetts,* 197 U. S. 11 (compulsory smallpox vaccination); *Compagnie Francaise v. Board of Health,* 186 U. S. 380 (health quarantine); *Kroplin v. Truax,* 119 Ohio St. 610, 165 N. E. 498 (summary destruction of tubercular cattle).

[12] *See v. City of Seattle,* 87 S. Ct. 1737 (1967) at 1739.

cupant of a residence, has a constitutional right to go about his business free from unreasonable official entries upon his private commercial property. The businessman, too, has that right placed in jeopardy if the decision to enter and inspect for violation of regulatory laws can be made and enforced by the inspector in the field without official authority evidenced by a warrant.

The Court concluded 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."[13]

This holding, like that in *Camara,* was hedged about by comments and reservations:

1. The Court, in footnote 6, with respect to the timing of a warrant, stated:

> We do not decide whether warrants to inspect business premises may be issued only after access is refused; since surprise may often be a crucial aspect of routine inspections of business establishments, the reasonableness of warrants issued in advance of inspection will necessarily vary with the nature of the regulation involved and may differ from standards applicable to private homes.[14]

2. The Court did not imply that business premises may not reasonably be inspected in many more situations than private homes.

3. The Court did not question such accepted regulatory techniques as "licensing programs which require inspections prior to operating a business or marketing a product."

The teaching of these cases is that an entry upon and inspection of private property, whether residential property or commercial property not open to the public, by government officials without proper consent is an "unreasonable search and seizure" within the Fourth Amendment and may not be enforced unless authorized by a valid search warrant.[15] Accordingly, the occupant may not be punished for refusing to permit a warrantless inspection. The restriction against entry on private commercial property would, of course, be applicable to the portions of multi-family houses reserved by the landlord, that is, boiler rooms, etc.

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[13] See footnote 12; p. 1740.

[14] This language would appear to limit the issuance of warrants in advance of refusal to permit inspection of residential premises to two situations listed at 87 S. Ct. 1737, 1736, that is, a citizen complaint or other satisfactory reason (and emergency?) for securing immediate entry.

[15] Although not an issue in these cases, corporations are protected by the Fourth Amendment against warrantless entries and inspections. "... [T]he Fourth Amendment has been held applicable to corporations notwithstanding their exclusion from the privilege against self-incrimination . . ." *Oklahoma Press Pub. Co. v. Walling,* 327 U. S. 186, 205 (1946); *Silverthorne Lumber Co. v. United States,* 251 U. S. 385 (1920); *Hale v. Henkel,* 201 U. S. 43 (1906); *United States v. Morton Salt Co.,* 338 U. S. 632 (1950)

Putting aside the problems relating to the development of inspection criteria designed to meet the probable cause requirement of the Fourth Amendment, as suggested by the Court, let us examine some of the other legal problems not mentioned in the decisions which will attend the administrative implementation of the Court's holdings.

Availability of Warrants

At the very threshold of our consideration we are confronted with the question, "Is there an available procedure for obtaining a search warrant to make an inspection?"

In *Camara*, the brief on behalf of the government pointed out that there was no specific provision in the San Francisco Code or in the State law under which a search warrant for inspection of the premises could have been obtained.[16] This situation is a generally prevailing one, since most state laws authorizing the issuance of search warrants are patterned on the federal authority which is limited to fruits of crime, instrumentalities and certain contraband.[17] Congress has never authorized the issuance of search warrants for the seizure of mere evidence of crime, although the Supreme Court has recently indicated that a search warrant could be authorized for such a purpose after fulfilling the probable cause and particularity requirements of the Fourth Amendment and after the intervention of "a neutral and detached magistrate."[18] Research has disclosed only eight states which, subject to the probable cause and specificity requirements of the Fourth Amendment, authorize the issuance of search warrants to search for and seize property constituting evidence of crime or tending to show that a particular person committed a crime.[19] Only one state, New Jersey, specifically authorizes the issuance of a search warrant to enter and inspect multi-family dwellings for housing code violations.[20] Clear authority for the issuance of inspection warrants (or

[16] Appellant's brief, p. 4.

[17] Rule 41 (b), Federal Rules of Criminal Procedures, provides:

"(b) Grounds for Issuance.

A warrant may be issued under this rule to search for and seize any property

(1) Stolen or embezzled in violation of the laws of the United States; or

(2) Designed or intended for use or which is or has been used as the means of committing a criminal offense; or

(3) Possessed, controlled or designed or intended for use or which is or has been used in violation of Title 18, U. S. C. § 957."

[18] *Warden, Maryland Penitentiary v. Hayden*, 87 S. Ct. 1642, 1650, 1651 (1967).

[19] New York: Code of Cr. Proc., § 792; Vermont: U. S. A., T. 13 § 4701; Montana: R. R. S. 1943, §§ 28-813; Oregon: O. R. S. § 141.010; Minnesota: M. S. A. § 626.07; Illinois: S. H. H. ch. 38, § 108-3; Calif.: Cal. Pen. Code § 1524 (only in case felony has been committed).

[20] N. J. S. A. 55:11-16.

equivalent Court orders) under Fourth Amendment safeguards is thus a matter of the highest priority.

In the light of the rulings in these cases, the Department of Health, Education, and Welfare has taken the position that inspection warrants may be issued under the specific authorities for inspection provided in the Federal Food, Drug, and Cosmetic Act and in the Federal Hazardous Substances Act. A few of such warrants have already been obtained, and the forms developed for such purpose are included in the Appendix. Whether a similar approach is feasible under state and local laws would, of course, depend on an evaluation of the prevailing statutory situation.

The Exclusionary Rule

Lest there be any temptation to do business as usual on initial inspections, one consequence of an illegal search, which should be noted here, is that any seizure made during an illegal search would itself be illegal, and if timely and appropriate objection is made, such items may not be used or remain in evidence.[21] This exclusionary rule, flowing from the command of the Fourth Amendment implemented by the Fifth Amendment, is applicable to the states under the Fourteenth Amendment.[22] The rule has traditionally barred from trial physical, tangible materials obtained either during or as a direct result of an unlawful invasion. But the policies underlying this rule do not invite any distinction between tangible and intangible evidence so that a verbal statement made during an illegal search has been suppressed[23] and testimony concerning objects illegally observed has been excluded.[24] Nor may conditions illegally observed be the basis for subsequently swearing out a search warrant.[25] The applicability

[21] *Weeks v. United States*, 232 U. S. 383 (1914); *Silverthorne Lumber Co. v. United States*, 251 U. S. 385, 391-392 (1920); *Boyd v. United States*, 116 U. S. 616, 630 (1886).

[22] *Mapp v. Ohio*, 367 U. S. 643 (1961). As the Court declared in *Ker v. California*, 374 U. S. 23, 30 (1963):

"In *Mapp v. Ohio*, at 646-647, 657 we followed *Boyd v. United States*, 116 U. S. 616, 630 (1886) which held that the Fourth Amendment, implemented by the self-incrimination clause of the Fifth, forbids the Federal Government to convict a man by using testimony or papers obtained from him by unreasonable searches and seizures as defined in the Fourth Amendment. This means, as we said in *Mapp*, that the Fourth Amendment 'is enforceable against them [the states] by the same sanction of exclusion as is used against the Federal Government' by the application of the same Constitutional Standards prohibiting 'unreasonable searches and seizures' 367 U. S. at 655."

[23] *Wong Sun v. United States*, 371 U. S. 471, 484-486 (1963); *Silverman v. United States*, 365 U. S. 505 (1961).

[24] *McGinnis v. United States*, 227 F. 2d 598, 603 (1955).

[25] *Silverthorne v. United States*, cited at footnote 21; *McGinnis v. United States*, cited at footnote 24.

of this rule emphasizes the importance of establishing clearly that consent has been obtained for a warrantless search based on consent.

Consent to Warrantless Search

With these considerations in mind, let us now examine the question of consent to a warrantless search, a consent which is needed under the Fourth and Fifth Amendments to assure the legality of the search as well as the availability of evidence so obtained. While the Supreme Court has held that constitutional rights protected by the Fourth and Fifth Amendments may be voluntarily waived,[26] the cases identify a gulf between acquiescence or submission and the consent necessary to constitute a voluntary waiver. Where officers demand admission to private premises in the name of the law or under color of office, their subsequent explorations have been held searches within the bar of the Constitution, even though the occupant opens the door to admit them.[27] Such entry, it has been said, is "granted in submission to authority rather than as an understanding and intentional waiver of a constitutional right."[28]

In short, the consent must be unequivocal and specific, freely and intentionally given. Where a search alleged to be based on consent is challenged, courts have required evidence showing that the consent was given in the knowledge that the occupant has the right to refuse such consent with impunity.[29] When entry into a person's premises by officers of the law not having a warrant is sought to be justified by that person's consent, the applicable standard is a rigorous one, and the Government has the burden of proving by clear and positive evidence, that such consent has been given.[30]

Evidence of consent may be oral or written and experience in the inspection field will show which is preferable.[31] Where a verbal consent is relied on, some Federal Courts have held that nothing short of a statement advising the person of his right to refuse a

[26] *Zap v. United States*, 328 U. S. 624, 628 (1946).

[27] *Amos v. United States*, 255 U. S. 313 (1921); *Johnson v. United States*, 333 U. S. 10, 13 (1948).

[28] *Johnson v. United States*, 333 U. S. 10 (1948) at 13; *United States v. Smith*, 308 F. 2d 657, 663 (1962).

[29] *Judd v. United States*, 190 F. 2d 649, 651 (1951); *Robbins v. MacKenzie*, 364 F. 2d 45, 49 (1966), cert. den.; *United States v. Como*, 340 F. 2d 891 (1955).

[30] *McDonald v. United States*, 307 F. 2d 272 (1962); *Judd v. United States*, cited at footnote 29; *Simmons v. Bomar*, 349 F. 2d 365, 366 (1965). *Kovach v. United States*, 53 F. 2d 639 (1931); *Channel v. United States*, 285 F. 2d 217, 219 (1960); compare *Parrish v. Civil Service Comm. of County Alameda*, 57 Cal. Rptr. 623 (1967).

[31] The Department of Justice "Handbook on the Law of Search and Seizure (1967)" recommends that the consent

(Continued on next page.)

warrantless search will meet the Fourth Amendment requirement of a knowing waiver imposed to prevent the possibility that the ignorant may surrender their rights more readily than the shrewd.[32]

Standing to Challenge Seizure

Under section 41 (e) of the Federal Rules of Criminal Procedure only a "person aggrieved by an unlawful search and seizure" has standing to move for the exclusion or suppression of the property seized. As illumined by the Supreme Court, this rule reaches not only the victims of the invasion, (generally described as having an interest in the premises, such as ownership, a right to possession or the interest of a lessee), but, as stated in *Jones v. United States*[33] "anyone legitimately on premises where a search occurs may challenge its legality by way of a motion to suppress, when its fruits are proposed to be used against him." In *Jeffers v. United States*,[34] the rule was extended to include the owner of property seized as the fruit of an unlawful search even though the premises searched were not his and he was not present at the time of the search.

California has adopted an even more liberal view on the exclusion of evidence and holds that evidence obtained by virtue of an unlawful search and seizure is inadmissible whether or not it was obtained in violation of the particular defendant's constitutional rights.[35]

(Footnote 31 continued.)
be in writing and suggests the following form (p. 52):

"I, John Doe, knew of my constitutional rights to refuse to allow a police search of any part of my house at 711 Royalty Road, Alexandria, Va. However, I have decided to allow Tom Smith and Bill Jones, members of the Metropolitan Police, to search every part of my house. They have my permission to take any letters, papers, materials, or other property they want. I have decided to make this consent carefully, of my own free will, and without being subject to threats or promises. I know that anything discovered may be used against me in a criminal proceeding.

Jan. 22, 1967
Signed John Doe

Witness 1. Bob Janitor."

[32] *United States v. Blalock*, 255 F. Supp. 268 (1966); *United States v. Nickrasch*, 367 F. 2d 740, 744 (1966). Contra: *Gorman v. United States*, 36 L. W. 2039 (1967) which held a specific Fourth Amendment warning unnecessary in the following factual situation:

"When the accused is directly asked whether he objects to the search, there must be at least some suggestion that his objection is significant or that the search waits on his consent. When this is combined with a warning of his right to counsel, which would seem in the circumstances to put him on notice that he can refuse to cooperate, we think it fair to infer that his purported consent is in fact voluntary."

[33] 363 U. S. 257, 267 (1960).

[34] C. A. D. C. 1950, 187 F. 2d 498, 501; affd. 342 U. S. 48.

[35] *People v. Cahan*, 44 Cal. 2d 434, 282 P. 2d 905 (1955); *People v. Martin*, 45 Cal. 2d 755, 290 P 2d 855, 857 (1955). Compare *State v. Schaffel*, 229 A. 2d 553 (1966).

Thus, where it is attempted to use evidence obtained in an unlawful search of a tenant's apartment against a landlord, the landlord may, under the Federal rule, be able to suppress the evidence on the grounds that he owned the property seized or, under the California rule, simply on the grounds that the search and seizure was unlawful.

"Particularly Describing . . . the Things to Be Seized"

The Fourth Amendment requirement that a search warrant "particularly" describe "the things to be seized" may occasion some difficulty for general housing and sanitation inspections which extend from defective appliances, hazardous conditions, and cleanliness to window screens, ratholes and the number of electrical outlets in a room. Such a broad-ranging inspection may require a thorough search of every room in an apartment, or entire commercial premises as well as closets, cupboards, storerooms and related accounts and records. But a warrant which was so broad that the appropriate limits of the inspection would depend on the discretion of the investigator and could not be verified by reference to the warrant itself, would obviously fall short of the Fourth Amendment requirement. As the Court observed in *Camara*, in the absence of a warrant, the appellant was unable "to verify . . . the appropriate limits of the inspection."[36]

While it could be argued that the Fourth Amendment requires that the warrant must specify in detail every item to which the inspection will be directed, a reasonable middle ground, which will permit the court's issuing the warrant to determine its necessity as well as enable the verification of the limits of the search, would call for a statement of the purpose of the search, that is, inspection of the physical condition of the premises, plumbing, electrical wiring and fixtures and related conditions bearing on violations of sections ..... of the Housing Code [and of sections ..... of the regulations issued thereunder]. It may also be desirable to attach to the warrant copies of the cited sections of the code.

Enforcement of Warrants

If the occupant of premises to be searched refuses to comply with a warrant, how is the warrant to be enforced?

In *See*, as noted earlier, the Court spoke of compelling entry "through prosecution or physical force within the framework of a warrant procedure", while in *Camara*, it indicated that force to com-

[36] See footnote 7; p. 1736.

pel entry into residential premises was not contemplated by the requirement of a warrant procedure.

While entry by force is the traditional method of enforcing compliance with a warrant,[37] this approach appears relevant only to seizing evidence of a crime which may be disposed of or secreted if entry is delayed. In the case of housing violations, these can be hidden from the inspector only by the desired remedial action, so that delay, except in the case of emergencies, does not ordinarily frustrate the public interest.

When entry under a search warrant is refused, the court could punish such refusal. In addition, the provisions in most housing codes, penalizing a refusal to comply with or resistance to the execution of the provisions of the code, would probably be adequate to support a penalty for refusal to comply with a lawful search warrant issued to implement the inspection provisions.

Consent to Warrantless Search as Condition of License

The court's recognition of "such accepted regulatory techniques as licensing programs which require inspections prior to operating a business or marketing a product" raises the question of whether a license may, as a condition of its issuance require consent to warrantless inspections after such issuance.

Such a requirement would be of little assistance, if any, in searching residential property, since the Supreme Court has consistently held that the search of apartments, hotel rooms, or boarding houses cannot, as far as the actual occupant is concerned, be consented to by the landlord or other proprietor.[38]

While of more apparent utility in the case of commercial premises, such a proposal raises the question of unconstitutional conditions. Unlike *Zap v. United States*,[39] where the petitioner, in order to obtain the Government's business, specifically agreed to permit inspection of his accounts and records and the court found a voluntary waiver of his claim to the privacy of such records, the licensee under this proposal would have to waive his constitutional protection under the Fourth and Fifth Amendments as a condition to engaging in business with anyone.[40] The dilemma that would confront the indi-

[37] Compare 18 U. S. C. 3109.

[38] *Stoner v. State of Calif.*, 376 U. S. 483 (1964); *Chapman v. United States*, 365 U. S. 610 (1961); *McDonald v. United States*, 335 U. S. 451 (1948); *Lustig v. United States*, 338 U. S. 74 (1949).

[39] 328 U. S. 624 (1945).

[40] This goes far beyond the requirement that a business maintain records which are to be made available for public inspection. Such records have

(Continued on next page.)

vidual is the choice between obtaining the benefit or privilege which the license would confer and the hazard of waiving his constitutional rights in advance, not knowing when or how they may be violated by the law enforcement agency. It could reasonably be argued that the threat of withholding the license would constitute duress vitiating the consent. Moreover, it is doubtful that a case could now be made for the proposition that the alternative means of a search warrant which is not subversive of constitutional rights is inadequate to protect the public welfare.[41]

Conclusion

The holdings of the Supreme Court in these two cases are a challenge to the inventiveness of administrators and lawyers to demonstrate that social programs intended to protect the public health and welfare can be developed and operated efficiently without invading private rights guaranteed by the Constitution. The cases should not be interpreted as requiring slavish adherence, the broad guidelines indicated by the Court, but rather as giving room for a variety of approaches to the problem which can be developed to meet the constitutional requirements. It would be unrealistic to assume that these decisions have settled the problems of regulatory inspections, or that further litigation of these issues should not be anticipated. An understanding of the thrust of the constitutional guaranties involved, and of the limitations on official actions spelled out in cases implementing these guaranties, however, is an essential ingredient of the development of legislation and programs capable of withstanding these challenges.

In dealing with problems such as these, where community and individual interests seem to conflict, we must bear in mind the statement of the Supreme Court in *Mapp v. Ohio:*[42]

> Nothing can destroy a government more quickly than its failure to observe its own laws, or worse, its disregard of the character of its own existence. As Mr. Justice Brandeis, dissenting, said in *Olmstead v. United States*, 1928, 277 US 438, 485, 48 S. Ct. 564, 575, 72 L. Ed. 944: "Our government is the potent, the omnipresent teacher. For good or ill, it teaches the whole people by its example . . . If the government becomes a lawbreaker, it breeds contempt for the law; it invites every man to become a law unto himself; it invites anarchy."

[The End]

(Footnote 40 continued.)
been held to assume the characteristics of quasi-public documents and their disclosure may be compelled without violating the Fourth Amendment. *Shapiro v. United States*, 335 U. S. 1 (1948); *United States v. Morton Salt Co.*, 338 U. S. 632 (1950).

[41] Compare *Parrish v. Civil Service Commission of County of Alameda*, 57 Cal. Rptr. 623 (1967).

[42] See footnote 22 at 659.

Appendix

Forms Used for Inspection Warrants under the Federal Hazardous Substances Act and the Federal Food, Drug, and Cosmetic Act.

Pertinent Statutory Inspection Provisions.

1. Federal Hazardous Substances Act. 15 U. S. C. 1270.

"§ 1270. Examinations and investigations—Authority to conduct

"(a) The Secretary is authorized to conduct examinations, inspections, and investigations for the purposes of this chapter through officers and employees of the Department or through any health officer or employee of any State, territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

"Inspection; notice; samples

"(b) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which hazardous substances are manufactured, processed, packed, or held for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such hazardous substances in interstate commerce; (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished materials, and labeling therein; and (3) to obtain samples of such materials or packages thereof, or of such labeling. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness."

* * *

2. Federal Food, Drug, and Cosmetic Act. 21 U. S. C. 374.

"§ 374. Inspection—Right of agents to enter; scope of inspection; notice; promptness; exclusions

"(a) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. . . ."

(Hazardous Substances)

In the Matter of
Establishment Inspection
of
..... Company
.....
....., ...
To the United States District Judge:
United States District Court
..... District of .....

APPLICATION FOR INSPECTION WARRANT UNDER THE FEDERAL HAZARDOUS SUBSTANCES ACT.

....., a duly authorized inspector of the Food and Drug Administration, Department of Health, Education, and Welfare, ..., ..., hereby applies for an inspection warrant, pursuant to 15 U. S. C. 1270, for the inspection of the establishment identified as follows:

.....
.....
.....

1. Hazardous substances are manufactured, processed, packed or held in this establishment for introduction into interstate commerce or after such introduction.

2. The establishment has not previously been inspected.
was last inspected on .....

3. This is a scheduled inspection undertaken as a part of a statutorily authorized inspection program designed to assure compliance with the Federal Hazardous Substances Act.

4. The inspection will be conducted within regular business hours. Written notice and the inspector's credentials will be supplied as prescribed in 15 U. S. C. 1270. The inspector will begin as soon as practicable after the issuance of this warrant and will be completed with reasonable promptness.

5. The inspection will extend to the establishment and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

6. Samples will be collected when necessary to a reasonable inspection and receipt will be given therefor.

7. The inspector may be accompanied by one or more inspectors, duly authorized pursuant to 21 C. F. R. 2.121(b).

8. A return will be made to the Court at the completion of the inspection.

9. The authority for the issuance of the inspection warrant is 15 U. S. C. 1270 and *Camara v. Municipal Court*, No. 92, and *See v. Seattle*, No. 180, decided June 5, 1967 by the Supreme Court of the United States.

Sworn to and subscribed by

.....
John Doe - 007
United States Food and Drug
Administration

Before me ....., Clerk of the United States District Court for the ..... District of ....., on this ..... day of ....., personally appeared ....., and upon oath stated that the facts set forth in this application are true to his knowledge and belief.

.....
Clerk, U. S. District Court

(Hazardous Substances)

WARRANT FOR INSPECTION UNDER THE FEDERAL HAZARDOUS SUBSTANCES ACT.

To ..... and any other authorized United States Food and Drug Inspector:

Application having been made, and probable cause shown, by ...., United States Food and Drug Inspector, for an inspection of the establishment described as:

.....

.....

Pursuant to the Federal Hazardous Substances Act and the decisions of the Supreme Court in *Camara v. Municipal Court,* No. 92, and *See v. Seattle,* No. 180, decided June 5, 1967, you are authorized to enter the above described premises at reasonable times during ordinary business hours, and to inspect in a reasonable manner and to a reasonable extent, including the collection of samples if necessary, the establishment and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

A return shall be made to this Court showing that the inspection has been completed.

Dated:

Judge .....

RETURN

Inspection of the establishment described in this warrant was made on .....

.....

John Doe - 007
Inspector, U. S. Food and Drug Administration

.....

(Foods, Drugs, Devices, Cosmetics subject to Inspection under 704)

In the Matter of
Establishment Inspection of
..... Company
.....
....., ...
To the United States District Judge:
United States District Court
..... District of .....

APPLICATION FOR INSPECTION WARRANT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

....., a duly authorized inspector of the Food and Drug Administration, Department of Health, Education, and Welfare, ..., ..., hereby applies for an inspection warrant pursuant to 21 U. S. C. 374, for the inspection of the establishment identified as follows:

.....

.....

1. Foods, drugs, devices, and/or cosmetics are manufactured, processed, packed or held in this establishment for introduction into interstate commerce or after such introduction.

2. The establishment has not previously been inspected.
was last inspected ....

3. It is a registered establishment under 21 U. S. C. 360, and is required to be inspected at least once every two years.

4. This is a scheduled inspection undertaken as a part of a statutorily authorized inspection program designed to assure compliance with the Federal Food, Drug, and Cosmetic Act.

5. The inspection will be conducted within regular business hours. Written notice and the inspector's credentials will be supplied as prescribed in 21 U. S. C. 374. The inspection will begin as soon as practicable after the issuance of this warrant and will be completed with reasonable promptness.

6. The inspection will extend to the establishment and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

7. Samples will be collected when necessary to a reasonable inspection and receipt will be given therefor.

8. The inspector may be accompanied by one or more inspectors, duly authorized pursuant to 21 C. F. R. 2.121(b).

9. A return will be made to the Court at the completion of the inspection.

10. The authority for the issuance of the inspection warrant is 21 U. S. C. 374 and *Camara v. Municipal Court,* No. 92, and *See v. Seattle,* No. 180, decided June 5, 1967 by the Supreme Court of the United States.

Sworn to and subscribed by .....
John Doe - 007
United States Food and Drug
Administration

Before me ....., Clerk of the United States District Court for the ..... District of ....., on this ..... day of ....., personally appeared ....., and upon oath stated that the facts set forth in this application are true to his knowledge and belief.

Clerk, U. S. District Court .....

(Foods, Drugs, Devices, Cosmetics subject to Inspection under 704)

WARRANT FOR INSPECTION UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

To ..... and any other authorized United States Food and Drug Inspector:

Application having been made, and probable cause shown, by ...., United States Food and Drug Inspector, for an inspection of the establishment described as:

.....

.....

Pursuant to the Federal Food, Drug, and Cosmetic Act and the decisions of the Supreme Court in *Camara v. Municipal Court,* No. 92, and *See v. Seattle,* No. 180, decided June 5, 1967, you are authorized to enter the above described premises at reasonable times during ordinary business hours, and to inspect in a reasonable manner and to a reasonable extent, including the collection of samples if necessary, the establishment and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

A return shall be made to this Court showing that the inspection has been completed.

Dated:

Judge .....

RETURN

Inspection of the establishment described in this warrant was made on .....

.....

John Doe - 007
Inspector, U. S. Food and Drug Administration

.....

(Prescription Drugs)

In the Matter of Establishment Inspection of
..... Company
....., ...

To the United States District Judge:
United States District Court
..... District of .....

APPLICATION FOR INSPECTION WARRANT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

....., duly authorized inspector of the Food and Drug Administration, Department of Health, Education, and Welfare, ..., ..., hereby applies for an inspection warrant, pursuant to 21 U. S. C. 374, for the inspection of the establishment identified as follows:

.....

.....

1. This establishment is engaged in the manufacture, processing, packing, holding of prescription drugs which are to be or have been shipped in interstate commerce.

2. It is a registered establishment under 21 U. S. C. 360, and is required to be inspected at least once every two years.

3. The establishment has not previously been inspected.
was last inspected .....

4. This is a scheduled inspection undertaken as a part of a statutorily authorized inspection program designed to assure compliance with the Federal Food, Drug, and Cosmetic Act.

5. The inspection will be conducted within regular business hours. Written notice and the inspector's credentials will be supplied as prescribed in 21 U. S. C. 374. The inspection will begin as soon as practicable after the issuance of this warrant and will be completed with reasonable promptness.

6. The inspection will extend to the establishment and all pertinent equipment, finished and unfinished materials, containers, labeling, and all other things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs are being produced in compliance with the Act, whether products not in compliance have been processed, packed, transported, or held, or whether conditions exist which otherwise bear upon violation of the Act.

7. Samples will be collected when necessary to a reasonable inspection and receipt will be given therefor.

8. The inspector may be accompanied by one or more inspectors, duly authorized pursuant to 21 C. F. R. 2.121(b).

9. A return will be made to the Court at the completion of the inspection.

10. The authority for the issuance of the inspection warrant is 21 U.S.C. 374 and *Camara v. Municipal Court,* No. 92, and *See v. Seattle.*

(Prescription Drugs)

WARRANT FOR INSPECTION UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

To ..... and any other authorized United States Food and Drug Inspector:

Application having been made, and probable cause shown, by ...., United States Food and Drug Inspector, for an inspection of the establishment described as:

.....

.....

Pursuant to the Federal Food, Drug, and Cosmetic Act and the decisions of the Supreme Court in *Camara v. Municipal Court,* No. 92, and *See v. Seattle,* No. 180, decided June 5, 1967, you are authorized to enter the above described premises at reasonable times during ordinary business hours, and to inspect in a reasonable manner and to a reasonable extent, including the collection of samples if necessary, all pertinent equipment, finished and unfinished materials, containers, labeling, and all other things in the establishment (including records, files, papers, processes, controls, and facilities) bearing upon whether prescription drugs are being produced in compliance with any applicable provisions of the Federal Food, Drug, and Cosmetic Act, whether products not in compliance have been processed, packed, transported, or held, or whether conditions exist which otherwise bear upon violation of the Act.

A return shall be made to this Court showing that the inspection has been completed.

Dated:

.....
Judge

RETURN

Inspection of the establishment described in this warrant was made on

.....

.....
John Doe - 007
Inspector, U. S. Food and Drug Administration

.....

.....

Introductory Statement

By FRANKLIN M. DEPEW

This Statement Introduces a Series of Articles Presented at the Twenty-Third Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, at the New York Hilton Hotel on January 23, 1968. Mr. Depew, the Chairman of This Section, Is the President of the Food and Drug Law Institute.

WHEN WE MET LAST YEAR there was one matter of absorbing interest to lawyers practicing in this field—the plans of the Food and Drug Administration, the Federal Trade Commission and the Department of Commerce with respect to regulations to implement the Fair Packaging and Labeling Act. Since that time the regulations in regard to food have been promulgated in final form with requirements that appear to be acceptable to industry and which should afford the additional consumer protection intended by the law. That these regulations were issued without challenge or request for public hearing is due in large part to the painstaking time and effort of members of the Section in working with the Food and Drug Administration for acceptable regulations. While the regulations have not been challenged, some of our members may have some reservations about certain provisions. You will hear more about this in our first report and perhaps in subsequent articles as well. The order promulgating the final drugs, devices and cosmetic regulations was just published for comment on January 11. The proposed regulations of the Federal Trade Commission covering other consumer commodities have not yet been republished since receipt of comments, and we still await final regulations of the Department of Commerce on procedures for voluntary standards.

Educational Efforts

The Food and Drug Administration has stepped up its educational efforts during the past year. Its Bureau of Education and Voluntary Compliance has just been revamped as a step to further

efforts to secure voluntary compliance. Education in the consumer interest means education for everyone concerned with the manufacture, distribution, labeling, advertising and buying of food and drugs. Thus, these meetings of the Bar operate as a most valuable aid in furtherance of this desirable goal of voluntary compliance.

The Food and Drug Law Institute has continued to foster educational work in this field. Its joint conference with the Food and Drug Administration held on November 27, 1967, attracted an attendance of some 750 persons. Messrs. H. Thomas Austern, George M. Burditt, Peter B. Hutt, Vincent A. Kleinfeld and Edward Brown Williams, members of our Section, made outstanding contributions to the success of the meeting. The proceedings are being published in the Food Drug Cosmetic Law Journal.* **[The End]**

PROGRESS IN VOLUNTARY STANDARDS PROGRAM

Two groups of food producers are voluntarily reducing the number of containers in which their products are packaged for retail sale. The National Coffee Manufacturers Association has announced that soluble coffee will be packaged only in quantities of even ounces between 2 and 16, and the Institute of Shortening and Edible Oils has reported that the number of containers in which salad and cooking oils are sold will be reduced from 15 to 7. Many other industry groups are either working with the Department of Commerce's National Bureau of Standards in developing voluntary standards or are in the process of setting their own. The actions being taken or considered are in accordance with the Fair Packaging and Labeling Act of 1947. The Act gives the Secretary of Commerce authority to determine when the proliferation of the containers of any given commodity has reached the point where consumers would have trouble making comparisons and value judgments, and it provides for voluntary cooperative action to fight such proliferation.

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* FOOD DRUG COSMETIC LAW JOURNAL, Vol. 22, No. 12 (December, 1967) and Vol. 23, No. 1 (January, 1968).

Counsel's Role in Current Good Manufacturing Practice

By RICHARD E. WILLIAMS

Mr. Williams Is with Richardson-Merrell Inc., New York, New York.

IN 1952, IN THE UNITED STATES VERSUS IRA D. CARDIFF,[1] the Supreme Court said, "The vice of vagueness in criminal statutes is the treachery they conceal . . . in determining . . . what acts are prohibited. Words which are vague and fluid may be as much a trap for the innocent as the ancient laws of Caligula!"

In 1962, Congress added to the Federal Food, Drug and Cosmetic Act a "trap for the innocent" in words truly vague and fluid. The 1962 amendment requires that drugs be produced using methods, facilities and controls that conform to and are operated and administered in conformity with "current good manufacturing practice" to assure safety, identity, strength, quality and purity.[2] Congress thereby recognized the record of accomplishment of which the industry as a whole is justifiably proud.

In its intent, then, this requirement is certainly reasonable, just as it is entirely reasonable for a parent to admonish a child to behave himself. But as a statutory standard which should define a required course of conduct, it is no more definitive than the parental "be good." The words "current good manufacturing practice" are vague in that there is no way in which an innocent manufacturer can with confidence define for himself what is the standard of good industry practice. And the words are fluid in that industry practices are in a state of constant change. A statutory standard, then, that requires one to conform to current practice is a statutory standard that is changing

[1] 344 U. S. 174.

[2] 21 U. S. C. 351(a)(2)(B).

constantly. This change in the statutory requirement is without notice to those who must comply, and further, it is in fact without notice to the enforcement agency itself. At the same time, the requirement to assure safety, identity, strength, quality and purity imposes an absolute standard of perfection—which no system yet devised by man has achieved.

What Is "Good Manufacturing Practice?"

So what does the requirement mean as a practical matter? I am reminded that some years ago a distinguished practitioner in this field restated the definition of a new drug, facetiously only in small measure, to wit: "A New Drug is what the Food and Drug Administration says is a New Drug." The same could be said about current good manufacturing practice. In the absence of a definitive standard, because the Food and Drug Administration is the only repository of information on industry practices, and because much of the information in that repository is in the trade secret area prohibited by law from public disclosure, good manufacturing practice is, for practical purposes, that which the Food and Drug Administration (FDA) says is good manufacturing practice.

How current is the repository of information? That is yet another question. It appears to be a practical, even a physical, impossibility for the FDA itself to determine, as of a given point in time, the level of good practice applicable to a particular drug produced in the circumstances of its own relationship to existing facilities, equipment, personnel and physical proximity to other drug materials.

But, vague and fluid as the statute may be in its words, the intent is reasonable: To provide, to the ultimate practicable extent, premarketing assurance of safety, identity, strength, quality and purity. Congress recognized, and the Food and Drug Administration recognizes, that special technical competence is necessary to achieve that end, and that it is hardly practicable to write into law specific requirements that could be specifically applicable to every one of thousands of widely differing and complex products, processed in many hundreds of existing establishments under infinitely differing circumstances.

In an attempt to provide better guidelines, FDA has promulgated interpretive regulations (21 CFR 133).[3] They are directed, for the most part, to manufacturers of the dosage form of the drug. However, the statute itself covers bulk chemical production intended for

[3] CCH Food Drug Cosmetic Law Reporter, ¶ 72,100.

drug use, as well as repackers, relabelers, and even wholesalers. Therefore, to the extent that these regulations do reflect good industry practice for the various categories of drug handlers, they are applicable to them. The regulations are all inclusive; starting with product development, they cover buildings, equipment, personnel qualifications and assignments, ingredients, packaging components, labeling, ingredient and product specifications, production procedures and instructions, record-keeping, analytical methods, shelf-life, storage and complaints. Like the statute itself, they are necessarily vague; in every section, requirements are qualified by such adjectives as "adequate," "appropriate," "suitable" or "reasonable."

Difficulty of Defining Terms

Using as examples, then, six of today's major compliance problems, industry's dilemma, and yours as Counsel, is to decide just what is meant by the words "adequate," "appropriate," "suitable," and "reasonable." For example:

1. What in-process controls are "adequate" to assure uniformity and integrity of products? In terms of the statute, you cannot be sure unless you know what the competition is doing, and this knowledge is not available to you.

2. What is a "suitable" labeled expiration date to "assure" full potency at time of use, and how much data are adequate to support it? There are no rules; it's a matter of scientific judgement. And with many products, the best data and the best scientific judgement cannot be so projected that there is assurance of the products' physical condition at some unknown date far in the future.

3. What amount of building space is "adequate" to permit the orderly placement of equipment "to minimize" product or ingredient mix-up? How orderly is "orderly," and how minimal is "to minimize." And even if you have done everything conceived to be possible and a mix-up then occurs, are you protected from regulatory action? Of course not; because in retrospect it is easy to see the additional step that should have been taken. I have yet to hear of a manufacturer with facilities, methods and controls so refined as absolutely to preclude product mix-ups, unless he has but one simple product in his line.

4. What operational control is "adequate" to prevent labeling errors and mix-ups? For this purpose, controls must be exerted at every step of the way from conception of label copy through the manufacture of printing plates and the printing operation to final

packaging. There are, probably, as many methods of control as there are manufacturers; no one system can be applied to the many varied circumstances under which many thousands of kinds of labels and many millions of copies are prepared, handled and used. An error-free system has yet to be devised. Let us assume the development of a unique but particularly effective control procedure, despite which an error occurs. The error itself is considered by FDA to be evidence of a lack of good manufacturing practice, and a system that is unique is not, in terms of the law, in conformity with current good manufacturing practice even though it may be a better system than any used by others. Surely, it was not intended by Congress that a better but non-conforming practice be deemed illegal, but this is a good example of your client's problems.

5. What factors are "appropriate" to control the hazard that may result from the ubiquitous Salmonella? This bacterial organism, capable of causing gastrointestinal illness, is so much a part of our environment that its total elimination cannot be expected. To a degree, the chances of contamination can be substantially reduced by rigid enforcement of well-accepted sanitary precautions and by testing of susceptible materials. However, the science of microbiological control has not advanced to the point that there is reasonable assurance of freedom from contamination in drugs or any other product whether prepared in a factory, drug store, restaurant or home.

6. What degree of spaciousness, cleanliness, lighting and ventilation is "adequate" to prevent cross-contamination; that is, physical migration of minute, possibly unmeasurable amounts of one chemical material to another material or product? Cross-contamination is, in my opinion, incapable even of reasonable definition. Certainly there cannot be permitted any amount of chemical contamination if there is any potential for adverse effect. But how much cross-contamination is permitted by a reasonable interpretation of the regulation? To eliminate it entirely would require a physically separate manufacturing facility for each drug, indeed, for each drug ingredient. Obviously, this is an economic impossibility and it is unnecessary. We are not concerned, nor should we be, with the presence of trace amounts of a relatively innocuous ingredient as long as such amounts have no reasonable potential for adverse effect on safety or effectiveness.

The subject of cross-contamination prompts me to cite an example supporting my thesis that current good manufacturing practice is what FDA says is current good manufacturing practice. The so-called penicillin amendments to the interpretive regulations (1) re-

quire procedures to control the hazard of cross-contamination of non-penicillin products by penicillin and (2) set analytical tolerances for the trace amounts of penicillin permitted to be present in such other products. Neither the control procedures deemed by FDA to be appropriate, nor the analytical tolerances set up in the regulations, represented good manufacturing practice current as of the effective date of the regulation. The interpretive regulation, therefore, appears to have been beyond the scope of the statute. In this instance, good manufacturing practice was what FDA says it was and not what manufacturers were actually doing.

I have discussed at some length the vagueness of the statute and the regulations. I hope I have made my point: even for the most experienced technical administrator, there is no way that he can be sure that he knows, and is following, the manufacturing standard set by his competitors. And so the law is defective to the extent that it fails to express a definitive standard of behavior.

Regulations and Self-Evaluation of Procedures

Nevertheless, the regulations do serve, and they serve well, to focus attention on problem areas which have been common to the industry. However lacking they are as a standard of practice, they are valuable guidelines which, if intelligently and diligently considered by your client, will help him in the proper evaluation of his own procedures. This evaluation will not be to determine whether his practices are appropriate, suitable or reasonable in conformity with current industry practice, because he cannot know this. Rather it will be to determine whether he has done all that he can possibly do that is appropriate, reasonable and suitable to achieve the statutory objective; that is reasonable assurance of product integrity.

The regulations are comprehensive and realistically drawn so that as guidelines they are applicable and adaptable to all conceivable kinds of drug operations. As statements of principles, there is little with which to disagree. It has been reported, however, that the Food and Drug Administration intends to propose revision to make the regulations more specific. I question the wisdom of such a move. For the reasons just discussed, the present guidelines have, I believe, resulted in substantial improvement in the segments of the industry where improvement was needed. It does not seem feasible to draft regulations as specific rules which could be widely applied without causing serious and unnecessary dislocations in drug production. I hope, therefore, that the Food and Drug Administration will continue

to recognize that there are many ways to achieve reasonable assurance of product integrity and that to require a specific way would achieve little, if any, improved consumer protection. In fact, specific procedures which might well be effective for one set of circumstances could, if applied in other circumstances diminish the effectiveness of a control system.

Let us consider again the objective of the statute; it is to provide assurance that every dose of every batch of every drug product meets its professed or expected standards of identity, strength, quality and purity. In other words, product integrity. More than that, dose integrity. Compliance with the letter of the regulations, even conceding the most stringent interpretation of the words "appropriate," "suitable," and so forth, will not provide the assurance sought.

In a recently published paper (FDA Papers/November 1967), Assistant FDA Commissioner Edward Tuerck wrote, "In essence, these regulations state a series of conditions which, if in existence in manufacturing, reduce to a minimum the probability of undetected error." I suggest that he is somewhat optimistic. Compliance with the letter of the regulations will not in itself result in effective controls. Error probability will be reduced only if such qualifiers as "reasonable" "appropriate" and "suitable" are properly applied to the complexities of a particular facility and then only if the system as set up is operated and administered with competence, diligence and wisdom. And these most essential factors are beyond the reach of regulation-writing capability.

Evaluating a Client's Compliance

Given, then, a statute and implementing regulations that are for the most part vague and fluid, and with the knowledge that unusual technical competence is needed in this field, what can counsel do to evaluate his client's state of compliance? And how can he advise his client what should be done for reasonable assurance that he does comply?

Management attitude is basically important. Does the client appreciate, first, the special obligation the drug industry has by reason of its presence in the health field, dealing in products which can have a profound effect on the well-being, indeed, upon the very life of the user? Does he realize that an obscure or unrecognized weakness in processing controls can lead to error having serious impact on the economic welfare of his company? In recall costs alone, a

labeling error can be financially ruinous. Adverse publicity, products liability, and FDC Act liability can seriously affect his future. Does he then have an enunciated company policy with respect to the quality of his products and his operations? And has this policy been communicated down the line? Most importantly, is the policy communicated by his day-to-day decisions whereby product integrity is not sacrificed to expediency or to cost reduction?

Because industry practice is the statutory standard, there must be a continuing effort by technically competent key people to keep in touch with industry developments. Part of their responsibilities, not their privileges, should be attendance at industry seminars, visits and continuing communications to other companies, reading of industry publications and technical journals. Unfortunately, I am aware of no available formal educational programs in this field.

Industry consultants, especially in the more technical fields such as analytical methods and equipment, can be a valuable source of information and appraisal.

A most useful tool is a company program of self-inspection. Assuming the presence of competent upper-level technical management, and assuming that they understand the legal and the company objectives and problems, a formalized methodical program of periodic self-evaluation can reveal weaknesses and lead inevitably to improved operational control and efficiency.

The Food and Drug Administration can be used as a source of information, and is probably the best guideline as to the state of compliance. I suggest that whenever possible, counsel accompany Food and Drug Inspectors during their visits to client's plants. If that is not possible, at the least you should get a full, documented report of all that went on during the inspection. Look carefully at all the inspector's recommendations. If at all reasonable, be sure the client follows those recommendations.

In addition, after the inspection, arrange to discuss the inspection report with the District Director. In this way, your client can have the benefit of administrative review of the raw data collected by the inspector. Also, improvements instituted as a result of the inspector's recommendations can be communicated to FDA. And again, if the administrative recommendations are reasonable, put them into effect.

I can think of no better posture, should error subsequently occur, than to be able to show that all FDA recommendations have been

duly noted and have been diligently followed. In Assistant Commissioner Tuerck's paper, previously cited, he also had this to say: "FDA operations are changing to emphasize communication to industry of inspectional findings which, to the extent management is responsive, tend to correct the poor practices observed. Non-responsiveness on the part of management, however, will still occasion the invoking of legal sanctions."

Continuing Effort

The drug industry as a whole is justifiably proud of its attainments in controlling the integrity of its products. Just as it is safe to say that no other industry is more intimately involved with the public health and welfare, so it is safe to say that no other industry has put forth a control effort that is equal to ours. But much remains to be done. Political and public pressures will not be allayed by excellence alone; and perfection has not been achieved. Regulatory actions are now being taken on product deviations once considered relatively unimportant. We must assume that such deviations are considered significant and deserving of enforcement action not because they are, per se, a hazard to the consumer but rather because they reflect a manufacturing deficiency which could result in serious error. Product recalls and publicity are being substituted for the legal sanctions provided in the Act. The weekly recall list published by the Food and Drug Administration is ample demonstration that current manufacturing practice has not achieved the standard sought by the statute: assurance of product integrity. Indeed, the certainty, or confidence, implied by the words "to assure" are probably impossible to achieve. No one, in any human endeavor, has devised a system which has resulted in zero defects and anything less than that may lead to recall and publicity.

Conclusion

In summary, then, for your client to avoid the "trap for the innocent," he needs not so much legal advice but rather your wise and practical counsel. The intent of the statute is to require a maximum effort towards error-free performance. That maximum effort should be based on literal compliance with the regulations upon which must be superimposed technical competence and managerial determination. Only through such effort can his regulatory jeopardy be reduced. I wish it were possible that it could be eliminated. **[The End]**

Federal Pre-emption in Consumer Laws

By ESTHER O. KEGAN

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THE TEMPO OF CONGRESSIONAL ACTIVITY on behalf of our 200 million consumers has been progressively increasing in recent years. Today I would like to share with you my concern that our national interest in protecting each of us in our role of consumer has caused Congress to diminish, if not destroy, certain responsibilities of state governments under the doctrine of express federal pre-emption. The flow of consumer protection *exclusively* under federal control has been so swift, it is time we dropped anchor to look where the current is leading us.

Under the United States Constitution, each state government is responsible for protecting the health, safety and general welfare of its inhabitants under its general "police powers." Congress can exercise welfare powers to protect "consumer" interests only when interstate or foreign commerce is involved; the Federal Government has no general police power. Our Constitutional system of limited federal power with residual power to the federated states provides Americans a system of governmental checks and balances. Fear of undue governmental centralization was a problem in 1789, and is still a concern today.

Yet, technology and our mode of living have significantly changed in 180 years. The geographical expansion of these United States from the original 13 to 50 states has been accompanied by unanticipated mobility and almost instantaneous communication. There are few, if any, happenings anywhere in the country which is not promptly publicized to the nation. Demands are constantly being made that the Federal, rather than state, Government "do something" for whatever problem arises. Congress has responded.

Within the past few years, the federal Food and Drug Administration (FDA) and other federal agencies have been directed, by

specific food, drug and related laws we shall discuss later, to assume certain regulatory responsibilities, regardless of whether the regulated activity begins and ends within one state. Nor is this a temporary emergency situation. Many bills await Congressional action in the present session[1] providing for the Federal Government to assume *primary* responsibility in the area of credit reform, garnishment and control over trading stamps. A National Consumer Counsel, a special lawyer in the Attorney General's office, was proposed to give the consumer "a stronger voice."[2]

The constitutionality of federal laws made applicable to intrastate activities has been sustained on evidence that the local activity, such as employment or taxation, "affected interstate commerce." But can it be shown that the corner grocery store is no longer a local matter? Should the Federal Government decree the demise of the corner drug store?[3] These are crucial socio-political questions of special importance to food and drug lawyers.

Over one-half of the states have adopted the food sections of the Model State Food, Drug and Cosmetic Act; fewer states have effective drug and cosmetic regulations. Sporadic and conflicting state regulations may be more than just a nuisance to a national food processor. Interstate shippers usually favor *one national* system of regulation. Inconsistent state laws require a multiplicity of labels and inventories in order to ship a single product throughout the country. Lack of uniformity among state food and drug laws frequently increases distribution costs, which may then be passed on to the consumer by higher retail prices. Such factors have influenced Congress to give to the Federal Government control over local activities.

In the light of present food and drug distribution systems within a 1789 framework of state boundaries, some administrative law experts have concluded that the interstate-intrastate concept established

[1] Pending in Congress now are, among other "consumer" bills, the Truth in Lending Bill, H. R. 11601, the Truth in Trading Stamp Act, H. R. 2914, 90th Cong. 1st Sess. and Truth in Promises Bill, to assure greater disclosure of guarantees: *Washington Report*, Nov. 27, 1967 Publ. UAU Citizenship-Legislative Dept., Washington, D. C. Benjamin Rosenthal proposed creation of an executive "Dept. of Consumer Affairs" to which would be transferred pertinent functions now exercised by the Departments of Agriculture, Commerce, Labor, and FDA.

[2] President L. B. Johnson's State of the Union message delivered to Congress January 17, 1968.

[3] Dr. James L. Goddard, FDA Commissioner, is reported to have said "I would say that the corner store should be closed down," advocating instead that drugs be dispensed in medical centers: (*New York Times*, Dec. 31, 1967).

in our U. S. Constitution is now obsolete.[4] I believe however, that the states still serve valuable functions. Perhaps we should seek creative new ways of improving, rather than destroying, the traditional federal-state relationship.

Indirect Federal Pre-emption

Express federal pre-emption by statute is relatively recent. However, some courts have invalidated state food regulations inconsistent with federal law on the principle of indirect federal pre-emption. The theory of such courts was that Congress *intended* to pre-empt the field and that the federal law was the supreme law of the land.[5] Onerous state regulations, such as economic hindrances on the sale of imported meat, were held to be unreasonable burdens upon interstate commerce.[6] State laws imposing health standards stricter than the federal have generally been upheld. No implied federal pre-emption was then found.[7]

We shall review only one case as illustrative of a state regulatory law which conflicts with federal requirements. An interstate shipper of poultry tried to restrain the Florida Commissioner of Agriculture from requiring poultry shipped from a federally inspected plant in Georgia to be inspected by Florida inspectors upon its arrival in a Florida plant. The Federal Court in the case of *Canton Poultry, Inc. v.*

[4] Report of Public Administration Service on *A Study of State and Local Food and Drug Programs* to the Com. of the Food & Drug Administration, Dept. of Health, Education and Welfare, Government Printing Office, Feb., 1965, p. 7.

[5] United States Const. Art. VI, cl. 2, USCA Const. p. 692 ff. See *The Constitution of the United States*, Anno. U. S. Printing Office, 1938, pp. 565-574.

[6] *Tupman Thurlow Co. v. Moss*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,223, 252 F. Supp. 641 (D. C. Tenn. 1966); *Ness Produce Co. v. Short*, 263 F. Supp. 586, 588 (D. C. Ore. 1966) affd. 385 U. S. 537, 87 S. Ct. 742, 17 L. Ed. 2d. 591 (1967); *International Packers Ltd. v. Hughes*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,279, 271 F. Supp. 430 (D. C. Ia. 1967). See also *Armour & Co. v. State of Nebraska*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,277, 270 F. Supp. 941 (D. C. Neb. 1967).

[7] *Hebe Co. v. Shaw*, 248 U. S. 297, 304, 63 L. Ed. 255, 39 S. Ct. 125 (1919); *Corn Products Refg. Co. v. Eddy*, 249 U. S. 427, 63 L. Ed. 689, 39 S. Ct. 325 (1919); *Pepperidge Farm v. Foust*, 66 Abs. 482, 117 N. E. 724 (1953); *People v. Breen*, 326 Mich. 720, 40 N. W. 2d 778 (1950); *Borden Co. v. Liddy*, 200 F. Supp. 221 (1961), Cert. den. 372 U. S. 953; *Kansas Packing Co. v. City of New York*, 309 N. Y. 696, 128 N. E. 2d 411 (1955) upheld city ordinance as to intrastate shipments but invalidated application of this more stringent law as applied to interstate shipments. See also *Florida Lime & Avocado Growers v. Paul*, 373 U. S. 132, 142, L. Ed. 2d. 248, 83 S. Ct. 1210 (1963). (Although Florida growers objected, the U. S. Supreme Court upheld a California regulation requiring 8% oil content in avocados, which was more stringent than the federal maturity standard as to the minimum oil content of avocados.)

Doyle Conner[8] refused to interfere with the enforcement of the Florida law and held interstate shippers were not denied the equal protection of the law because the law was equally applicable to local as well as out-of-state shippers.

The evidence presented in the *Canton* case supports the position that "not everything the Federal Government does is good."[9] The evidence disclosed there was only limited federal inspection of poultry shipped into Florida and that there were only 3 United States inspectors to check 9,913 retail stores and 200 wholesale outlets in Florida, whereas the Florida Department of Agriculture had 46 inspectors who made 42,254 regulatory inspections in one year. Probably most persuasive to the Court was the proof that one-half of the 76,800 pounds of poultry condemned in a given period had been previously inspected and passed by Federal inspectors. Thus most state laws imposing standards higher than those of FDA or the Meat Inspection Division (MID) are upheld, as the Courts determine, as a matter of law, that Congress *did not intend to oust the states from their historic undertaking to safeguard their people.*[10]

Pre-emption in Federal Laws

Congressional hearings may point up a need for specific consumer protection, either because local laws are outmoded or inadequately enforced, or even non-existent. Intent of Congress to fill the gap has been expressly set forth in food and drug laws passed within the past five years.

The thalidomide tragedy and the Kefauver hearings precipitated the passage of the Drug Amendments of 1962, which was the first Federal law expressly regulating *all* manufacturers of drugs.[11] Drug

[8] CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,254, 263 F. Supp. 1008 (ND. Fla. 1967), interpreting Fla. Stat., § ch. 583,01. The U. S. Supreme Court vacated the decision and remanded to the District Court for appeal to the Court of appeals;—U. S.—, 18 L. Ed. 2d. 1319, 81 S. Ct. 211.

[9] At a Dept. of Agriculture meeting held in Springfield, Illinois on December 11, 1967, federal and state meat inspection chiefs were in accord at that meeting that the USDA does not have sufficient manpower to take over state meat inspection duties, whereas the Illinois Department of Agriculture at that time did have sufficient manpower. It was suggested however, that USDA should conduct training sessions for state inspectors.

[10] *Swift & Co. v. Wickham*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,234, 364 F. 2d 241, 246 (1966), construing Federal Poultry Inspection Act, 21 U. S. C. sec. 451-469. (It is of interest that the U. S. Department of Justice filed an amicus brief contending that the Federal Poultry Products Inspection Act does *not* pre-empt state regulation of poultry labeling.)

[11] Secs. 502 and 510 were added to the Federal Food, Drug and Cosmetic Act by sec. 305 of Pub. Law 87-781. See 21 USCA §§ 352(o) and 360; CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 71,081.

manufacturers with local distribution, as well as interstate shippers, are required by this law to be registered with FDA. Congress declared that Federal control over *intrastate* drug establishments was necessary to avoid discrimination against *interstate* commerce in such drugs.

This all-pervading drug registration law was followed in 1965 by the Drug Abuse Control Amendment and the Cigarette Labeling Law. FDA was given authority to control *all* traffic in depressant, stimulant and hallucinogenic drugs which have officially been determined to have a potential for abuse.[12] Congress declared that regulation of intrastate commerce in such drugs was necessary because, among other reasons, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin. FDA Commissioner George P. Larrick hailed this bill's achievement in eliminating the requirement that FDA inspectors prove that illegal drugs have moved in interstate commerce. The Federal District Court in Illinois recently upheld the FDA's position.[13]

The Cigarette Labeling and Advertising Law of 1965 expressly stated that Congress intended to establish a comprehensive uniform federal law to inform consumers of the relationship between smoking and health.[14] The law specified pre-emption as to mandatory warning statements on package labels.

The furor caused by a misleading photograph on a frozen cherry pie package resulted in the Fair Packaging and Labeling Act of 1966.[15] Every consumer package must disclose the identity of the product, its ingredients, and the identity of the manufacturer or distributor and the net content. However, Congress singled out only the net content requirement for exclusive federal control. There is no federal pre-emption as to the other labeling requirements of this law. State regulations concerning the identity and ingredients of the product would thus govern on all packages sold exclusively within one state.

A different kind of federal pre-emption was adopted in the Child Protection Act of 1966.[16] This law amended the Federal Hazardous

[12] P. L. 89-74 added on July 15, 1965, 21 USCA § 360a. Under this Drug Abuse law, FDA could deputize state officials to enforce the Federal law.

[13] George P. Larrick, "The Mid 60's," *Bull. Association of Food & Drug Officials*, 1965, p. 9, 14. See *U. S. v. Freeman*, 275 F. Supp. 803 (D. C. Ill. 1967).

[14] 15 USCA § 1331 ff., Pub. Law 89-92, 79 Stat. 282. Enforcement of this law is vested in the Federal Trade Commission.

[15] 15 USCA 1451 ff. (Sec. 12); S. 985, Pub. Law 89-755.

[16] 15 USCA § 1261 ff. 80 Stat. 1305, Pub. Law (1966) 89-756, 89th Cong. S. 3298, CCH Food Drug Cosmetic Law Reporter ¶ 9051 ff.

Substances Labeling Act of 1960, which was also enforced by the Food and Drug Administration. The special national concern for protecting against sale of dangerous children's toys, caused Congress to pre-empt the field of cautionary labeling requirements on articles covered by the Act. Any state labeling law inconsistent with the federal law is declared "null and void."[17] However, during the Senate hearings, it was acknowledged that this federal pre-emption as to labeling was limited and would not preclude the states from absolutely *prohibiting the sale* of articles permitted under federal law, if the state authorities considered such articles to be too dangerous.[18]

A more comprehensive federal pre-emption is found in the 1967 Amendments to the Flammable Fabrics Act of 1953,[19] which extended fire safety controls to all household and personal fabrics in addition to clothing. The original Flammable Fabrics Act applied federal control over interstate shipments only. The recent amendment flatly pre-empted any state or local law which would be inconsistent with its provisions with the following rationale:

> The mass production, high volume, and national marketing character of the textile industry requires that flammability standards be uniform throughout the country. Accordingly, the bill would pre-empt any law of any State or political subdivision thereafter which is inconsistent with its provisions.[20]

Other techniques to control intrastate food regulations are evidenced by the new Wholesome Meat Inspection Act of 1967.[21] Under Federal mandate by this law, state meat inspection laws are to be upgraded to federal level within two years, or the Federal Government will step in to take over intrastate meat inspection. Is meat to the individual consumer any more of a federal area of dominance now or is it that we now look to the Federal Government for solutions to all our governmental problems? Congress attempts to support its proposed extension of federal meat inspection to intrastate packers, by rationalizing as follows:

> Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled and packaged.

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[17] 15 USC 1261, § 17(b), CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 9175. See note to 15 USCA § 1261.

[18] S. Rept. 1551(89) accompanying S. 3298(89), Senator Magnuson, p. 3 (Aug. 30, 1966).

[19] 15 Fed. Code Anno. § 1191 ff., as amended.

[20] S. Rept. 407(90) to accompany S. 1003(90) (July 25, 1967) p. 7, 16.

[21] Pub. Law No. 90-201, 81 Stat. 584, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 1315, amending 34 Stat. 1260-65; 21 USC 71-97.

These police power prerogatives would appear to be equally applicable to control over the nation's milk supply, bread, and other foods, particularly since the basis for control of intrastate commerce was explained by Congress as follows:

> The unwholesome, adulterated, mislabeled or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally.

Would not these same opportunities for lower prices and unfair competition be available to all food processors not covered by federal law?

Actually the spectre of federal control over local meat packing plants is tempered by the statutory authorization to assist the states to bring the state meat inspection laws up to MID standards within two years. Moreover, the states can expect to be financially assisted to the extent of 50% of the cooperative program, if approved by the Secretary of Agriculture. But what if one or more states do not adopt federal-like state meat inspection laws? Federal pre-emption may then be applicable on a patch-quilt basis.

The constitutionality of these recent federal laws exerting pre-emptive powers on a selective, or almost arbitrary basis, is not free from doubt. Judges are likely to be swayed by factual evidence presented in the specific case rather than by the broad political principles of interstate-intrastate jurisdictional limits. As far as the individual consumer is concerned, it is immaterial whether the food he eats comes from another state or is locally produced. The consumer is entitled to, and generally receives, wholesome and properly labeled foods. But which governmental agency shall punish the small minority of food and drug processors violating the law? Not always is the Federal agency more effective than the states, even though the Federal Government admittedly has a larger tax and base available for salaries, personnel recruitment, training personnel, and scientific laboratories.

Possible Federal-State Relationships for Consumer Protection

In my opinion, the role of states in food and drug control is still important even in this age of instantaneous communication. Foremost is the great value of checks and balances among governmental officials, national or state. By striving for maximum efficiency, we might lose the valuable intangible of protection against the possible risk of authoritarianism. Secondly, federal centralization to the de-

gree exemplified by recent federal pre-emption provisions ignores the vastness, and differing conditions, among the 50 states, the territories and the Commonwealth of Puerto Rico.

My State of Illinois is trying one approach to the halcyon goal of trying to get the best of the two worlds—to take advantage of federal financial resources and expertise, and yet retain state control over foods and drugs to adjust for local conditions. The 1965 Illinois Food, Drug, Cosmetic & Pesticide Law Study Commission, of which I was privileged to be one of the five public members, surveyed the Model State law proposed by the Association of Food and Drug Officials of the United States (AFDOUS), as modified by various states. We were aware of the thousands of federal food additive and other regulations established after extensive scientific investigations. Our recommended bill was enacted into law, effective as of January 1, 1968.[22] Illinois thus became the first state to adopt automatically, without affirmative state action, all existing and future federal regulations pertaining to standards of identity of foods, special dietary foods, new drug requirements for safety and efficacy, pesticide regulations, color additives approvals, and food additive regulations. The obligation to reprint the thousands of federal regulations is thus avoided. However, the Illinois bill was not designed on a "me too" policy. Flexibility to local situations was assured under the Illinois statute permitting the Director of Public Health to hold hearings, on his own initiative or upon complaint of an Illinois resident, to determine whether or not the federal regulations would be reasonable for the local Illinois situation.

This Illinois law is the first of this pattern. The FDA has welcomed this approach. Federal-state cooperation is evidenced by FDA's assignment for six months of its Atlanta District Director, Mr. John W. Sanders, Jr., to help Illinois set up the necessary administrative organization to implement the new law. Such loan assignment was requested by state officials and made possible by the 1966 Comprehensive Health Planning and Public Health Service Act.[23]

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[22] Ill. Rev. Stat. 1967, CH 56-1/2 § 501, 509, 521. Tennessee law permits the State Commissioner to promulgate standards of identity of foods "which shall conform" to the Federal standards (Tenn. Code, Sec. 52-109, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 33,019) and Virginia law provides that the state food standards "may conform as far as practicable" to the federal standards (Va. Code, Sec. 3. 1-394, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 35,019. See T. E. Sullivan, "The Desirability of Uniformity Between State and Federal Laws in Food Additives," 16 FOOD DRUG COSMETIC LAW JOURNAL 34, 35 (January 1961).

[23] 42 USCA § 246. The sum of $62 million for fiscal year ending June 30, 1968 was authorized for aid to states, under the control of the Secretary of Health, Education and Welfare.

Other approaches to keep state control viable have been proposed. A well-known economist recommended unconditional federal financial grants to states, concluding that independent state action is advisable:

> States are an essential feature of our system of government . . . . It should also be added that the state governments do not have a monopoly on incompetence — some of the federal agencies administering grants are something less than models of efficiency.[24]

State-local needs have outstripped the potentialities of their revenue system, which by virtue of their constant tax rates are, on balance, regressive. Accordingly, it is recommended that the Federal budget should allow for sharing of a specified portion of the federal income tax with the states, on a permanent basis, with unconditional grants supplementing the existing grant-in-aid system. If states receive aid primarily on the basis of population, in significant amounts, they could reestablish their historical role of effective protection of public health, safety and welfare.

Other proposals to achieve "real uniformity" of food and drug regulations include the suggestion for a single national food and drug regulatory compact. The present Federal Food, Drug and Cosmetic Act and regulations would be incorporated in this national compact to be enforced by a national agency with federal and state representatives.[25] This federal-state food and drug compact would eliminate questions of pre-emption and constitutionality because this would involve only one law, approved by Congress and, presumably, by all state legislatures. Again, this proposal may appear administratively efficient, but the absolute uniformity thus sought would destroy the checks and balances provided by the constitutional limitations on interstate-intrastate jurisdiction. In my opinion this federal-state compact proposal is like throwing the baby out with the bath water because the water got dirty.

Conclusion

Health and safety is everyone's concern, and always was. What is different now? President Johnson in his recent State of the Union message told Congress that "We can make this truly a new day for consumer protection, and live in history as the consumer conscious

[24] Statement of Walter W. Heller (Professor of Economics Univ. of Minnesota) and Joseph A. Pechman (Director of Econ. Studies of Brookings Inst.) to the Subcommittee on Fiscal Policy of the Joint Economic Committee, August 2, 1967.

In 1966 there were almost 400 separate authorizations for federal grants in aid to states.

[25] David E. Engdahl, "Consolidating State and Federal Regulatory Power Over Foods and Drugs", 20 FOOD DRUG COSMETIC LAW JOURNAL 587, 595 (October 1965)

era . . . So let us act now."[26]

Within the past five years, Congress has passed many laws regulating intrastate activities, pre-empting to the Federal Government direct or indirect control even over activities exclusively within a tiny hamlet. The motives of our Congressmen may be laudable. As lawyers, however, maybe we should pause to evaluate what kind of governmental controls are advisable even in the space age of the 70's. If a state does not accept its responsibility for the health and general welfare of its consumers, what should Congress do? Are we ready to abolish, even for consumer protection, the constitutional limitation of Congress to interstate activities? Do the consumers have a responsibility to urge state action?

To date there has not been to my knowledge any Supreme Court decision invalidating statutory federal pre-emption in the area of consumer legislation. Congress may have to discipline itself to avoid complete Big Brother surveillance. Dramatic publicity "happenings" have precipitated federal pre-emption clauses in consumer laws within the past five years with no apparent letup in public pleas for complete federal control. This federal club over state legislatures and administrative agencies has been sought by militant consumer groups as an answer to indifferent or recalcitrant state agencies. Would such federal control, even though more effective than checkerboard or haphazard country-wide enforcement by different state programs, be in the interest of all Americans?

Instead of stretching the constitutional limitation of "interstate commerce" to virtual annihilation, I suggest that a greater Congressional challenge would be to devise new techniques to motivate the lagging state governments to take care of their own consumers. The pattern of reward and punishment to states with lagging meat inspection laws as established in the 1967 Wholesome Meat Act may be offensive to constitutional lawyers and yet be an effective deterrent to the necessity for federal control. Safeguarding health and safety is an ongoing responsibility. But federal regulation of all industry is not the answer. All governmental agencies, federal, state and municipal, together with private industry and their associations, can cooperate effectively. Each consumer is also involved in the policy determination of how public health and safety may be protected without permitting exclusive national control under statutory federal pre-emption. **[The End]**

[26] Delivered to Congress on January 17, 1968.

Some Applications of Drug, Device and Narcotic Laws for Health Science Practitioners

By SIDNEY H. WILLIG

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MAKING DRUGS AVAILABLE TO THE PUBLIC is a health care responsibility jointly undertaken by the government agency, the regulated industries and the health science practitioners. This is essentially a cooperative endeavor and may be sapped of initiative and vitality if the parties are set against each other in attitudes and postures that frustrate their efficiency. None should be called upon to renounce their own wisdom, authority or prerogatives in the name of cooperation, but rather each must respect the legal and ethical principles that overlie their mutual function and purpose. Therefore, they should not be placed in adversarial roles through foolhardiness or strategy, to satisfy whims of the scientifically unsophisticated or the politically hyperacute, when to do so represents a disservice to the national and international community.

The Federal Food, Drug and Cosmetic Act and related statutes, by intent and content, serve to guide all three in the performance of their essential and interrelated functions for the public good, albeit with varying degree of intensity or direction. It may serve therefore, if devised and considered constructively, as a basis for their mutual understanding. It is our role as food and drug lawyers to provide reasoned counsel in keeping with this concept.

The regulated industries are bound to innovate, produce and distribute in accordance with the law; the government agency is bound to enforce it fairly; and the physicians, dentists, pharmacists and others must observe its effects on their practice. It is to this latter aspect that this paper is directed.

The Federal Food, Drug and Cosmetic (F. F. D. C.) Act, as amended (Title 21, U. S. C.), is a criminal statute. It can be enforced against articles of drugs or devices, or against persons, and by injunction, seizure or criminal prosecution. The state statutes are also criminal or quasi-criminal in character and violators can suffer heavy fines and prison sentences, the offense being generally a misdemeanor.

Since they control every aspect of a drug's availability for use and distribution, anyone who seeks to administer, direct or supply a drug's usage must respect the drug laws.

Drug Laws and the Pharmacist

Of all health science practitioners, the pharmacist is undoubtedly best acquainted with the force of drug and narcotic laws and regulations upon his practice. This is true both from the standpoint of federal and local application. As a key member in the distribution scheme, his inventory is defined, the conditions precedent and subsequent of its order, receipt, storage and dispensation are set out in certain terms, and his own activities and prerogatives with respect to these are carefully circumscribed within the language of Chapters 2, 3 and 5 of the F. F. D. C. Act.

Although *U. S. v. Sullivan*[1] early clarified the interstate character of the pharmacist's professional activities, his intrastate functions are nonetheless carefully delineated by state and city drug, device and cosmetic laws, and regulations and rules established by Boards of Health and Pharmacy.

The pharmacist has been taught the meaning of "adulteration" and "misbranding" in the classic pharmaceutical concept as well as in the basic legal connotation, but he fails to recognize some of the more sophisticated turns these definitions have taken in the last decade and sometimes he needs to be reminded of these. Homemade relabeling with technical incompleteness, commingling of like products of differing control numbers, and in very rare instances, substitution of a prescribed drug with its non-specified chemical counterpart, are types of violations where he needs explanation and reminder.

In urban practice, competitive anxieties plus difficulties in securing written or oral confirmations and renewals of prescriptions, often in the light of state requirements more stringent than federal, beget some amount of violative conduct also. While the Drug Abuse Control Amendments of 1965 (DACA) added enforcement potential as to subject drugs, since 1951 under Durham-Humphrey, oral prescribing

[1] 332 U. S. 689, 68 S. Ct. 331 (1948).

and authorization for the refilling of a prescription has required evidence of the prescribing physician's confirmation. State regulations quickly bolstered this requirement with their additions and set various limits like 48 hours, 72 hours and the like as the time period. In the sixteen years since, physicians have grown to know the law. However, the demands on their time, including telephone time, have grown to such proportions that telephone communication, as to a refill especially, between the physician and the pharmacist, often represents a frustrating improbability for the latter.

The pharmacist knows his obligations under the Durham-Humphrey Amendment, 503(B) of the Act, and its state equivalents. He recognizes that, with its responsibilities and legal implications for him in terms of prosecution and product liability, it also endows him with the prerogative to be the last contact point between the public and those that advise them, safeguard them and supply them.

Since this is so firm a socioeconomic and legal reality, it is remarkable that the governmental agencies, the prescribing professionals and the regulated industries have not invested a greater amount of effort in bringing to the pharmacists a true image of their public service, their *raison d'être* and their goals in maintaining the high measure of achievement that has distinguished America's total health care.

These professionals have a prominent but sadly unrecognized position. Theirs can be front line aid in establishing a legislative climate not overwrought by unreasoned hysteria, and with public appreciation for professional and industrial expertise and innovation, to subdue the smouldering fires of misunderstanding and resentment that engender malpractice and product liability litigation.

However, the drug statutes are not selective in their effect on pharmacists. The statute can be invoked against violators among lay persons and other professionals as well. This has been established, tested and affirmed through a myriad of cases.[2]

What the physician sometimes loses sight of is that while drug, device and narcotic laws contain little or no mention of direct control as to his activities, they manage nonetheless to achieve some substantial impact on his practice by their control of his and his patient's therapeutic necessities and the suppliers that provide them. For example, a drug or device which comes to a physician for his use and is misbranded because the accompanying labeling, the "claim-warning-

[2] *U. S. v. Drown*, 198 F. 2d 999, (CA-9 1952); *U. S. v. Brown*, 250 F. 2d 745, (CA-5 1958); *U. S. v. Shock*, CCH Food Drug Cosmetic Law Reports ¶ 80,169, 372 F. 2d 29, (CA-8 1967).

usage information," is false or misleading in some particular, or incomplete, is liable to seizure and condemnation. Or, a drug or device that is labeled to benefit from the 1.106 exemption to Section 502(f) —the prescription only products—that is misbranded because it is delivered to a non-physician or non-dentist unqualified by state law to receive it, is subject to seizure and condemnation.[3]

Adulterated products that have been shipped to physicians may represent a hazard to the practitioner and those whom he serves, and are similarly liable to seizure. This is of special concern to the government agency, as a practical matter, in the case of dispensing physicians. However, the provisions for multiple seizures available against an adulterated product are spelled out in the statute.[4] Therefore, if the doctor has in his possession misbranded or adulterated drugs or devices, they are subject to seizure and condemnation on the federal and state level. In fact, the government's right to seize and condemn violative drugs and devices has been upheld to a point even beyond the practitioner—that is, in the very hands of the ultimate consumer or user.[5]

We tend to forget this because the thrust of enforcement seeks injunction, seizure or criminal prosecution at an earlier stage in the distributive scheme. Also, because on the local level, many of the drug and device laws seem to be manufacturer, wholesaler and pharmacy oriented and enforced. The health science practitioner is generally less conversant with them than he should be. However, a reading of the legislative preface will show them to relate in broad language to "the manufacture, sale and possession of drugs, devices and cosmetics" and, therefore, to include all persons participating in these activities, except as specifically excluded in the language of certain sections or subsections.[6]

Responsibility in Prescription

Since the physician, no less than the pharmacist or the consumer, may have adulterated or misbranded articles in his possession, an effort should be made to describe those terms within the full meaning of the federal and state statutes that apply to him. This is a part of the program we carry out through our Institute for Law

[3] See footnote 2, *U. S. v. Shock.*

[4] Federal Food, Drug and Cosmetic Act, Sec. 501, Ch. 3.

[5] *U. S. v. Olsen*, 161 F. 2d 669, (CA-9 1947), 332 U. S. 768, (cert. denied, S. Ct.).

[6] For example, Pennsylvania Drug, Device and Cosmetic Act, No. 693.

and the Health Sciences at the professional schools which are part of Temple University.[7]

While Section 704 of the Federal Food, Drug and Cosmetic Act differs from most state drug laws in that it seemingly offers some inspective exemption to retail pharmacies and practicing physicians, this partial exemption is disallowed if the pharmacists or physicians exceed the regular "course of their business of dispensing or selling drugs at retail" or "course of their professional practice."[8]

Up to now, inspections of a physician's records and drug stocks have been truly rarities set aside for suspicion of serious irregularities. There is little doubt, however, that within the authority of normal regulatory procedures, or possibly pursuant to an appropriate warrant on the basis of "probable cause," such inspections are possible under the state and federal drug, device and narcotic laws.

Fundamental to the issuance of any order for a prescription drug is the actuality of a bona fide doctor-patient relationship. This is true in state and federal law and was the key to successful criminal prosecution of Drs. DeFreese, Brown, and a host of others. Application of this principle, which clearly affected physicians under a law intended to regulate the interstate commerce of foods and drugs, has been upheld by the Supreme Court of the United States.

The physician is especially vulnerable in the area of the so-called "dangerous drugs" and narcotics where the stringencies are greater and where receipt of such drugs by illegal "prescriptions" makes the recipient "patient" susceptible to a charge of illegal possession as well.[9]

The F. F. D. C. Act, however, generally has not been interpreted in a fashion that would make the physician's administration of medication an act vulnerable to regulatory application. The FDA's position is illustratable in that if a physician were to take a vial of injectable drug he had purchased, and then relabel it indicating other dosage, or deleting cautions, or adding indications for use, and then sell or give such relabeled material to another who is not his patient, he would be chargeable with misbranding on any of several counts. Since the fact pattern is rather that the physician sometimes administers the product himself or prescribes for the drug within Chapter

[7] *Manual of Legal Considerations for the Dental Practitioner in Pennsylvania*, Temple College of Dentistry, Philadelphia, Pennsylvania, Part Two, pp. 28-36.

[8] See also Pa. Act No. 693, Sec. 17 (see footnote 6).

[9] For example, Pa. Act No. 693 (see footnote 6).

Five's prescriptive exemption labeling design,[10] the non-conformance to the normal distributory labeling is outside of the Act's purview and simply employment of the physician's prerogatives of practice.

To emphasize this point, court decisions based on the federal statute, and state drug laws in their own explicit language require that where the physician does not enter, or goes beyond, the regular practice of medicine, and acts as either a distributor or a pharmacist, then he is held to the record keeping, the labeling and every other proscription of the law. In short, the dispensing physician, once he has completed his physician's duties, is viewed as having the same responsibilities flowing from the dispensing act, as would a pharmacist. He has to keep records of receipt and distribution of dangerous drugs and must maintain the integrity of the product's labeling until he relabels it as a pharmacist would do, in giving it to his patient for auto-administration.[11]

Physicians' Experimental Innovations

Once a drug is approved for marketing, its indications for use, dosage, precautionary information and the like are made known to the physician by a combination of his own efforts and those which are really the promotional efforts of the drug's commercial sponsor.[12] In labeling, the FDA may bring into force any means the government at its option decides to employ—seizure, injunction or criminal prosecution—where the drug's commercial sponsor publishes a different statement than that which the agency of the government has deemed acceptable and approved in the NDA or Antibiotic approval procedure.

The manufacturer's disseminations are from a script submitted to the government agency and eventually approved by it. In between, both the manufacturer who knows most about the drug, has greatest confidence in it and seeks broadest terms of use, and the government which bears the responsibility of safeguarding the public and tends to conservatively assess the assembled documents of safety and effectiveness, go through what may be called a non-collective bargaining period when they evolve labels and labeling to accompany the product to professional and patient use.[13]

Since the majority of potent drugs used today are classed as "new drugs" by the federal agency, the latter has maintained control of

[10] Act cited in footnote 4, Sec. 502 (f), 21 CFR 1.106.

[11] Act cited in footnote 4, Ch. III, V; Pa. Act No. 693, Sec. 7 (see footnote 6).

[12] Sadusk, 190 *Journal of the American Medical Association* 907-909, 1964; 192 *Journal of the American Medical Association* 460-463, 1965.

[13] Toulmin, *Food and Drug Law*, Section 25.5.

what comprises the manufacturer's full disclosure as to claims, usage, warnings and other "pros" and "cons" of the product that appear in its labeling, brochures, product cards, mailing pieces and package inserts. This also serves to keep rein on what the manufacturer can say in his advertisements to physicians.[14]

The physician can use the drugs in such a fashion, or he may innovate prescriptively as to dosage, duration, concomitant drugs, precautionary recommendations and even new indications. Whether he does this directly or through the pharmacist, the federal law has been devoid of application inasmuch as the physician and pharmacist are engaged in the practice of their professional prerogatives. Therefore, parenteral mixtures as well as other mixtures prepared or prescribed by a physician for use on his own patients in the normal course of his practice are exempt from the new drug requirements and most other federal and state restrictions.

But, apart from the drug laws, the doctor is responsible for the safety and effectiveness of these mixtures and any adverse effects that may occur to the patient. Where he has made or directed the intermixture himself he has in some circumstances nullified the liabilities of the manufacturer of the component products. There are other circumstances conceivable, where by practice or policy, the product's identity might be obscured in sufficient fashion to focus legal liability upon the professional practitioners involved, or a hospital, rather than a manufacturer.

Since 1961, this "full disclosure" information is required to accompany the product, despite the fact that the manufacturer and practicing physicians may feel its uses have been unnecessarily circumscribed by agreement with the government, essential to marketing clearance. These, then, in a sense, since they reflect the best judgement of a scientific agency with recourse to all the manufacturer's information on the drug, have seemingly become part of the legal parameters as to the safety and effectiveness of these drugs. As evidence, cases can be cited in many jurisdictions that allow admission of such labeling into evidence.[15]

The admissibility of package inserts and their equivalents in agency approved labeling, is generally predicated on the attempt to show that the physician failed to meet usual and acceptable standards in prescribing or administering the drug, or in monitoring its effects.

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[14] Jennings, *FDA Papers*, Nov. 1967/15.

[15] *Magee v. Wyeth*, 29 Cal. Rep. 322; *Sanzari v. Rosenfeld*, 167 A. 2d 625; 84 ALR (2) 1350.

As such, courts have taken a more flexible view of what constitutes hearsay.

This is not to say that such evidence cannot be outweighed by testimony of competent medical experts to the effect that the physician's usage of the drug had more therapeutic validity than did the manufacturer's advice, or that the physician's usage of the drug represented a reputable medical minority opinion. But this area of product labeling, and the possibility of a charge of negligence or malpractice, presents problems to the physician less in terms of the drug laws than in terms of modern decisional law.[16] Some courts, however, continue to exclude the manufacturer's brochure to the physician, or only admit it for the limited purpose of reading and comment by an expert witness.[17]

In most instances it boils down to a mere need on the practitioner's part to show that he met acceptable standards of care in using the drug as he did, that he displayed ordinary skill, prudence and judgment, or that as a matter of balance, his usage seemed better for the patient than the conventional usage indicated in the product labeling. These are qualifications that should represent no special difficulty, since every practitioner undertakes to satisfy them in his every professional act.

Will "dear doctor" letters then gain admissibility to prove knowledge and notice? There is no certainty as to this. A major factor to consider is that the physician's self-education must be a voluntary activity and cannot be regarded as uniform in quantity or in quality. As human identities, doctors defy the constricting concept of equivalency, as do those with proprietary interest in that which they produce. Further, there is no one method assured of giving *all* physicians *all* information at any certain time.

Product Labeling Problems

Now that the National Academy of Sciences and the National Research Council are completing their important task of review, revisions of product labeling are foreseeable. This will be true of many drugs with which practicing physicians are today completely conversant. If some of these get additional precautionary information or contraindications, or their dosage or indications are circumscribed, this will place an additional learning and unlearning burden on practitioners that may add to the concern evidenced today.

[16] See also *Love v. Wolf*, 38 Cal. Rep. 193; 192 *Journal of the American Medical Association* 460-463, 1965.

[17] *Granitham v. Goetz*, 401 Pa. 349, 164A 2d 229, *Crouch v. Most*, 432 P. 2d 250.

Before leaving this problem, we should note that it has created a widespread furor and anxiety amongst teachers and text writers,[18] since it would seem to require that they conform their instructions as to product usage to that which the FDA has approved for the manufacturer, or pose a risk to those that they teach or service. In addition, many believe that such danger must be obviated by accompanying their material with disclaimers to put practitioners on notice whenever what they are saying is at variance with "official" product information.

Following this line of thinking along another devious path, there is further concern that if a physician feels he has been misled and, as a result, in danger of a malpractice judgment against him, he will then either seek to shift or share the blame with the author that moved him to the misprescription. While legal theory may be enlisted to support this, somewhat like the anxiety that accompanied demands for Good Samaritan legislation, research discloses no precedent upon which to predicate this alarm.

While attacks on the format, the spectrum of information, and the purpose of the package insert have questioned its legal basis, challenged its usefulness, and suggested that it be revised in a manner to better protect physicians against potential malpractice charges, the FDA has maintained a firm posture at this time. A few years ago, a highly respected and informed FDA official[19] stated

[18] W. Modell, *Medical Tribune*, June 15, July 13, July 31, Aug. 1, Sept. 21, Nov. 20, 1967.

[19] J. Hauser, 1965 Lecture on New Drug Amendments at Temple University Law School.

"Returning to the original subject as to new drug warnings being so inclusive as to drastically reduce any liability on the part of the manufacturer, I do not pretend to be well informed on civil liability matters. However, in the interest of patient safety, FDA will vigorously require fully inclusive drug warning information in labeling, especially for new drugs, and a brief summary of side effects and contraindications in prescription drug advertising. The approval of a new drug by FDA involves evaluation of the ratio between its potential benefits and its hazards. The use of the drug by a physician involves a similar evaluation on his part in relation to the particular patient. The drug cannot be used with maximum safety and effectiveness unless the physician is fully informed. In view of these public health considerations, FDA has no intention of compromising the full disclosure of warning information for any reasons of civil liability, irrespective of any controversy between physicians and manufacturers. In these circumstances physicians should know that, especially for new drugs, labeling in the possession of the nearest pharmacy may contain warning information of critical importance to their patients and to their civil liability that may not be readily available elsewhere. FDA recognizes the need for and promotes education of consumers to understand and accept that the use of drugs necessarily involves a calculated risk as well as information to physicians that labeling disclosing these risks is available to them."

the FDA belief that to alter the labeling concept embodied in the package insert would abdicate their responsibilities to the public and professions in general. Present pronouncements are along similar lines.

If one reads the prohibitions listed in Chapter Three (Sect. 301) of the F. F. D. C. Act, the non-physician effects of the Act are rather easily noted. However, providing the case can be made out for "interstate commerce," doctors using investigational drugs without clearance should be aware of Sect. 301(d) which makes the drug seizable, its use and distribution enjoinable, and the doctor subject to prosecution where Sect. 505 is deemed violated.

"New Drug" Laws and Experimentation

With the onset of the Kefauver-Harris New Drug Amendments and the regulations elaborated pursuant to them (Sect. 505 of the F. F. D. C., 21 CFR 1.130 and following), investigation of new drugs and experimental therapy underwent a considerable formalization. The writing of the law and the regulations was for the most part directed to the manufacturer, yet certain subsections explicitly involve the health science practitioner, and in total the new language affects him in fairly obvious manner. However, where direct control over his activities is sought, the manufacturer is actually the means of accomplishing such ends.

A manufacturer may not knowingly provide a commercial drug to a practitioner for such types of experimentation as will cause it by use or method of use to be a "new" or "investigational" drug, unless the precedent exemption has been formalized by the multiple submissions and filings of the FD 1571, 1572, 1573, "IND" and investigator forms.[20]

Yet the physician is not in violation of the drug laws, as indicated in our previous discussion, in usual practice circumstances, when he exerts his professional prerogative and uses a commercially approved drug as a "new" drug on his patients. For what the FDA regards as "newness" of a drug, Title 21, Chapter 1, 130.1(h) sets out five parameters "among other reasons."[20a]

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[20] For details of this see: *Lex et Scientae*, 4/110, 1967.

[20a] (h) The newness of a drug may arise by reason (among other reasons) of:

(1) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component.

(2) The newness for drug use of a combination of two or more substances, none of which is a new drug.

(3) The newness for drug use of the proportion of a substance in a combination, even though such com-

(Continued on next page.)

The regulations have dictated a formal relationship contractual in nature, (FD 1572, 1573), in which the legal as well as the scientific ground rules and protocol for the study becomes part of the undertaking. To make certain that the physician will respond to this indirect approach, the receipt of this form is a condition precedent to placing the experimental material in his hands, with one minor Phase 3 exception. Failure to live up to its terms makes it incumbent on the manufacturer to foreclose further study by the scientist involved. (Sect. 505, F. F. D. C. Act. 21 CFR, Part 130). However, a recent FDA proposal would interject some element of "due process" and "hearing" at this point.

There is also access to distributive and experimental records and reports in the hands of clinical investigators in this body of regulation. Where an administrative agency is given access to books and records of the regulated parties, it may directly or indirectly have subpoena powers as well.[21]

Even more directly, however, where a professional practitioner seeks to sponsor his own new drug research, if it is other than a local study, he is required to comply with the federal regulations for exemptive and informational filings in much the same manner as a commercial sponsor.[22]

Some states, such as Pennsylvania, further affect physicians in this regard, inasmuch as they require notice from commercial sponsors and/or private sponsors as to such investigations, in a similar format to the federal, to precede experimental therapy. While most of these demands are waived where the federal submissions have been made, these still pose regulatory necessities insofar as the Pennsylvania physician or investigatory facility is concerned.[23]

Enforcement of Regulations

This seems to be a matter of judgment for the FDA in that in view of their shortage of funds and field staff, they will seek to enforce

(Footnote 20a continued.)
bination containing such substance in other proportion is not a new drug.

(4) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body.

(5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

[21] 376 F. 2d 147.

[22] 334 F. 2d 844.

[23] PHD, Ch. 3-333, Sect. 6 Rev. 5/22-/64; Pa. Act No. 693, Sec. 16 (see note 6).

these regulations only where they are of the opinion a public danger exists. Technically, in the light of various decisions, the FDA can construe virtually any study as being interstate on the basis of source of ingredients, the travel of patients, and so forth.[24]

While preliminary research seems to indicate that there is little or no intent to enforce these legal requirements insofar as the professional practitioner of medicine is concerned, certain implications must remain for the latter's consideration. The governmental agencies, federal or state, are not cloaked in a real adversary costume, nor is it their role. The only real adversary here is the adversary in the court room who is trying to establish that the physician's tortious conduct was the causative agency of his injury or harm, and that the physician should pay damage therefore.[25]

The part that statutory and regulatory language can play in determining the sufficiency of the plaintiff's cause of action is always indefinite. It depends on many subjective and circumstantial incidents to the case as well as the particular finding and attitude of the trial court.

There is, however, ample decisional basis for invoking the principle that violation of a public statute established to preserve the public's well-being may be negligence per se and as such can make out a prima facie case in negligence against a defendant. There is also considerable evidence that in a decade that has seen the scientific sophistication of attorneys as never before, this approach to getting a case before a jury is not being neglected.[26]

The 1962 Amendments and the pertinent regulations further established the requirement that physicians using drugs on human beings investigationally must obtain the "consent of such human beings or their representatives except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings."

While there was initial concern in industry and among physicians at the statutory notice that such a safety measure must be taken, because of its possible value to plaintiffs, following the copious ex-

[24] *U. S. v. Nutrition Service, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,060, 227 F. Supp. 375, (DC Pa. 1964); *U. S. v. Forty Cases Labeled "Pinocchio Brand Oil,"* 289 F. 2d 343, (CA-2 1961, rev'g DC N. Y.); *U. S. v. Drown* (see footnote 2); *Heart of Atlanta* case in application of 1964 Civil Rights Law. Is the doctor servicing an interstate flow of persons who seek medical aid?

[25] *Marchese v. Monaco*, 52 N. J. Super No. 74; *Reed v. Church*, 175 Va. 284.

[26] Goodman and Rheingold, *Lawyers Drug Handbook*.

plorations of the matter by I. Ladimer[27] and others, a sense of realism and a practical legal approach calmed the situation somewhat.

Therefore, when the final regulations were issued to interpret the legislative intent implicit in the 1962 Amendments to Section 505, they were greeted with more composure.[28] However, the fact remains that these are controls spelled out in law for physicians, that can have evidentiary impact in a tort action against the physician. This again is the futuristic approach rather than the immediate. Insofar as the immediate effect of these regulations is concerned, they can make it non-feasible, in the best interests of his total study and new drug application, for the sponsor to continue the association with an investigator who is not observing the regulations. This drug regulation's force against the physician is rather, then, economic and reputative, rather than legally punitive.

"Consent" in Therapy

Consent is mandatory in all experimental drug therapy, according to the federal regulations, except in Phase 3 when it need not be in writing, and in certain defined instances where it is not feasible.[29] Decisional law has already indicated that consent may be drawn from inferences as well as from actual oral or written consents.

Decisional law has also fairly thoroughly defined "non-feasibility of consent" in terms of emergency circumstances, unavailability of consentors, or where psychic damage creates a real danger as a probable result of such revelation. But, in the main, the test is one where the physician must in ordinary prudence and judgment be convinced he can justify nondisclosure or incomplete disclosure in some manner acceptable to his peers.

Aside from the federal definition in Part 130.37, many courts have urged that the standard of divulgence here is to give the patient the degree of explanation and information as is customary in practice by similar practitioners in the area. Further, that it should be "reasonably" informative and that the old doctrine of weighing the benefits against the risks should preponderate for the former in the judgment of the ordinary prudent practitioner.

Therefore, although the method may seem circuitous, by its control of manufacture and interstate shipment, the Federal Food and Drug Administration does achieve some control over the scope,

[27] *Journal of Clinical Pharm.*, 7:125, May-June 1967.

[28] 21CFR 1.130137 (1967).

[29] 21CFR 130.37(f).

methodology and administrative details of scientific studies concerning drugs by the medical profession and its ancillaries.

Narcotic and "DACA" Drugs

A combination of federal and state regulatory controls determines the right of a physician to receive, order, administer, prescribe and dispense narcotic drugs. State licensure to practice precedes federal registration for narcotic privileges.

Order forms, inventories, triplicate prescription blanks, requirements to write here, send forms there and a whole complex of state and federal language has made this for physicians a "shun" area. The facts are, however, that all the law that applies to the physician has been summarized by the Federal Bureau of Narcotics into eleven easy-reading pages.[30] Further, the state regulations are virtually the same, except that in some states additional safeguards have been written into law because of special needs or special interests. In many states also legend drugs and investigational drugs are classed as dangerous.

I would be remiss if I did not indicate, in passing, my personal belief that the present status of drug legislation and most especially that which concerns investigational, "dangerous" or narcotic drugs, makes it as locally inacceptable to be against the proliferation of inflexible intricacies, as to be against the Boy Scouts, the YMCA or motherhood. Yet perhaps the best interests of the public would be served, as has been pointed out many times, if we budgeted satisfactorily so that our agencies could operate with appropriate staff depth and training, could educate and enforce for compliance in a manner that would encourage and enhance innovation and productivity and carry out the legal intent and content of laws we already have on the books.

Some of the apparently lesser known facets of federal and state narcotic laws, as applicable to physician practice, are more direct in their effect on the physician than the drug law, since they carry punitive consequences that can mean fines, imprisonment, revocation or suspension of license and highly unfavorable publicity for the physician and for his colleagues.

In essence, the physician's own professional needs must be obtained on an official order form from an approved supplier rather than through a questionable prescription from a retail pharmacist.

[30] H. L. Giordano, *The Physician and the Federal Narcotic Law*, U. S. Comm. of Narcotics, 4/67.

Where the doctor writes a narcotic prescription for a patient, the dispensed contents of that prescription are solely for such patient's use. The doctor or his agents may not use any part of it for another patient or another purpose. As a matter of law, and it is essentially criminal law, the dispensed contents of that prescription may only be used by that patient, and in that container, and as prescribed for his own needs.

A narcotic prescription should be for a current need for a bona fide patient and for medical purposes only. The states often provide that a physician may prescribe a Class A or Class B narcotic only after a physicial examination of the patient at the time the prescription is issued. Therefore, while oral prescriptions of Class B narcotics are permissible, to do it pursuant to a telephone "q" and "a" violates a public health regulation.[31]

The entire area of prescriptions of narcotics for the addicted is one which has seen much press coverage and some resultant legal tinkering. At the same time some recognizable legal criteria have existed and continue to exist.

Where the physician writes prescriptions "not being issued by him in the course of professional treatment in the attempted cure of the habit," such an act is a perversion of the physician-patient relationship contemplated by 2(b) of the Harrison Act.[32] If simply "to cater to the appetite or satisfy the craving of one addicted to the drug," the prescription issued protects neither the physician who issues it nor the dealer who knowingly accepts and fills it.

Subsequently the Supreme Court indicated the government must show the doctor's bad faith, disregard of standards of practice, or reckless impropriety to find him guilty.[33] Legally and medically, ambulatory treatment for drug addiction is viewed negatively, while recognized institutional treatment of addicts is viewed positively. These seem to be the decisional and statutory parameters that determine whether a practitioner will be held guilty or not guilty.

Moral Responsibility of Physician

While the physician incurs no legal obligation, he has a moral responsibility to assist others to respect and observe their legal requirements. For this reason physicians are adjured to write or phone prescriptions for Class X (exempt narcotics federally) where their own state law has given these products a non-exempt status. This

[31] Pa. Act No. 693, Sect. 4(w) (see note 6).

[32] 249 U. S. 96, 86.

[33] 268 U. S. 5.

is especially true of paregoric and other products containing named opiates, derivatives or synthetics. Where state law is stricter than federal law, the pharmacist and the patient, as well as the physician, are bound to observe the stricter law.

Similarly written confirmation of valid oral prescriptions (and this means oral between the doctor and the pharmacist—not doctor to patient to pharmacist), or written confirmation of renewals are vitally necessary from the doctor for keeping the pharmacist in legal compliance. If the physician doesn't supply these, he subjects the pharmacist to a misbranding offense. As to federally controlled (DACA) dangerous drugs, the practitioner, in writing or orally ordering a prescription, may indicate refillability. These prescriptions are only valid for a six-month period and the doctor can only allow for five refills within that period.

Physicians actually are rarely bothered by state or federal narcotic investigators and even more rarely criminally prosecuted, since both federal and state bureaus of narcotic control require special authority from headquarters before initiating such an action. Pharmacists are more apt to undergo a check. This is an administrative fact of life.

However, narcotics officials are authorized to furnish information on questionable conduct to appropriate licensing boards, and the latter may act upon these, within the powers of state medical practice acts, where the evidence warrants, even if prosecution is not initiated. To this end, narcotics officials can lend assistance in the form of witnesses, reports of investigation, exhibits and records they may have accumulated.[34]

Just as in the case of narcotics, it is illegal for a physician to sell or dispense "dangerous drugs" unless he prescribes them for legitimate medical reasons.

It is impossible, of course, in a brief presentation of this type to cover the important legal considerations for each practitioner of a health science in every state and under the federal statutes that pertain to their practice.[35] However, if we serve to alert practitioners to the general recognition that responsibilities that accrue from either the language or effect of ancillary public health statutes, such as the drug and narcotic laws, deserve their notice, we can make a welcome contribution to their safety and to the general public weal that is the shared responsibility of Law and the Health Sciences. **[The End]**

[34] For example, Act of May 1, 1933, P.L. 216 as amended, Comm. of Pa.

[35] See *Manual of Legal Considerations for the Dental Practitioner in Pennsylvania* (see footnote 7), as the prototype of this broad approach to public health statutes and public safety regulations.

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