VOL. 29, NO. 11 NOVEMBER 1974

Food Drug Cosmetic Law JOURNAL

The FDA Today: Critics, Congress and Consumerism . . .

ALEXANDER M. SCHMIDT

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.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $25; single copies, $3. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

November, 1974
Volume 29 • Number 11

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . November, 1974

Volume 29 Number 11

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Mary A. McEniry and *Sidney H. Willig* are co-authors of "The Federal Food, Drug, and Cosmetic Act and the Medical Practitioner." The article explores the licensing and disciplinary functions of the Food, Drug, and Cosmetic Act and how these mechanisms affect the practice of medicine. Ms. McEniry is Assistant to the Director for Regulatory Affairs in the Bureau of Drugs, FDA. Mr. Willig is a Professor of Law and the Health Sciences and Director of the F. D. C. Unit in Temple Law School. The paper, which begins on page 548, was presented to the Federation of Medical Boards of the U. S. at an AMA Congress of Medical Education in Chicago.

Selma M. Levine, a member of the firm of Wald, Harkrader & Ross, discusses safety issues in the field of cosmetics, emphasizing the concept of premarket testing, clearance and review, in her article "Cosmetics: Is New Legislation Needed?" Ms. Levine's paper, which begins on page 564, was presented at the AMA Conference on Cosmetic Legislation, which was sponsored by the AMA Committee on Cutaneous Health and Cosmetics. The conference was held in Washington, D. C., March 10 to 12, 1974.

A description of the pressures that confront the Food and Drug Administration—a triangular criticism emanating from consumers, industry and Congress is the main thrust of *Alexander M. Schmidt's* article, "The FDA Today: Critics, Congress and Consumerism." The Commisioner of FDA's article was presented before the National Press Club in Washington, D. C. on October 29, 1974. The paper begins on page 575.

Vol. 29, No. 11 November, 1974

Food·Drug·Cosmetic Law
Journal

The Federal Food, Drug, and Cosmetic Act and the Medical Practitioner

By MARY A. McENIRY and SIDNEY H. WILLIG

Ms. McEniry Is Assistant to the Director for Regulatory Affairs in the Burecu of Drugs, FDA. Mr. Willig Is a Professor of Law and the Health Sciences and Director of the F.D.C. Unit in Temple Law School.
The Paper Was Presented to the Federation of Medical Boards of the U. S. at an AMA Congress of Medical Education in Chicago.

THIS PAPER will deal with the major interfaces of the Federal Food, Drug, and Cosmetic (FFDC) Act,[1] with the medical profession and their licensing and disciplinary mechanisms established by the sovereign states. It will also consider some of the major problems that confront the Food and Drug Administration (FDA)[2] today. This organization has been charged with a responsibility to provide for the American public, either through a medical practitioner intermediary, or for autotherapy, safe and effective drugs that have been approved by a substantial tradition of medical-clinical experience, or have been approved through the accumulation of substantial evidence in a manner statutorily mandated.[3]

Some exploration of the impact of the Federal Food, Drug, and Cosmetic Act on the practice of medicine is especially timely in

[1] 21 USCA 321 et seq.
[2] An agency within the U. S. Dept. of HEW.
[3] 21 USC 355(a) et seq.

light of recent actions by the FDA and the increasing need for communicating and explicating these actions to the medical profession and those to whom its stewardship has been entrusted.

The authors have welcomed an opportunity for an exchange with officials responsible for medical licensing, because the state medical practice act, as other professional practice acts, determines the qualification of a practitioner to prescribe within the authority offered by the Federal Food, Drug, and Cosmetic Act.[4]

Violations of the FFDC Act

Therefore, when a medical practitioner unqualified by licensure within a state writes a prescription, it is not only the doing of an act which connotes illegal practice of medicine, it is an actionable violation of the Federal Food, Drug, and Cosmetic Act that can result in criminal prosecution.

When a professional practitioner, licensed after qualification by the state, prescribes drugs which have a use and purpose outside of the legitimate scope of his area of practice as described in terms of his state's professional practice act, he is not only chargeable with illegal practice of medicine but with violation of the Federal Food, Drug, and Cosmetic Act.[5] For example, a dentist who writes a prescription for contraceptive pills to satisfy his family needs or accommodate a female patient may be vulnerable.

Where lay persons impersonate physicians and write prescriptions or administer prescription drugs and/or devices, they too are in violation of the Federal Food, Drug, and Cosmetic Act besides the Medical Practice Act.

Physicians who are violating the FFDC Act fall into the general category of those who may be disciplined under the medical practice act for "unprofessional conduct." Should FDA prosecution be terminated in a plea of nolo contendere, as it was in the case of Dr. Bennett Robin, or the physician be found guilty as in the cases of Drs. DeFreese,[6] Brown, Taller and others, then the medical practice act generally provides for punishment in the form of suspension or revocation of license.

---

[4] The authors addressed themselves to the Federation of Medical Boards of the U. S. at the AMA Congress Medical Education, Chicago, Feb. 1973.

[5] *U. S. v. Drown*, 198 F. 2d 990; *U. S. v. Brown*, 250 F. 2d 745; *U. S. v. Shock*, 372 F. 2d 29.

[6] *U. S. v. DeFreese*, 270 F. 2d 737.

"Controlled Substance" Law

A companion law[7] dealing with physicians' authority to purchase, store, research, prescribe, dispense and distribute those drugs designated as "controlled substances" within a five-schedule schema adopted by many states as well, likewise holds several gradations of punishment for errant physicians. In the context of that law, it is possible to remove one schedule or all of such articles from the physician's purchase, use, prescription and dispensing prerogatives without instituting further punishment. This would not be feasible under the Federal Food, Drug, and Cosmetic Act and therefore it relies for effectuation at the interface of medical practice, on the predominant goodwill and judgment of the medical practitioner and the licensing discipline of the state medical board.

While the public has a right to expect that the medical boards will initiate disciplinary action against their licentiates who violate the drug laws, the boards are urged to bring to the attention of the appropriate federal or state agency any violators who are not their licentiates.

FFDC Act—Criminal Statute

The Federal Food, Drug, and Cosmetic 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 for the most part mimic it and are also criminal or quasi-criminal in character. Violators can suffer heavy fines and prison sentences, the offense being generally a misdemeanor. These statutes are unique in that proof of criminal intent is not a prerequisite for criminal punishment.

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.

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

[7] The Comprehensive Drug Abuse Control Act of 1970.

in these activities, except as specifically excluded in the language of certain sections or subsections.

Drugs Prescribed for Unapproved Use

Of major concern to the FDA and of interest to all is the widespread prescribing of some prescription drugs for conditions not named in the FDA approved labeling. Numerous questions have been raised as to the legal responsibilities of physicians for such use. To clarify the requirements of the Federal Food, Drug, and Cosmetic Act with respect to such use for the medical profession and the pharmaceutical industry, and to specify the sanctions available to the FDA where problems are presented, a proposed regulation[8] was published in August 1972. Judging from the comments received on the proposal, there remains misunderstanding of, as well as disagreement with, FDA's position. FDA's position was viewed in most of the comments received to be an encroachment on the medical profession. The position published is as follows in pertinent part:

"The labeling of a drug is derived from data submitted with a new drug application. It presents a full disclosure summarization of the drug use information which the supplier of the drug is required to develop from accumulated clinical experience and systematic drug trials. These trials consist of preclinical investigations and adequate well-controlled clinical investigations that demonstrate the drug's safety and the effectiveness it is required to possess. This package insert, then, represents a summary of the conditions under which the drug has been shown to be safe and effective by adequate scientific data submitted to FDA."

Legal Liability—The Physician

If an approved new drug is shipped in interstate commerce with the approved package insert and neither the *shipper* nor the *recipient* intends that it be used for an unapproved purpose, the requirements of the act are met. Once a new drug is in a local pharmacy the physician may prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those that are approved, without informing or obtaining the approval of the Food and Drug Administration.

Such prescribing is thus *not a violation* of the Federal Food, Drug, and Cosmetic Act.

However, with this freedom to prescribe drugs for unapproved uses—no less than when he has prescribed drugs at dosage levels greatly variant than apparent from the accompanying labeling—the

[8] *Federal Register*, Aug. 15, 1972.

physician takes on additional obligations which reflect on his civil liability. He must have done a balancing out of benefits against risk. He must be sure that in changing the approved dosage, the approved frequency and mode of administration,[9] or prescribing for an unapproved indication, was based upon an adequate professional judgment. There are moral and ethical considerations applicable to the safe use of investigational drugs in humans besides those set out in the law. In fact, hindsight many times indicates that an ensuing complaint might not have created a full-blown litigation, had he shared the basis for his decision with his patient or patient's representatives.

Physician Should Share Findings

The FDA also believes that it is desirable for the physician to share with the FDA his experiences with such drug uses even though the law is clear and it is freely stated that the physician is not required to file an investigational drug plan under the conditions of use just described. Without information on how drugs are being used and the results of the uses, the FDA is not in a position to assure the safety and effectiveness of drugs and cannot protect the public. Drug experiences may be shared with FDA by completing the new simplified adverse experience reporting form, by filing of simple investigational drug plans or by submitting a brief narrative report of the experience. This can be done without sacrifice of the confidentiality surrounding the physician-patient relationship.

It should be apparent then that the medical practitioner has considerable freedom and authority for varied use of products.

The physician can use the drugs exactly as labeled, or he may innovate prescriptively as to dosage, duration, concomitant drugs, precautionary recommendations and even new indications. Whether this is done 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.

---

[9] See, for example, *Crouch v. Most*, 432 P. 2d 250; *Grantham v. Goetz*, 401 Pa. 349.

FDA Investigates Unapproved Drug Use

However, 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.

When an unapproved use of a drug becomes widespread, or presents a hazard to patients or appears to be beneficial to patients, the FDA is obligated to investigate and resolve the issues by seeking the necessary data, initiating labeling changes, placing limitations on the usage of the drug, or other sanctions as the facts warrant. The actions generally available to the FDA do not include sanctions against the physician but may deprive him of the drug's use, if it is removed from the market or his ability to use it is removed, or if the drug is restricted to use by specific specialists to which group he may not belong. Adverse publicity resultant from such circumstances is undesirable for all concerned and feeds the suspicions of patients who are unhappy with results.

FDA May Limit Drug Use

Within the language of product or device labeling, it is often apparent that the products be used by certain types of trained specialists, or be limited to hospital usage, etc. However, the federal system places the burden on the states to maintain their standards of licensure as to who may prescribe drugs. It is desirable in granting licenses to consider the wide spectrum of available drugs, the potential for research involvement, and the wide range of sophistication required for using many drugs or engaging in some of the research. The FDA must rely on medical education and the boards. It is the position of the FDA that it has the authority necessary to place any restrictions on drug distribution necessary to protect the public health, thus affecting usage. They have gone so far as to remove a misbranded medical device from a satisfied user's home.[10]

A more general example has been the limitation placed on methadone usage, such restriction being found necessary in the

[10] *U. S. v. Olson*, 161 F. 2d 669 (Spectro-Chrome).

public interest. Still another example of distributive restriction was the approval of methotrexate some years back, with labeling limiting dispensing and administration of the drug to physicians. Subsequent problems arising from this inconsistency and extensive use of the drug for unapproved dermatological use resulted in confusion, malpractice suits and ultimately an extension of the labeled indications following careful review of the situation by FDA.

Investigational Drug Plans

Turning to other areas of the Federal Food, Drug, and Cosmetic Act which affect physicians, the investigational drug provisions undoubtedly regulate physician activities most directly. Under the Act, new drugs to be marketed must be established to be effective by "substantial evidence" which was defined by the Congress as "adequate and well-controlled studies by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." The FDA, in its review of investigational drug plans, determines from review of the investigator's background if he is adequately qualified to undertake clinical research. Investigational drug plans may be delayed or denied by FDA if it appears that an investigator does not have adequate expertise or facilities for the kind of study proposed. Drug development research is widely undertaken by the medical profession. FDA files currently indicate there are between 15,000 and 20,000 physicians engaged in clinical research. The impact of the June 17, 1973 Supreme Court decisions and their agreement with FDA concepts of requirements for "substantial evidence" as defined in the FFDC Act, will of necessity augment those numbers.[11]

The investigational drug regulations establish formal obligations on physicians engaged in clinical research when an investigational drug plan (IND) is filed with FDA. If the investigator is undertaking the study under a pharmaceutical firm's sponsorship, he is required to sign a form which establishes the ground rules for his receiving the drug for study. His failure to abide by the commitments made in signing the form obligates the sponsor of the investtigation to discontinue shipments of the drug to him. Under this arrangement the pharmaceutical sponsor is responsible for monitoring the investigation and supplying the FDA with all the required information. The only action that may be taken against the inves-

[11] *Weinberger v. Hynson, Westcott & Dunning Inc.; Weinberger v. Bentex Pharmaceuticals Inc.; USV Pharmaceutical Corp. v. Weinberger; Ciba Corp. v. Weinberger*, U. S. Supreme Court, June 17, 1973, 412 U. S.

tigator by the FDA under this arrangement is to declare the investigator ineligible to receive investigational drugs for study. If this action is taken, after the investigator has been given an opportunity for an explanation, he and the sponsor of any investigation in which he has been named are notified that the investigator is no longer entitled to receive investigational drugs.

The "Al Capone" Statute

When physicians are called upon to fill out and/or submit any forms to the FDA, in the course of various phases of new drug investigation for example, they are bound to do so in compliance with the FFDC Act. The rare failure to do so, or the withholding of information required, or dishonesty in response not only violates the FFDC Act but is punishable under Section 1001 of the federal penal law, the so-called "Al Capone" statute which carries very harsh punishment. Therefore, like wilful evasion of income tax, it can serve as an acceptable basis for revocation or suspension of medical licensure.

Where a physician undertakes to sponsor his own drug research, he is required to comply with the same regulations in obtaining an exemption and make the required reports as a commercial sponsor. In this role, the investigator is subject to the same sanctions of the law as the commercial sponsor, including criminal prosecution, since every violation of the FFDC Act represents at least a potential misdemeanor without the need to prove intent.

Informed Patient Consent

An essential element of clinical trials is informed patient consent. Congress has included in the 1962 amendments to the law the mandate that informed consent be a condition of the exemption required for shipment of a drug for clinical investigation. Two exceptions to consent are provided where it is not feasible or in the best interest of the patient. The FDA has defined informed consent, amplified the conditions under which the two exceptions are applicable and has specified that written consent is required in phases I and II. This is a very sensitive area of clinical research which is of increasing public interest. The FDA is reviewing its guidelines for informed consent with a view toward providing any additional safeguards that may be warranted. Certain congressional committees are also active in this field and professional experience hopefully will dissuade actions which may impede or confuse research projects, since

the motivation for public safety is common to legislators, administrators and the profession at large.

Committees Organized for Patient Protection

There has been in effect for almost two years a requirement that clinical drug investigations conducted on institutionalized subjects be reviewed by a committee to assure that the rights and welfare of the subjects are adequately protected. These committees are for the purpose of assuring protection at the local level for individuals in prisons, nursing homes, mental institutions or hospitals. They assure appropriateness of methods to obtain consent and consider the risks and potential benefits of the investigation. The committee members should have the ability to comprehend the nature of the project or activity in terms of institutional regulations, relevant law, standards of professional practice and community acceptance. With principles like these to be upheld, the FDA regulations require a committee made up of persons of varying backgrounds. The federal agencies are beginning a very modest surveillance program to determine how well these committees operate with a view toward taking any educational steps as may be indicated to assure their effectiveness. There is also a need to provide an equivalent committee review to protect noninstitutionalized patients who are subject to research investigations. This is an area in which perhaps local medical groups could be helpful, by encouraging alertness to professional responsibility with regard to subjects or patients involved in clinical trial.

Interstate Commerce Regulations

The FDA relates to medical practitioners primarily through its regulation of drugs and devices in interstate commerce. It is responsible for determining that there is adequate evidence of safety and substantial evidence of effectiveness before a new drug can be available for prescribing by the medical profession—and is responsible for assuring that the drug label bears truthful, accurate and full disclosure information under which the drug may be safely and effectively used by the physician.[12] FDA approves the *drug labeling* for all new drugs and antibiotics as they go on the market. This is the approved labeling that must accompany the drugs in interstate commerce and that forms the basis of information in all promotional material for such a drug. The states, of course, determine who is licensed to use the drug.

[12] *Magee v. Wyeth*, 29 Cal. Rptr. 332; *Sanzari v. Rosenfeld*, 167 A. 2d 625.

Cardinal sins under the FFDC Act, which the FDA is pledged to seek out, are misbranding, adulteration and new drug violations.

"Misbranding"

While "misbranding" is a statutory term within the FFDC Act, it is a term commonly used to denote a defective product. One who "misbrands" a product for the patient, or who utters a "misbranded" product to a patient is not only vulnerable under the FFDC Act to loss of product, fine and imprisonment, but may find a *prima facie* case in professional negligence has been prepared for the injured patient.

Manufacturers "misbrand" drugs and medical devices by labeling them in a manner noncompliant with the FFDC Act. The technical parameters of labeling are established in law to protect the public whether articles are used in autotherapy, directly or indirectly by physician's order.

The manufacturer further misbrands a product if the labeling is untruthful, inaccurate or inadequate to permit the product to be used with safety and effectiveness for the claims made for its use.

The practitioner can help effectuate the application and purpose of the FFDC Act by his own effort, to an extent virtually impossible for the FDA apparatus to accomplish on its own. It is the doctor treating and observing the patient who is the best judge of whether a product is properly, honestly and adequately labeled. Often, his experience in administration also points out adulterative liabilities of the product as marketed, such as its failure to maintain proper composition, solubility, freedom from particles, sterility, etc.

Adverse Experience Information

Improving procedures for obtaining adverse experience information from physicians has been a high priority item for the FDA. There is no question but that in reporting significant or unusual adverse drug reactions (even if already reported in literature or the package insert) as well as unanticipated novel events that are suspected to be drug related, the physician is performing a public service and makes possible a better assessment than is now possible of the frequency of certain side effects. These reports would greatly extend FDA's ability to keep the entire medical profession informed of developments in this area and physicians may thereby help colleagues avoid or be aware of similar reactions. Toward this end, FDA has developed a new simple adverse experience reporting form.

The forms are self-addressed and prestamped. The FDA is committed to retain the identity of the reporting physician and the patient as confidential and their identities will not be released. Forms were included in the mailing of the October, 1972 FDA drug bulletin and the response has been quite gratifying. The FDA received more adverse experience reports from physicians in the first 15 days than in the previous six years (1200 reports).

Communications to Physicians

The FDA is concerned with the adequacy of its communications to the medical profession. They recognize problems in getting physicians to implement the regulatory decisions in their prescribing habits. The publication of the efficacy conclusions on about 4,000 drugs approved on the basis of safety and introduced to the market between 1938—1962 is virtually complete. Those drugs were reviewed for efficacy by the National Academy of Sciences-National Research Council (NAS-NRC), Drug Efficacy Study Group to enable FDA to determine if the drugs met the efficacy requirements of the 1962 amendments. As a result of this undertaking, many drugs lacking substantial evidence of effectiveness are already off the market and the labeling of large numbers of drugs has been revised to delete unproven indications and to update their use and adverse effect information. Within the next two to three years, resolution of the efficacy of the remaining drugs should be essentially complete.

Do "dear doctor" letters from the manufacturers or the agencies serve to inform physicians of newer limitations on use, newer warnings and contraindications, newer dosages? Are they useful for plaintiff's attorneys to show doctors had knowledge and were on notice of dangers inherent in the use of particular drugs? A major factor for all to consider is that the physician's self-education is a voluntary activity. It cannot be regarded as uniform in quantity and quality even when it becomes a requirement through the action of his medical society or medical licensing board as "continuing education." As human identities, doctors defy the constricting concept of equivalency. However, while no one method assures giving *all* physicians *all* information at any certain time, a confluence of all methods must be attempted.

The position taken by courts, in recent holdings, as to products liability, implies that whatever methodology is taken to assure dissemination of information on a product for promotional purposes should probably be used to acquaint physicians of new warnings and

other matters seriously related to safety and efficacy.[12a] Many of the indications for which today's marketed drugs have been widely prescribed in the past are no longer a part of the approved labeling—but do physicians know this? How can the FDA communicate this information which has such profound medicolegal implications for all medical practitioners?

Efforts are made to identify significant labeling changes and to communicate with physicians through the FDA Drug Bulletin which is mailed to approximately 600,000 health professionals, including physicians, medical schools, pharmacists, etc.

Benefits to Patients

Physicians must find ways to translate the scientific reviews and conclusions of a drug's effectiveness and safety into patient benefits. To accomplish this the FDA must get the attention of the profession. Needless to say, this is vital to the medical licentiate since he is desirous of using drugs in the manner recommended by his fellow experts. In addition, his knowledge of revised labeling information about important units within his armamentarium serves at the very least as partial prophylaxis against suits that arise from alleged improper prescribing.

Until the advent of the 1938 amendments to the Federal Food, Drug, and Cosmetic Act, through the legislative energies of a physician-senator, Dr. Royal S. Copeland, the impact of that law on the practice of medicine was comparatively unknown. Subsequent to the terrible "elixir sulfanilimide" tragedy of that time with the ensuing Copeland Act, the FDA was authorized to keep from the physician's armamentarium of prescribable drugs, those new drugs which had no satisfactory proof of safety for use as directed. Physicians were given the prerogative and responsibility to be designated as such experts, as might find such a new drug safe for public use, either in autotherapy or subject to prescriptive order.

Durham-Humphrey Amendment

The importance of the physician's role in implementation of the Federal Food, Drug, and Cosmetic Act was further enhanced in 1951 by the passage of the Durham-Humphrey Amendment.[13] This law is well-known for modern classification of drugs into those which may be promoted and sold directly to the public minus the inter-

[12a] *Sterling Drug Inc. v. Yarrow*, 408 F. 2d 978.

[13] 21 USC 353(b).

cession of a medical practitioner, and commonly called OTC's (over-the-counter) or proprietary drugs, and a second class of potent drugs called prescription drugs. These are sometimes called "legend drugs" because until the physician authorizes them to be dispensed to a patient or administers them himself, they must bear a legend stating that federal law requires them to be dispensed only via prescription. To help the physician and the patients he serves, this law in effect outlaws certain undesirable practices which would be detrimental to the physician-patient relationship. Some of these details are not too well-known. For example, the pharmacist may not dispense, and the physician may not prescribe nor dispense such drugs in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail. The pharmacist is bound to dispense the exact product the physician has ordered and is bound to label it in complete accuracy in accordance with the physician's instructions. In addition, he is bound to package it in a manner prescribed by official compendia, or by law in the matter of child-safety packaging, so the product will retain its integrity and household endangerment will be minimized.

Thus, this section of the FFDC Act recognized the physician's interest on behalf of the patient, in confining use of potent medication to the physician-patient relationship. While it was not intended to interfere with conventional self-medication by individuals with minor ailments, it was intended to make unavailable to them any drug that required a physician's pretreatment diagnosis, or might be dangerous for its manner of use, or might create hazard for a patient collateral to its administration or due to its dosage and duration of use.

Prescribing Via the Telephone

At the same time the section recognized that a physician must be allowed to use agents and that telephone and other communicative devices were clinical necessities to the medical practitioner. So with the exception of nonemergency prescriptions of Schedule II Controlled Substances affected by another federal law, the FFDC Act presents no legal objection to the physician's right to prescribe and even diagnose, by telephone. Under some state laws, restrictions do exist, and of course at least with regard to diagnosis, civil liability potential is increased.[14]

In one case, after the original prescriber refused renewal of a prescription, the child's mother obtained a new prescription from

[14] *O'Neill v. Montefiore*, 202 NYS 2d 436; *Incollingo v. Ewing*, 282 A. 2d 206.

her gynecologist who had never seen the child, as a patient or otherwise. He then subsequently granted renewal authorization for the prescription for the infant on numerous occasions. The child died from aplastic anemia resultant from use of the drug. Needless to say, the doctor was held liable along with the drug's manufacturer.

Where doctors prescribe by telephone or make changes in prescriptive orders via telephone, providing care is taken in pronunciation and in giving directions, the extra risk is minimal. Realistically however, when a pharmacist misreads the doctor's handwriting that is very likely to be the pharmacist's problem. However, when the pharmacist mishears the doctor's order communicated acoustically, it may turn out to be the doctor's problem in terms of civil liability. As for the FFDC Act, however, whether the pharmacist has misread the prescription or misheard the prescription, or aside from any such error in communication, has given another product or brand of product in place of what the doctor has authorized, the pharmacist has "misbranded" the drug.

Within the language of the law, the doctor can misbrand a prescription drug or device also, independently of the manufacturer, pharmacist or other distributor.

Illegal Prescribing

If a physician writes a prescription order for a person for whom no physician-patient relationship exists, then drugs or devices issued pursuant to such a prescription are misbranded and the physician can be criminally prosecuted for causing such an event (Section 301, 303 FFDC Act).

If a physician distributes prescription drugs or devices to persons without benefit of a physician-patient relationship, he has issued misbranded articles within the meaning of the FFDC Act and he is again subject to the possibility of criminal prosecution (Section 301, 303, FFDC Act). There are numerous examples of both such circumstances where the Food and Drug Administration has had no choice but to have the U. S. Justice Department prosecute the doctor and see to his punishment. In one such noted case, *U. S. v. DeFreese,* the U. S. Circuit Court of Appeals stated clearly that a doctor who prescribes, dispenses or administers drugs without a valid physician-patient relationship has no more status than a lay person to do so. Dr. DeFreese, who had distributed large amounts of dangerous and abusable drugs to persons sent to him to procure same by his wife, with never any attempt to examine them, ascertain their

complaints, take a history, "or even put them on a scale," received a severe sentence.

Physicians must also be wary of having nurses or other assistants prescribe, dispense or otherwise distribute "legend" drugs or controlled substances independently of the physician's order or supervision. For these actions he may find himself vicariously liable.

There are less obvious areas of medical practice which are affected by the FFDC Act and its effectuating regulations, but which are additionally germane to the task of supervision of medical practice in each state.

When physicians undertake to manufacture or compound or distribute drugs for other than their own patients, they must register under federal law as any other manufacturer and be subject to all sections of the Act that relate to manufacturing. That means that they must abide by the labeling provisions, good manufacturing practices and be subject to inspection as is a manufacturer. Even as a nonmanufacturer, a physician may not possess and administer misbranded or adulterated drugs although the more serious punishments involve a "knowing" situation.

Adulteration Provisions of the FFDC Act

The Federal Food, Drug, and Cosmetic Act has strong adulteration provisions also. The rare careless physician who fails to keep potent drugs in an uncontaminated state, or in appropriate aseptic condition, or mixes labels or fails to refrigerate as required may be found in criminal violation of the Federal Food, Drug, and Cosmetic Act (301(k) 303).

There are many areas in which the Federal Food, Drug, and Cosmetic Act affects the physician. We have touched on a few of those of major concern to the FDA today. Much of this deals with the complex problems of drug development. These problems of drug usage or development by physicians relate directly to the responsibilities of the licensing authorities. Licensed practitioners (physicians, dentists, osteopaths, chiropractors, etc.) are those which are authorized to prescribe drugs or perform research under the federal system. Our view is that: with the authority to use drugs goes the responsibility to use them according to current scientific standards; with the authority to perform research in human subjects goes the responsibility to abide by the ethical principles of human research

and to recognize the difference in accepted medical practice and research; with both goes the responsibility to share drug experience information as a public service obligation.

Use of Experts

It is important to realize that the FDA in the past three years has greatly increased its use of experts. Presently over 300 of the nation's outstanding physicians and other scientists are advising the Agency. One or another group of FDA consultants meets almost daily to give them the benefit of their knowledge and experience. It is also planned to use outside experts more extensively to follow IND's and New Drug Applications (NDA's) through the drug review process. It is fair to say that today for most major problems or decisions, the advice of the nation's experts is sought.

It is one thing to enlist the physician's efforts in such a cooperative enterprise, but quite another, apparently, to convince him that advice given the FDA by selected groups of his peers must predetermine availability of single entity and combination drugs which he has been using in his practice. Therefore, the FDA can and will exhibit a willingness to hear and consider the objections of medical practitioners when they are raised against a proposal.[15]

Combined Effort

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 End]**

[15] *J.A.M.A.* Editorial, 222:1553, 1972.

Cosmetics: Is New Legislation Needed?

By SELMA M. LEVINE

Ms. Levine Is a Member of the Firm of Wald, Harkrader & Ross.
The Paper Was Presented at the AMA Conference on Cosmetic Legislation, Sponsored by the AMA Committee on Cutaneous Health and Cosmetics, Washington, D. C., March 10 to 12, 1974.

THE RAPID DEVELOPMENTS involving cosmetic legislation in recent weeks suggest that the title I opted for 5 months ago —Is there a need?—may well be outdated. Whether or not there is a need, Congress may impose some new controls. The only remaining questions seem to be *what kind?* and *when?*

But plainly the shape of any legislation regulating cosmetics—and the day of its coming—is affected by what Congress, consumer groups, and the Food and Drug Administration (FDA) perceive to be the nature and incidence of problems involving the health of Americans. There are two relevant questions. Is there hard evidence that cosmetics today present new or significant safety problems? If so, is existing regulation sufficient to deal with them?

Cosmetics—Safety Problems

Since you've heard it so often, I will only briefly summarize where we stand today.

FIRST: The consensus is that the safety of cosmetics poses no current or critical high priority problem to consumers generally.

This is the view of FDA Commissioner Schmidt, the Panel on Chemicals and Health of the President's Science Advisory Committee (September 1973), Congressman Sullivan, and expert dermatologists. To quote the Commissioner:

"The sum of all known, reported and suspected problems of cosmetic safety do not add up to anyone's first priority when compared with most other safety issues before society."[1]

[1] Remarks before the Cosmetic, Toiletry and Fragrance Association (CTFA) Convention, February 27, 1974, reported in *F-D-C Reports*, March 4, 1974, p. B1.

Unlike devices, where the postwar era saw the emergence of new, complicated and sophisticated medical equipment (such as pacemakers and kidney machines), cosmetic ingredients and products marketed today have by and large been around for a long time, and we know a good deal about them.

Dr. Naomi Kanof has observed that

"Extensive usage over long periods of time have demonstrated the safety of almost all of the categories of cosmetics now available to consumers, the more so since the removal of products that could cause a higher-than-acceptable incidence of primary irritation, sensitization or photosensitization."[2]

Adverse reactions are considered low relative to production and use and, for the most part, as transient in character.

SECOND: To suggest that cosmetic safety is not an urgent problem is not to say that cosmetics present no risks for any consumer. Hexachlorophene, feminine hygiene sprays, Mennen-E are familiar words, indicating that there are risks.

But precise and reliable information as to the incidence, cause, or severity of these risks is unknown.[3]

Figures ranging from 60,000 to 10,000 so-called "injuries" per year have been cited as indicating the alleged hazard. The reliability of the widely quoted 60,000 estimate—mentioned in the Report of the Commission on Product Safety and relied on by Senator Eagleton when he introduced S. 863—is open to serious question. The President's Panel on Chemicals and Health called it a "rough and doubtful estimate." It was based, as Dr. Murray Berdick has pointed out, almost entirely on accidental ingestion, with no indication that ingestion was in any sense harmful.[4]

Other figures, including an estimate for fiscal 1973 of about 15,000 by the National Electronic Injury Surveillance System (NEISS), which monitors 119 hospital emergency rooms, cover "injuries" related to the container, "poisonings" and "accidental ingestions." Dr. Berdick's analysis of the NEISS estimate indicates that less than 10,000 of the "injuries" were related to or associated with, but not necessarily caused by, a cosmetic product.[5]

In an effort to obtain reliable information on the national incidence of "adverse reactions," particularly to establish a valid base

[2] Letter of February 5, 1974, attached to CTFA testimony on S. 863, before the Subcommittee on Health, Senate Labor and Public Welfare Committee, February 21, 1974.

[3] Commissioner Schmidt, in remarks to the CTFA convention, said: "None of us has totally reliable data which reveal the true incidence of injuries and adverse reactions from cosmetics." As reported in *F-D-C Reports*, March 4, 1974, p. B1.

[4] Letter, 182 *Science Magazine* 1080-82 (December 14, 1973).

[5] *Id.*

against which "product experience" reports can be evaluated. FDA has awarded a $190,000 contract to the Westat Company in Rockville, Md., to survey 10,000 households covering 34,000 samples.[6]

THIRD: Responsible cosmetic makers do not market new products without careful safety evaluations, which take account of past experience and knowledge and include extensive testing whenever needed.[7] One experienced testing laboratory in the field has observed.

"The toxicological methods used today have kept pace with scientific development and progress in the relevant biochemical, biological, and medical fields."[8]

FOURTH: New FDA regulatory programs initiated in the past 2 years will provide both FDA and consumers with important information about cosmetics and their manufacturers. Three programs, developed at the instance of industry, are voluntary.

(1) *Registration.* Cosmetic products establishments are requested to register with FDA.[9]

(2) *Formula and Ingredient Information.* Cosmetic manufacturers are asked to supply semi-quantitative information on the formulation of each cosmetic. Cosmetic ingredient suppliers are asked to submit information on raw materials they make.[10]

(3) *Product Experience Reporting.* Manufacturers are requested to file "cosmetic product experience reports,"[11] relating to what some call "adverse reactions." This seeks, for each product, reports on the *number, rate* and *type* of "reportable experiences" (i.e., injuries or allergic reactions not considered "spurious" under an approved screening procedure).[12] Experiences will be divided into one of several categories: irritation, allergic reactions, infection, corrosive reaction, and "other." Firms are also requested to file "Summary Reports" of all their product experiences by product category.

(4) One mandatory program, resulting in part from a petition filed by Professor Page and Anthony Young at Georgetown University

[6] *F-D-C Reports*, October 15, 1973, p. 12.

[7] As the CTFA pointed out in its testimony on S. 863, a manufacturer today "avails himself of the existing scientific and medical literature, ingredient safety data, supplier data, marketing experience with similar products, usage information from test panels and medically supervised panels, as well as the results of testing performed by manufacturers, suppliers, and trade associations, government agencies and academic institutions."

[8] Letter of February 15, 1974, from J. C. Calandra, Industrial Bio-Test Laboratories, attached to CTFA testimony on S. 863, February 21, 1974.

[9] 21 C. F. R. § 700.3.

[10] 21 C. F. R. § 720.1.

[11] New Part 174, 38 *Fed. Reg.* 28913 (1973).

[12] 21 C. F. R. § 730.4.

Law School, requires a label declaration of each cosmetic ingredient in descending order of predominance.[13]

Despite this FDA activity, some believe that not all cosmetics are properly evaluated for safety, and that new remedies are warranted. We have had a vast array of suggestions.

A. Premarket Testing and Clearance

The impetus for new regulation, until recently, has been Congressional, with the consumer groups—Nader, Professor Page, Consumers Union—as the primary supporters.

Their thesis at the hearings on S. 863, the bill introduced by Senator Eagleton,[14] was that cosmetics are nonessential products from a medical (or even a social)[15] point of view. None "meet the test of indispensability which might otherwise allow the tolerance of any significant risk," said Nader.[16] While they concede that serious harm has *not* been demonstrated, they believe that an almost fail-safe system can and must be provided to assure consumers of the absence of any harm. To this end, they say, comprehensive premarketing testing—*a la* S. 863—and clearance is indispensable. As evidence of the existence of a problem, the consumers cited principally the incidents involving feminine hygiene sprays and Mennen-E.

B. Premarketing "Review"

S. 863, Senator Eagleton's bill, would require premarket testing and filing with FDA, 90 days in advance of marketing, of "full reports of investigations adequate to substantiate the safety of [each] cosmetic or cosmetic ingredient."[17] An elaborate list of required investigations is specified. In addition, the bill would make mandatory what is now voluntary: registration, filing of formulas, and complaint reporting.[18] FDA would have a veto power on marketing.

---

[13] 21 C. F. R. § 1.205(a) (38 *Fed. Reg.* 28913 (1973)).

The primary source for proper name identification is the CTFA *Cosmetic Ingredient Dictionary*. Individual fragrance or flavor ingredients need not be identified by name.

No identification is needed for an ingredient recognized by FDA as a "trade secret." A manufacturer will be required to show that the ingredient "is unique, that it is important to the product, and that it is not known to competitors." Eirmann, "Cosmetic Ingredient Labeling," 29 *Food, Drug, Cosmetic Law Journal*, 68, 71, 1974.

[14] Cosmetic Safety Act of 1973, 93rd Congress, 1st Session (1973).

[15] Testimony of Ralph Nader on S. 863, before the Subcommittee on Health, Senate Labor and Public Welfare Committee, February 21, 1974, p. 1.

[16] Money spent on cosmetics is a social waste, Nader stated, though he conceded that this is not something about which Congress can or should legislate.

[17] 93rd Congress, 1st Session § 203.

[18] *Id.* § 301.

It now appears that premarketing "clearance" or "review"—and testing of the type commanded by the Eagleton bill—will go by the boards. There appears to be little support for the regulatory system envisioned in Sec. 203, which insists on the conduct—and filing with FDA—of a prescribed series of tests, including those for the degree of human ingestion, inhalation, percutaneous absorption, as well as for short-term and long-term carcinogenic, mutagenic and teratogenic effects.

Aside from its inflexibility and its failure to take account of other factors traditionally relied on to appraise cosmetic safety, the testing section has been characterized as "unrealistic" from a scientific point of view.[19] Moreover, an industry study showed that the cost testing requirement of S. 863 was enormous. One estimate was that it might be in excess of $6.5 billion, and would divert scarce medical and scientific resources from investigations having higher priority,[20] a diversion which is troubling to FDA.

FDA itself wanted to duck the mandatory submission of premarket testing data imposed by the Eagleton bill. "I have this recurring nightmare," Commissioner Schmidt is quoted as saying, "in which our building across from HEW, which is a fairly large building, being totally inundated with small files of cosmetics. . . ."[21] Moreover, the mere filing of data would impose some responsibility on FDA to take action, a major task the Agency is not in a position to perform. FDA thus opposed as "unmanageable and unnecessary"—and the equivalent of a clearance system—the suggestion that FDA be given 90 days to veto safety data filed with it. Nor was FDA happy about the notion of specifying in fixed legislation categories of tests.

C. Premarketing "Substantiation"

So, in a surprise countermove, FDA submitted a proposed alternative bill on February 18, 1974, designated as S. 3012, the Food,

[19] "Certain types of risks are even more difficult to quantify than are benefits. The assessment of potential allergenicity and irritant action is difficult enough but to *secure evaluation of carcinogenicity, mutagenicity and teratogenicity is exceedingly complex and difficult.* Any attempt to establish from scratch, in a reasonable time period, the carcinogenic, mutagenic and teratogenic risk of the thousands of substances currently used in cosmetics is unrealistic. It is rational to ask if consumer protection necessitates this type of evaluation of all of the many substances which have been in use for years and have yielded no recognized evidence of such reactions." Irvin H. Blank, Ph.D., Associate Professor of Dermatology, Harvard Medical School, letter of February 11, 1974, attached to CTFA testimony on S. 863, February 21, 1974 (emphasis supplied).

[20] Arthur D. Little, Inc. *Report to the Legislative Planning Group of the CTFA*, February 15, 1974, pp. 1-2.

[21] As quoted in *F-D-C Reports*, Special Supplement, February 25, 1974, p. A8.

Drug and Cosmetic Amendments of 1974.[22] Commissioner Schmidt characterizes this bill as requiring "premarketing subtantiation." The term is not equated simply with premarket testing. It is, he said to the CTFA, the demonstration of safety by testing "if none has been done, reference to existing data if available, or seeking safety data from chemical suppliers."[23] FDA plans to develop guidelines to determine what tests are required.

The FDA preference for S. 3012 is easily understandable. For, as an amendment to Section 702(c) of the Federal Food, Drug, and Cosmetic Act, *Examination and Investigation (not* Section 704, the Factory Inspection provision), FDA would be granted broad authority—equivalent to that for "new drugs"—to require the *maintenance and inspection of whatever records* FDA decides should be required.

Cosmetic companies, as well as food, drug, and device manufacturers, would have to

(1) *"maintain* such records, *make* such reports, and *provide* such information as the Secretary may, by regulation, reasonably require . . . ."

(2) "permit the *inspection* of appropriate books, records, and papers relevant to determining" whether the company is complying with the Act.[24]

Subpoena power would be conferred on the Agency.[25]

What FDA would do with this sweeping and generalized mandate is clear. The "record keeping" language would be read to require cosmetic makers to provide, Commissioner Schmidt has said, a *"current listing of all products, formulation data, customer complaint files, product test results, and data to substantiate safety as well as labeling claims substantiation."*[26] In short, substantiation not only of safety but also of efficacy—adequate by as yet undefined standards—would be demanded.

The "Factory Inspection" Section 704, would also be amended to authorize examination of "quality control records (including all records relating to composition, processing, product claims, and complaints or adverse reactions)."[27]

A few questions immediately emerge, and doubtless many others will, when hearings on S. 3012 are held before subcommittees of the Senate Commerce Committee. It is debatable, in my view, whether the "record keeping" language can be properly read to require not only the disclosure of information on hand but also the conduct of

[22] 93rd Congress, 2nd Session (1974).

[23] As quoted in *F-D-C Reports,* March 4, 1974, p. B3.

[24] S. 3012, 93rd Congress, 2nd Session § 123 (emphasis added).

[25] *Id.*, § 124.

[26] As quoted in *F-D-C Reports,* March 4, 1974, p. B2.

[27] S. 3012, 93rd Congress, 2nd Session § 121 (1974).

prescribed tests. The language is vague and confers almost unlimited authority on FDA to impose new requirements.

Second, it is not clear how the additional authority to be conferred by Sec. 702(c) would relate to Sec. 704, the factory inspection provision, nor how FDA would enforce it. Would FDA proceed against a recalcitrant firm under its new subpoena powers (proposed new Sec. 702(f))? Or under its newly proposed inspection authority to demand "quality control records"? Would FDA possibly construe the failure to "maintain" or "provide" requested information on safety or efficacy as a case of adulteration or misbranding sufficient to warrant detention (under newly proposed Sec. 304(g)) or seizure? The Agency has already announced the proposition—though the legal underpinnings are shaky—that any ingredient or product whose safety is not substantiated prior to marketing may be deemed to be adulterated, and in any event will be deemed to be "misbranded" unless it contains a label warning stating that safety has not been determined.[28]

There are obviously a myriad of legal problems which need to be explored or defined.

D. OTC Monograph

The last volley in the FDA arsenal was fired at the CTFA convention, where the Commissioner is reported to have "focused" on a suggestion by his Deputy Commissioner for Medical Affairs, Dr. Novitch, that the monograph system for over-the-counter (OTC) drugs should be applied to cosmetics.

As you all know, cosmetic ingredients appearing in drug-type products, such as anti-dandruff shampoos, sunscreen agents, feminine hygiene sprays and the like, are already under the OTC drug review. Under the cosmetic monograph system, Dr. Novitch said, FDA would list ingredients "shown by adequate studies to be safe for various categories of cosmetic use," subject to labeling statement required for a particular type of product. Dr. Novitch added:

"Any product that conforms to a cosmetic monograph . . . [could] be regarded as having been made of individual ingredients adequately substantiated for safety. Basic sensitivity tests might also be needed regardless of formulation, and other tests might also be required for certain types of final formulations—*e.g.*, eye irritation studies."[29]

---

[28] Proposed § 176.10, CCH F. D. Cosm. L. Rep. [1970-73 Transfer Binder] ¶ 40,855. The theory stated in the Preamble to the Proposed Regulation on Aerosolized Products, requiring a warning against intentional inhalation, is that the product would be misbranded under Sec. 201(n) for "failure to reveal material facts with respect to consequences which may result from use of the article." CCH F. D. Cosm. L. Rep. [1970-73 Transfer Binder] ¶ 40,854 at 42,222.

[29] As quoted in *F-D-C Reports*, March 4, 1974, p. A5.

A product with an ingredient falling outside the monograph, Dr. Novitch said, would be required to show safety by "independent means."[30]

What the legal framework will be for the cosmetic monograph system, and the relationship it will have to any premarketing "substantiation" legislation, has not been disclosed.

How all these proposals—legislative and administrative—will work out is anyone's guess.

It may well be that nothing will happen until the "product experience" reporting program under Part 174 gets underway, the degree of industry participation is measured, and the hard evidence required to appraise possible problems is collected.

Under Part 174, a participating firm can report, on a semi-annual basis, all claims of alleged bodily injury or, as an alternative, only those determined not to be "unfounded or spurious" when evaluated by a screening procedure filed with FDA.[31] The screening procedure is subject to FDA "audit" to ensure—in the words of the regulation—that the "procedure is consistently being applied" and that it is "not disregarding reportable information."[32] "Unusual reportable experiences"—those of a kind, severity and frequency which differ "significantly" from previous or normal reported experiences[33]—should be filed within 15 days of receipt.

CTFA has now issued a suggested screening program for its members. When a "consumer communication" is received, a firm can determine whether on its face it is "spurious" or "reportable." If there is insufficient information for that determination, the consumer should be contacted. If there is a response, the firm may deem the experience "reportable" whether or not a doctor was seen, or may decide further information is needed before the final evaluation of its reportability is made.[34]

FDA will thus collect a wealth of information as to incidence, causes and severity if the cosmetics industry takes part in this im-

---

[30] *Id.*

[31] 21 C. F. R. § 174.1(d), 38 *Fed. Reg.* 28916 (1973).

[32] 21 C. F. R. § 174.1(c), 38 *Fed. Reg.* 28916 (1973).

[33] 21 C. F. R. § 174.1(e), 38 *Fed. Reg.* 28916 (1973). In FDA's view, the definition would cover any experience requiring hospitalization, such as "a serious eye injury (requiring medical attention) when the product is used according to label directions . . . ." It would also cover certain types of misuse, such as "aerosol 'sniffing deaths' and accidental injuries due to the flammability of a product . . . ." Wenninger, "Voluntary Cosmetic Product Experience Reporting," *29 Food, Drug, Cosmetic Law Journal* 88, 91, 1974.

[34] Voluntary Reporting of Cosmetic Product Experience—*CTFA Guideline for Product Experience Screening Procedure* (1974), p. 5.

portant voluntary program. The issue of greatest concern at the moment, aside from determining the meaning of "audit," is that of the confidentiality of the reports.

Freedom of Information Regulations

FDA's response to this concern appears in Sec. 174.8: the "rules applicable to public disclosure of information by the Food and Drug Administration"[35]—the so-called Freedom of Information (FOI) regulations—are to govern. Under proposed Sec. 4.26(f) of these regulations, disclosure is the rule of the day with specified exceptions.[36] The name of both the complainant and the reporter will be deleted from a product experience report, or a "compilation"—whatever that is—before it is made public. Two other portions of the reporting program will be kept confidential on request—the names of the manufacturer and product brand. Other parts will not be disclosed "if good cause is shown to justify confidentiality."[37] If a request for confidential treatment is denied, the submission can be withdrawn.

Two uncertain aspects may deter voluntary filings. The FOI regulations are still not in effect. While stated Agency policy is that "legitimate trade secrets or other confidential information" will not be disclosed,[38] there is no assurance as to the scope of protection that policy will accord information submitted at this time.

Additionally, we cannot predict what the scope of confidentiality will be when the FOI regulations become final—whether it will remain the same as proposed Sec. 4.26(f), be narrowed or, as is unlikely, be expanded.

My understanding is that FDA will not make the FOI regulations final at least until a decision has been handed down in *Morgan v. FDA*, pending since January, 1973, in the Court of Appeals for the District of Columbia Circuit.[39] At issue in *Morgan* is whether scientific studies conducted by a manufacturer in order to obtain an NDA for oral contraceptives constitute "trade secrets and commercial or financial information obtained from a person and privileged or confidential,"[40] and thus are exempt from disclosure under the Freedom

[35] 37 *Fed. Reg.* 9128 (1972).

[36] Proposed 21 C. F. R. 4.26(f), 37 *Fed. Reg.* at 9133 (1972).

[37] Proposed 21 C. F. R. 4.26(a), 37 *Fed. Reg.* at 9132 (1972).

[38] Preamble ¶ 5, Part 174, Voluntary Filing of Cosmetic Product Experiences, 38 *Fed. Reg.* 28915 (1973).

[39] No. 71-1709. [See "Addendum" below.]

[40] 5 U. S. C. § 552(b)(4).

of Information Act.[41] FDA is contending, and the District Court agreed, that clinical and toxicological research tests about safety and efficacy are confidential because they "contain valuable commercial information and trade secrets, including scientific methodology, processes and developments as well as confidential statistical data."[42]

Though the proposed FOI regulations treat NDA submissions and "adverse reaction" reports differently,[43] and the nature of the data in the two differs, it may be that the *Morgan* decision will shed light on the scope of confidentiality FDA will accord to *any* voluntary submission. Thus Sec. 4.26(f) may be modified in light of the decision and events of the past two years.

Conclusion

Never a shy Agency when it comes to asking for or asserting additional authority, FDA regards cosmetics in the low hazard category, requiring a cautious approach to additional regulation. Dr. Schmidt agrees that "we should not institute an elaborate, expensive system which over-regulates products which present marginal safety questions."[44] Advocates of an NDA-type clearance system believe it will provide near fail-safe protection to consumers. But, as the Commissioner himself remarked, "adequate testing and governmental regulation [cannot] eliminate all problems, particularly problems involving individual idiosyncratic allergic reactions."[45] A case in point is the Mennen-E incident in which, despite thorough premarket testing by Mennen and postcomplaint testing by FDA, the cause of the irritation could not be found.[46]

As a result of new regulations requiring label declaration of ingredients, consumers will be able to make a more informed judgment about some risks. And, for the first time, the "reportable experience" program will provide a reliable guide to the nature of any remaining problems and the need for additional regulation to deal with them.

Yet, Senators Kennedy and Eagleton are strongly of the view that this program should *now* be made mandatory. And FDA, despite its attitude on the priorities, has now taken the initiative with a bill more sweeping in its provisions than S. 863. The thrust certainly

---

[41] 5 U. S. C. § 552.

[42] Affidavit of Dr. Henry Simmons, filed in support of the Government's motion for summary judgment, *Morgan v. FDA*, No. 71-1709 (D. C. Cir.), App. 23. [See "Addendum."]

[43] Compare proposed § 130.32, 37 *Fed. Reg.* at 9135 (1972), with proposed § 4.26(f), 37 *Fed. Reg.* at 9133 (1972).

[44] As quoted in *F-D-C Reports*, Special Supplement, February 25, 1974, p. B4.

[45] *Id.*

[46] 36 *F-D-C Reports*, Special Supplement, February 25, 1974, p. A9-10.

seems to be in the direction of mandating cosmetics makers to develop and disclose broad and costly proof of the safety of their products, if FDA and industry can agree on testing requirements. It remains to be seen whether the bound-to-be-controversial S. 3012 is the proper vehicle to that end. **[The End]**

Addendum. The Court of Appeals decided the *Morgan* case on May 24, 1974, holding—on a procedural ground—that the NDA information there at issue was confidential and hence exempt from FDA disclosure under the Freedom of Information Act. CCH F. D. Cosm. L. Rep. ¶ 41,147 (D. C. Cir.) The precedential value of Morgan is unclear. The decision was prompted solely by plaintiff's failure to oppose Dr. Simmons' affidavit attesting to the confidential nature of the NDA submissions. The Court thus felt compelled to accept as true the facts in the affidavit and to affirm dismissal of plaintiff's action. It explicitly pointed out, however, that it was *not* deciding whether the Agency's contentions as to the confidentiality of NDA materials "are beyond dispute." Thus the extent to which voluntary submissions to FDA will be protected from disclosure is still unresolved.

STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION (Act of August 12, 1970: Section 3685, Title 39, United States Code)

1. Title of publication: Food Drug Cosmetic Law Journal. 2. Date of filing: October 1, 1974. 3. Frequency of issue: Monthly.

4. Location of known office of publication: 4025 W. Peterson Ave., Chicago, Cook, Illinois 60646.

5. Location of the headquarters or general business offices of the publishers: Chicago, Ill. 60646.

6. Names and addresses of publisher, editor, and managing editor: publisher: Commerce Clearing House, Inc., Chicago, Ill. 60646; editor: Allen E. Schechter, Chicago, Ill. 60646; managing editor: George H. Harris, Chicago, Ill. 60646.

7. Owner: Commerce Clearing House, Inc., Chicago, Illinois 60646. Names and addresses of stockholders owning or holding 1 percent or more of total amount of stock: Bull & Co., Winston Salem, N. C.; Carothers and Clark, Wilmington, Del.; Cede & Co., New York, New York; Eddy & Co., New York, New York; Pitt & Co., New York, New York; Reing & Co., New York, New York; C T Corporation System, New York, New York; The Corporation Trust Company (Delaware), New York, New York; The Millbrook Tribute Garden, Inc., Millbrook, New York; Justus L. Schlichting, Toms River, New Jersey; George T. Whalen, as Trustee under the will of Oakleigh Thorne, Millbrook, New York.

8. Known bondholders, mortgagees, and other security holders owning or holding 1 percent or more of total amount of bonds, mortgages or other securities: None.

9. For optional completion by publishers mailing at the regular rates: 39 U. S. C. 3626 provides in pertinent part: "No person who would have been entitled to mail matter under former section 4359 of this title shall mail such matter at the rates provided under this subsection unless he files annually with the Postal Service a written request for permission to mail matter at such rates." In accordance with the provisions of this statute, I hereby request permission to mail the publication named in Item 1 at the reduced postage rates presently authorized by 39 U. S. C. 3626. (Signed) Allen E. Schechter, editor.

10. For completion by nonprofit organizations authorized to mail at special rates: Not applicable.

11. Extent and nature of circulation:

11A. Total number copies printed (Net Press Run): Average number copies each issue during preceding 12 months: 1,462. Actual number of copies of single issue published nearest to filing date: 1,450. 11B. Paid circulation: 1. Sales through dealers and carriers, street vendors and counter sales: Average number copies each issue during preceding 12 months: None. Actual number of copies of single issue published nearest to filing date: None. 2. Mail subscriptions: Average number copies each issue during preceding 12 months: 1,046. Actual number of copies of single issue published nearest to filing date: 1,016. 11C. Total paid circulation: Average number copies each issue during preceding 12 months: 1,046. Actual number of copies of single issue published nearest to filing date: 1,016. 11D. Free distribution by mail, carrier or other means: 1. Samples, complimentary, and other free copies: Average number copies each issue during preceding 12 months: 66. Actual number of copies of single issue published nearest to filing date: 34. 2. Copies distributed to news agents, but not sold: Average number copies each issue during preceding 12 months: None. Actual number of copies of single issue published nearest to filing date: None. 11E. Total distribution (Sum of C and D): Average number copies each issue during preceding 12 months: 1,112. Actual number of copies of single issue published nearest to filing date: 1,050. 11F. Office use, left-over, unaccounted, spoiled after printing: Average number copies each issue during preceding 12 months: 350. Actual number of copies of single issue published nearest to filing date: 400. 11G. Total (Sum of E and F—should equal net press run shown in A): Average number copies each issue during preceding 12 months: 1,462. Actual number of copies of single issue published nearest to filing date: 1,450. I certify that the statements made by me above are correct and complete. (Signed) Allen E. Schechter.

The FDA Today: Critics, Congress and Consumerism

By ALEXANDER M. SCHMIDT

Dr. Schmidt Is Commissioner of the Food and Drug Administration. His Paper Was Presented Before the National Press Club in Washington, D. C. on October 29, 1974.

I HAVE SPENT A LOT OF TIME on speakers' platforms, and have listened carefully to introductions for many years. In general, introductions and the lack of response thereto are both valuable opportunities lost. They are routinely rather rote recitations of facts from an outdated curriculum vitae. Etiquette has them generally flattering, but innocuous, particularly for high officials. The main value of most introductions lies in their providing a covering noise for the few moments everyone shifts and shuffles to find a position comfortable enough to last the requisite time—in our case today, about 20 minutes.

Humorous Introductions

My favorite introduction of me was by Hans Hecht, who, before his death, was Chairman of Medicine at the University of Chicago, even if he didn't like administrators. Hans had trained me as a cardiovascular investigator, and deplored my career switch to medical administration. His total introduction of me to an audience once was: "And now we are going to hear from Mack Schmidt, who was a bright and promising young cardiologist, before his brains all fell out and he became Dean of Medicine at the University of Illinois."

My favorite story about introductions, and one of my favorite Washington-type stories, concerns an introduction once given by Chauncey DePew for President William Howard Taft. Chauncey DePew was in the Senate at the time, and Taft had just been elected President. DePew was, and remains, best known as an orator and after-dinner speaker; and he pulled out all his stops for the new President. In his introduction, he early hit on the use of the word

"pregnant;" and as he warmed to his task, he described Taft as being "pregnant with ideas," "pregnant with inspiration," "pregnant with potential," and on and on, ending with the call for a "pregnant message."

When he finally finished, Taft stood up, patted his ample girth, and replied: "If it's a boy, I'll call it 'Americus.' If it's a girl, I'll call it 'Columbia.' But if, as I suspect, it's just gas, then I'll call it Chauncey DePew."

When your invitation to me to appear here today became known in the FDA, Wallace Janssen, our Historian, thoughtfully informed me that to his knowledge, I am the first FDA Commissioner and only the second FDAer to be so honored. The first was Harvey W. Wiley, famous as a leader, scientist, and as the "Father of the pure Food and Drug Law," signed by Theodore Roosevelt in 1906.

I was quite envious as I read of Dr. Wiley's visit to the National Press Club. He moderated a debate between two members of the House of Representatives and two Senators, and imposed a strict time limit on each speaker. Nicholas Longworth, the Speaker of the House, was one of the debaters. During the course of his remarks he was interrupted by members of the Press Club with interjections—some pertinent, some impertinent. Longworth, finally exasperated, turned to Dr. Wiley with the plea, "Mr. Chairman, I hope you will not charge these interruptions to my time." Wiley replied, "Certainly I *will* charge the interruptions to your time. As a matter of fact, the interruptions are much the best part of your speech."

Somehow, this response, and Taft's, have an emotional appeal for me that is hard to explain. It may well have something to do with the quality of my own exchanges with Congress. A recent one went like this: I was trying to say, during a hearing, that in order to answer the questions being pressed, I would have to read my testimony as background. The waspish reply was, "Well, you can obviously testify to whatever you want, Mr. Commissioner. . . . If you want to sit here, I will turn this over to the staff . . . and I will come back and question you later on. . . ." Somehow, I seem not to have come off that one as well as Wiley. Perhaps it was the setting.

At the very least, the elegance of most public exchange has disappeared in the past 50 years. But I suppose the day of leisurely lunchtime debate is gone; and a pity it is, particularly if all that remains are the hurried and harsh messages, often received via the press (rather than in person) that one is subject to nowadays.

I don't know if you have debates here anymore; but if you do, I'll volunteer, especially if I get to select the Senators and Congressmen, and set the rules of the debate!

Medical Administrators

However, to get back to my introduction: you heard that I came here from the life of a medical educator, and thus it is perhaps understandable that I thought I might usefully share with you some of the things I've learned about my present life as a government regulator.

Since Medical School Deans often have a somewhat greater-than-normal need for loving regard, perhaps the hardest lesson for me to learn was that no one seems to love a regulator, even though we really do some very laudable things. For example, in a recent six-month period, we took action against defective dog food, hair spray, intrauterine contraceptive devices, canned mushrooms, motion sickness pills, chocolate Easter eggs and rubber condoms.

The dog food was laced with potentially lethal doses of lead; the mushrooms were contaminated with botulism organisms; the Easter eggs had salmonella. The IUD's were boring holes in the women wearing them, and the condoms already had holes in them. The hair spray was squirting vinyl chloride; and the motion sickness tablets contained almost five times as much active ingredient as the label said—enough to make one very dizzy and nauseated.

Now, all that sounds like good and necessary activity that would make us loved. At the very least, you'd think we'd be applauded. However, with each of those actions, someone thought we had acted too early, or too late; that we either had gone too far, or not far enough.

It took me some time to learn that no matter what we did or how we did it, criticism was sure to follow. Often, only one person would yell, but would find a receptive ear in Congress, or in the press, and off we'd go.

I think I've even learned a general principle: that criticism of the FDA is played in the press in direct proportion to the colorfulness of the language used by the critic, but bears no discernable relation to the validity or usefulness of the criticism.

Glossary of Adjectives

Another thing I've learned, and this might be of special interest to you men and women of letters, is that an FDA Commissioner has to become accustomed to a whole new vocabulary. I don't mean just the government lingo. I've started a glossary of adjectives most used to describe me or some action taken by FDA.

Last week, after one of Senator Proxmire's press releases, I even had to go look up a word in a dictionary. He accused me several times in the same release of "misfeasance." I was quite upset, until

I found this in my dictionary: "Misfeasance; from the French, mesfaisance, meaning 'the Senator doesn't agree with your decision.'"

The winner to date of the adjectival sweepstakes is the word "outrageous." In particular, consumer advocates are fond of the term. They said it was "outrageous" that we didn't act before we did against DES as a growth promotant in food animals. However, regulated industry finds it "outrageous" that we ask for so much data and take so long to approve a new drug application. And, not to be outdone, one Congressional critic recently found our plan to approve a new injectable contraceptive "outrageous *in the extreme.*"

Other popular terms are "captive," the reference being to FDA's supposed cozy relationship to regulated industry; "harassment," meaning the way we treat the Agency's employees; "flout," meaning the way we respond to the laws we're supposed to enforce, and "revolving door," meaning the way that key officials allegedly shuttle between FDA and the regulated industries.

I had thought I was getting rather thick-skinned about all this, but then a few weeks ago I testified before Senator Kennedy. The press was there in force and in reporting the event, one young commentator wrote that the entire FDA leadership made "jackasses out of themselves." I didn't let that throw me; I even kept my cool when the commentator wrote about my "monotone voice" and "plodding" speech delivery.

However, then, he went too far. He called me "beefy." I couldn't make up my mind whether to write a nasty letter or go on a diet.

Happily, my common sense prevailed against the first inclination and my wife reassured me on the second. In the best wifely fashion she told me that what the writer mistook for beefiness was really my broad shoulders.

Since then I've learned to rely even more on my wife's objectivity and good judgment—and to be more selective with my newspaper subscriptions.

I'm being facetious. Quite seriously, I think I have learned to live with both the frequency and harshness of the criticism. I regret both, though, not because of any tenderness on my part or because I think we shouldn't be criticized, but rather because so much of the criticism is so coarse and undiscerning as to render it often valueless. We need more of the kind of criticism that helps us to describe, define and meet appropriate standards. However, the constant top-of-the-voice carping that often fills the air dulls the public ear and thus the public's ability to recognize and respond to the truly critical issues involved. It is a matter of selection and balance. Valid crit-

icism points out the excellent, as well as the inadequate; I hope we can stimulate better criticism than we've recently received, and will honestly try to do so in ways I shall shortly relate.

Perhaps I've indicated more concern with this subject than I feel. The truth is, I've had an exceptionally long and pleasant honeymoon as commissioner. I shall always remember it with tender, loving memories.

FDA's Accomplishments

In fact, as far as commissioners go—and they've gone pretty fast in recent years—I've been lucky. I *do* think that during the past year we have done a number of significant, and even controversial things, doing them reasonably well, I believe, and suffering minimal damage in the process.

We approved a number of good and useful drugs, while at the same time we kept a number of not-so-good drugs off the market. We developed new procedures to lessen the cost, delay and duplication required to get new drugs approved. We announced the first results of a major review of the safety and effectiveness of several hundred thousand over-the-counter, or nonprescription, drugs.

We inventoried the entire canned mushroom market and, while we can't prove a negative, the fact is that nobody died from eating commercially canned mushrooms during the so-called "mushroom crisis."

We pushed ahead with a revolutionary program to change the food labels in this country so that consumers get more and better information about the nutritional quality and comparative value of the foods they select in the supermarket. Nutrition labeling is here to stay, and should have a positive overall effect on the efficient expenditure of household budgets for food.

Food Labeling Program

To be completely honest, however, I have to add that the food labeling program has been somewhat less than 100 per cent accepted. In fact, the vitamin-mineral labeling part of the program has caused more controversy and more letters to Congress than any recent event save Watergate. More than a million "outraged" (there's that word again!) citizens wrote their Congressmen and more than 250 "outraged" Congressmen sponsored legislative proposals to stop the regulations.

We're still working on that one. The courts have upheld both our basic authority to act and the general direction of our regulations. What we need now is a relatively short time to recast our regulations in line with the Court's direction and without Congressional action on what I fear may be highly emotional and unwise legislation. If

Congress will give us the time, I am certain that we will come up with regulations that will satisfy the Courts, the Congress, and our own mandate for consumer protection. Congress can easily wait to see our new regulations and still act if they think it necessary, as the effective date of any regulations has now been put off to July 1, 1975. We are thus not trying to "bamboozle" Congress, as feared by Congressman Hosmer, and we are not trying to take away individual's freedom of choice.

On that last point, I quite agree with the Englishman who said that everyone has a right to go to Hell in his own way. All we're trying to do is to post a few warning signs along the way.

One of the things I'm proudest of is that we've turned the Agency around in an emphatic response to the Freedom of Information Act. It wasn't too long ago that FDA routinely kept 80 to 90 per cent of its information secret, and released 10 to 20 per cent. The situation today is essentially reversed. FDA is among the leaders in government in spelling out positive and specific rules for operating a truly open agency. We are now putting the finishing touches on our final FOI regulations, which I predict will become a benchmark for all regulatory agencies.

Another thing I've learned has to do with the meaning of the word "pressure." To most people, "pressure" connotes all sorts of devious mechanisms employed by the robber barons and captains of industry to try to get their way with FDA. The term conjures up secret meetings with industry, and regulatory "deals" that favor industry over the public good. Well, I was Commissioner for more than a year and hadn't seen any of this happening, and I was beginning to worry that the industries didn't know who was boss around FDA. So for that—and a lot of better reasons—I decided to require that all key FDA officials list, every week, all their meetings with industry and others outside government. This "open calendar" has now been published for about a month, and so far, the only interesting thing I've discovered is that I have so few meetings with industry. With so many taking it for granted that industry is always pressuring FDA, it's sort of embarrassing to find out it isn't so.

However, quite seriously, I've thought a good deal about this business of pressure on FDA and I've learned a curious thing. It may be one of the most interesting things I've learned in my 16 months as Commissioner. To begin with, we all know that regulated industry frequently writes comments, seeks information, calls for hearings, files petitions, appeals our decisions and even takes us to court when we don't regulate as they think proper. That is

all "pressure," in a sense, but it is done according to well-known and public procedures, and is legitimately described as "due process."

However, the interesting thing I've learned is that when it comes to pure unadulterated and directly applied "pressure" on the FDA, the industry can't hold a candle to Congress, and that pressure is very one-sided and biased.

For example, in all of FDA's history, I am unable to find a single instance where a Congressional committee investigated the *failure* of FDA to approve a new drug. However, the times when hearings have been held to criticize our approval of new drugs have been so frequent that we aren't able to count them.

Perhaps the best recent example concerns the enzyme chymopapain, a drug used to alleviate herniated intervertebral discs. It's made the news several times because of its still experimental use on famous athletes.

Last year the prestigious American Academy of Orthopedic Surgeons criticized the FDA for not having yet approved the drug. The Academy passed a formal resolution demanding that we do so, on the basis of its proved safety and effectiveness.

This month, a well-known orthopedic surgeon got rave notices in the press when he used the forum of a Congressional hearing to blast FDA, in colorful and thus widely reported language, for considering approval of a dangerous drug that he said was nothing more than "purified meat tenderizer." The drug, of course, was chymopapain. Our approval, or even planned approval, of several other controversial drugs have resulted in critical Congressional hearings.

The message to FDA staff could not be clearer. Whenever a controversy over a new drug is resolved by its approval, the Agency and the individuals involved likely will be investigated. Whenever such a drug is disapproved, no inquiry will be made. The Congressional pressure for our *negative* action on new drug applications is, therefore, intense. It seems to be increasing, as everyone is becoming a self-acclaimed expert on carcinogenesis and drug testing.

Approval v. Disapproval

What I see as a seriously unbalanced and deleterious pressure can be remedied only by Congressional and public recognition that the *failure* to approve an important new drug can be as detrimental to the public health as the approval of a potentially bad drug. It's often forgotten—and sometimes conveniently so—that our responsibility to get good new drugs into medical practice is at least as im-

portant as our responsibility to keep worthless or dangerous drugs off the market.

Until perspective is brought to the legislative oversight function, the predominant pressure from Congress will obviously be for FDA to *disapprove* new drugs. This very well could be a negative and deterring influence on health care in this country. More and more, in the future, we will be evaluating potent new drugs with dangerous side effects and narrow therapeutic ranges, useful perhaps in a well-defined but small group of patients. We must be able to make such drugs available to those who need them, without each decision precipitating a crisis in public confidence. I think that part of the process necessary to this goal will be our defining more accurately than we now do what the basic controversies are about—what it is that our critics should be concerned about. For example, it is clear to me that a number of potentially toxic drugs are being held hostage because of the possibility of their being misused by physicians. Is that a good reason to withhold approval? Shouldn't problems of medical practice be solved by the medical profession, rather than by FDA fiat?

FDA admittedly has some real problems carrying out our drug approval process in the best possible way, but right now we are too often taking a bum rap. We need help in bringing before the public the real issues to be resolved. We could begin by always asking the question, when safety issues are raised, what is the degree of risk? Sometimes the scariest headlines have no justification on the basis of scientific estimates of risks involved. We really must be specific about probabilities, when we begin yelling about the risk of brain damage in children!

That gets us down to the nitty-gritty of most controversies swirling about FDA—benefit v. risk—in the foods that nourish us, the drugs that cure us and the cosmetics that serve our vanity. It's not always easy for everyone to understand this concept, or to accept it, and that's one of the main reasons we get more complaints than plaudits about our work.

Therapeutic Drugs

Perhaps the most misunderstood benefit-to-risk judgments that we in FDA make for society concern the safety and usefulness of the drugs we approve for human use. Safety of any kind, of course, is a relative rather than an absolute concept, in a world of probabilities. Nowhere is this more true than with therapeutic drugs. By their very definition, all drugs are toxic to the human body in some

dose, and all are capable of bad effects as well as good. The trick is to find the line between benefit and risk, and to approve only those drugs on the positive side of the equation. Some decisions are less difficult than others, but none is easy—and none is guaranteed to remain forever valid.

It takes no special sophistication to recognize that if a drug or other product poses an unusual or serious risk, then its benefits must be proportionately high and urgently required.

The complexity of benefit-to-risk decisions looms larger every day. In fact, the entire history of food and drug legislation is a reflection of society's growing sense of the uncertainties that go hand-in-hand with the benefits of scientific progress.

One of the most impressive lessons brought home to me in the past year or so is that science and government regulation can only go so far in making benefit-to-risk decisions for society. As scientists and as scientific regulators, we find facts, measure results, define probabilities and propose limits. Perhaps most important of all, our function is to quantify risk.

Beyond this, there are moral and ethical considerations with which society and its social institutions must contend. At some point, the amount of risk that society is willing to assume in order to achieve a given set of benefits becomes a matter for the public at large to decide, or, in their stead, Congress.

On these larger issues, the scientists and the regulators can only serve as educators and as expert witnesses to society as a whole. I might add that on these larger issues, the role of education is shared by the press, no less than by scientists and regulators.

The Press

I think it obvious that press contribution to public education is not always achieved by the easy exploitation of disharmony or by a heavy emphasis on the sensational and colorful.

That's not a dig at the press—it's an exhortation! The public simply must have the benefit of even and fair reporting of both sides of benefit-risk issues, whether involving new table sweeteners, injectable contraceptives, or fortification of food.

Finally, as Commissioner of Food and Drugs, I've learned again something I've learned in every job I've held—that, to paraphrase a familiar saying, "Process is our most important product."

Agency Improvements

The recent Kennedy hearings into FDA operations have served to spotlight errors in our drug approval process. We already were

correcting most of the errors, and we will correct the others. We are totally reviewing and revising Agency procedures, and will publish them for comment before adopting them as regulations. Our revised procedures will make clear that we are determined that what we do, we will do openly, above board, and in such a way that we explain the bases of our actions. We will try to ensure that every question raised is dealt with fairly and honestly. If any issue of fact arises, or if we have not dealt fairly with valid criticism, we will stop and deal with the issues.

I have been criticized recently by friends inside and outside FDA for taking steps that, and I quote, "play into our critics hands," or "make me appear weak." One example that concerns some is my making public immediately materials relating to my investigation of the various charges made at the Kennedy hearings. Another example is the means we used to grant a limited approval of Depo Provera as an injectable contraceptive. In this instance, although we needn't have, we chose to lay out in a *Federal Register* statement our reasoning for doing what we did. Congressman Fountain raised a safety issue we had carefully considered, but he also raised a procedural question, in that we had not used our advisory committees in this instance to consider fully the issue of carcinogenicity. Mr. Fountain's letters to the Secretary and me were mature, muted, well-reasoned a balanced; I was happy to comply with his request to hold a hearing and stay the order.

It may be that in the end, Mr. Fountain and I will have a difference of opinion, but the issues will be clear and well-explored, the public will benefit from the debate, and our process will have been sound.

An Effective FDA

Public hearings, advisory committees, open calendars, open files, public discussion of issues, lengthy preambles to our orders, white papers: All these are time-consuming and expensive ways to do business, and they don't appeal to the autocrat. However, they are how we will proceed. I know that the openness of these procedures invites criticism, and I am prepared to accept that criticism. However, I hope it will be wise and informed criticism based on real issues. To have that hope fulfilled, I must provide to you and the Congress, and through you, to the public, the knowledge requisite to the task. This I pledge we will do. **[The End]**

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
RETURN POSTAGE GUARANTEED

SECOND CLASS POSTAGE P
AT CHICAGO, ILLINOIS AND
AT ADDITIONAL MAILING OFFICES

A COMMERCE CLEARING HOUSE PUBLICATION

BUSINESS REPLY MAIL

NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY–

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS of TOPICAL LAW REPORTS

4020 W. GLENLAKE AVE.

CHICAGO, ILL. 60646

ORDER
CARD

MAIL TODAY!

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.