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

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The Food and Drug Administration and the Economic Adulteration of Foods.—This article by *Wesley E. Forte,* a member of the Pennsylvania Bar, concerns the Federal Food and Drug Administration and its role in the field of the economic adulteration of foods. "The History of our Economic Adulteration Law," Part I of this multipart article, begins in this issue of the JOURNAL on page 533. The 1906 Food and Drugs Act and the Federal Food, Drug and Cosmetic Act of 1938, and their provisions dealing with the economic adulteration of foods, is discussed in this first part. The standards used to determine economic adulteration, the individual subsections of Section 402(b) of the Federal Food, Drug and Cosmetic Act and the conclusion are discussed in the subsequent parts. These will appear in the next issue of the JOURNAL.

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Administering That Ounce of Prevention: New Drugs and Nuclear Reactors

By DAVID F. CAVERS

This Article, Reprinted from the West Virginia Law Review (Vol. 68, Nos. 2 and 3, March and April 1966) with the Permission of West Virginia University School of Law and of the Author, Is a Slightly Revised Version of the Edward G. Donley Memorial Lectures, Delivered December 2 and 3, 1965, at the College of Law, West Virginia University. The First Part of This Article Appeared in the September Issue of the *Food Drug Cosmetic Law Journal*. Mr. Cavers Is Fessenden Professor of Law, Harvard Law School.

MY FIRST LECTURE DEMONSTRATED how hard it is to administer the ounce of prevention in the case of new drugs, despite the fact that approval proceedings in the Food and Drug Administration (FDA) are secret and unencumbered by legal formalities, affording much room for the exercise of discretion by the FDA's scientific staff. Yet both the pharmaceutical industry and the medical profession are chafing at the paperwork and delays and complain that the fate of new drugs is at the mercy of the administrators. At the same time, some congressional and journalist champions of the public are sharply critical of the FDA and suspect that, behind the screen of secrecy, the bureaucrats are being soft on the drug industry.

Has the Atomic Energy Commission (AEC) escaped this crossfire in administering the ounce of prevention for nuclear reactors? Here we shall see a process marked by resort to public hearings, even where no one has challenged the administrative decision. This, however, was not always the case; the AEC began with a process almost as private as the FDA's is now. To understand the AEC's present problems, some background is essential.

The Control Plan for Nuclear Power

The nuclear power industry is unique in the history of regulatory law in that the regulatory law had to be enacted before the industry could be created. Man's mastery of nuclear fission as a source of energy was acquired in secret and remained under the cloak of the military until 1946. Then the McMahon Act created the Commission assuring civilian control of the atom, albeit with some military strings. The 1946 Act not only prescribed exclusive government ownership of fissionable materials but also left little room for private enterprise in their use.[1] Yet, in the early Fifties, the initiative of a pool of electric power, equipment and chemical firms, with AEC encouragement and cooperation, led to the belief that generating electric power from nuclear energy on an economic basis was more than a remote possibility.

The United States Congress responded to this group's call to emancipate the atom. It adopted the Atomic Energy Act of 1954,[2] an essentially new measure, as a framework for a nuclear industry. The federal government still kept exclusive title to fissionable material—the "special nuclear materials," U-235, U-233, plutonium, and materials enriched in any of those substances—but it provided for an elaborate scheme of licensing to enable industry to use these materials while minimizing the dangers that lack of constant vigilance in their use might create.

Perhaps I should testify at this point concerning the magnitude of these dangers and thereby prove the importance of prevention in the regulation of nuclear power as I sought to do in my first lecture with respect to new drugs. For nuclear reactors, the AEC has done my work for me. In 1956, it commissioned a study of the damage that might result from a runaway reactor, resolving every uncertainty in the most pessimistic manner possible.[3] The resulting hypothetical accident levied an exceedingly improbable toll but one that underlines the need for care. It killed 3,400 people, injured 43,000, and caused property damage of $7,000,000,000. The Congress recognized the improbability that injuries and damages would rise to such heights, but,

[1] For the legislative history of McMahon Act 60 Stat. 755 (1946), 42 U. S. C. §§ 1901-1819, and an analysis of its provisions, see Newman & Miller, *The Control of Atomic Energy* (1948).

[2] 68 Stat. 919, as amended, 42 U. S. C. §§ 2011-281 (1958), as amended 42 U. S. C. §§ 2014-296 (hereinafter cited as AEA).

[3] "Theoretical Possibilities and Consequences of Major Accidents in Large Nuclear Power Plants" (commonly referred to as "The Brookhaven Report"), 1 CCH ATOMIC ENERGY LAW REPORTER ¶ 4031 (1957).

nonetheless, in 1957 the Price-Anderson Amendments[4] to the Atomic Energy Act required every reactor operator to provide insurance which, in the case of large reactors, must go to the maximum amount the insurance industry can write, a sum that has risen recently from $60,000,000 to $74,000,000.[5] On top of this, Price-Anderson provided a governmental indemnity of half a billion dollars. Finally, the law has cut off claims for injuries above the $560,000,000 total. Last fall the Price-Anderson Act was renewed for ten years more without significant change.[6] Surely these facts relieve me from arguing the importance of prevention for nuclear power reactors.

Confronted by hazards of this order, Congress prescribed strict requirements for power and test reactors.[7] A company wishing to build a reactor had first to get a construction permit from the AEC and then, when its reactor and power plants were complete, to get an operating license. Moreover, the AEC was to determine that the licensee had satisfied the statutory standards of promoting "the common defense and security" and protecting "the health and safety of the public."

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[4] 71 Stat. 576 (1957 (codified as amended in scattered sections of 42 U. S. C.), as amended, 42 U. S. C. §§ 2014, 2210. For commentaries on the act, see *AEC study of the Price-Anderson Indemnity Act* (February 15, 1965) in Selected Materials on Atomic Energy Indemnity Legislation, Subcommittee on Legislation, Joint Committee on Atomic Energy, 89th Cong., 1st Sess. c. 1 (1965); Cavers, "Improving Financial Protection of the Public Against the Hazards of Nuclear Power," 77 *Harvard Law Review* 644 (1964).

[5] For the amendment to 10 C. F. R. § 140.11, increasing the insurance required to be carried for reactors having a rated capacity of 100,000 kwe or more to $74,000,000, see 30 *Fed. Reg.* 14779 (Nov. 29, 1965), 3 CCH ATOMIC ENERGY LAW REPORTER 20,800.

[6] P. L. 89-210, 89th Cong., 1st Sess. (1965). The principal change was to provide in AEA § 171.c. & d., 42 U. S. C. § 2210(c) & (d), for the reduction in the amount of the government indemnity as the amount of the private insurance available increases. Thus the effect of the increase in the latter from $60 to $74 million will be to reduce the indemnity to $486,000,000. In reporting the bill, the Joint Committee on Atomic Energy (JCAE) disclosed its intention to devote further study to such problems as the basis of liability and the statute of limitations. See H. R. REP. No. 883, 89th Cong., 1st Sess. 13 (1965).

[7] Financial protection is required not merely for reactors but for any other "utilization or production facility" required to be licensed under § 103 or § 104. AEA § 170.a., 42 U. S. C. § 2210(a) (1958). The AEC has, for example, brought within the category a spent fuel processing plant. See In the Matter of Nuclear Fuel Serv., Inc. & New York State Atomic Research & Dev. Authority, Docket No. 50-201, 2 CCH ATOMIC ENERGY LAW REPORTER ¶ 11,244 (1963). For a counterpart to the Brookhaven Report, cited at footnote 3, see Guthrie & Nichols, "Theoretical Possibilities and Consequences of Major Accidents in U^{233} and Pu^{239} Fuel Fabrication and Radioisotope Processing Plants" (Oak Ridge Nat'l Lab. 1964).

The AEC interested certain industrial companies and electric utilities in pioneerng power reactors. It set up a division within the Commission staff to pass on permit applications; it adopted regulations[8] governing its licensing process and created the Advisory Committee on Reactor Safeguards, a fifteen-man part-time body of distinguished experts to review license applications—a body embodying the "best man" principle of decision-making noted in my first lecture. Though a public filing of the application was required, no public hearing was called for until the AEC had published a notice of its decision to issue a permit or a license. 30 days were then allowed for any "affected person" to request the hearing for which the statute provided.

The Control Plan Challenged: The PRDC Case

Plainly this plan would minimize resort to hearings. The application alone would give a protestant little chance to identify possible grounds of objection to the permit.[9] However, the plan was not leakproof. In 1956 the Power Reactor Development Corporation (PRDC) applied for a construction permit for a fast-breeder reactor to be built 30 miles from Detroit on the Lake Erie shore. The fast-breeder concept was very advanced; only one experimental reactor of that type had been built. A breeder reactor has the virtue of being able to produce more fissionable material than it consumes. It would create more fissionable atoms of plutonium in U-238, the relatively plentiful isotope of uranium, than it would consume atoms of the relatively rare fissionable isotope, U-235.[10]

PRDC was the offspring of a group of major utilities and equipment makers. Its moving spirit was the Detroit Edison Company, the prospective purchaser of the power. Unfortunately for the project, the Advisory Committee on Reactor Safeguards (ACRS) was not wholly convinced of its safety. The ACRS communicated its doubts to the AEC, but these were overridden. The atomic industry was then

[8] See AEC, Licensing of Production and Utilization Facilities, 10 C. F. R. c. 1, pt. 50, 3 CCH ATOMIC ENERGY LAW REPORTER ¶ 14,543.

[9] The evaluation of an application by the AEC staff and by the Advisory Committee is a protracted proceeding, requiring expertise which even now is possessed by relatively few and involving frequent contacts with the applicant's staff.

[10] "In a reactor utilizing plutonium fuel . . . , one of the neutrons from each plutonium fission would sustain the chain reaction and most of the remainder (1.9 on the average) presumably could be captured by U-238 to produce new plutonium atoms." Charpie, "The Geneva Conference" in *Atomic Power* 53, 56 (Scientific American ed. 1955). In the fast-breeder reactor, the speed of the neutrons released by fission remains fast, not being reduced by collision with a "moderator," for example, graphite, used in the more usual "thermal" reactors.

passing through one of its periodic spells of euphoria, and to its more enthusiastic members the ACRS experts doubtless seemed hypochondriacs. The construction permit was issued.

Then, as I have intimated, came a leak. Just before the 30-day period was to expire, the United Auto Workers (UAW), together with certain other Detroit unions, having learned of ACRS's misgivings, intervened in the proceeding, and demanded a hearing.[11] The AEC recognized the unions as "affected persons." Their members' lives, homes and livelihoods would be jeopardized if the vast quantity of highly radioactive material the reactor would accumulate were released over the countryside and, depending on air currents, over Detroit itself.

Thus began an epic battle. The intervenors saw as the Achilles' heel in the Commission's case the fact that, when it acted, much relevant information of importance to safety was still to be supplied by the applicant. This is a problem that besets the licensing of reactors. In a developing art, to require the detailed design of a complex machine to be completed before its construction could begin would stretch out the interval between the venture's start and its completion. The company wanted to provide enough information to sustain a provisional construction permit. As the reactor's design and construction proceeded, it would fill in the missing parts. When the time came to issue the operating license, the Commission could then make the definitive findings required of it.

The intervenors insisted that this sequence defeated the law's purpose in requiring a construction permit. As they saw it, this was to prevent the AEC from being faced by a *fait accompli* in the form of a completed reactor into which millions of dollars had been sunk, perhaps with staff encouragement and approval and conceivably with AEC financial aid.

The upshot of the intervention was a protracted hearing before an examiner, protracted deliberations in the Commission which stuck

[11] For the series of administrative actions thereby initiated (together with the subsequent judicial opinions), see 2 CCH ATOMIC ENERGY LAW REPORTER ¶ 11,201. The JCAE insisted on disclosure of the ACRS report on the PRDC application to the AEC. Senator Clinton Anderson, then JCAE chairman, refused to accept it on an "administratively confidential" basis, as AEC Chairman Strauss requested. The AEC released the report three months later, Chairman Strauss conceding that his effort to preserve secrecy was a "mistake." For their correspondence, related statements and the ACRS report, see JCAE Staff, 85th CONG., 1st SESS., A Study of AEC-Procedures and Organization in the Licensing of Reactor Facilities app. 6, 7, 8 (Jt. Comm. Print 1957).

to its guns,[12] and an appeal to the Court of Appeals of the District of Columbia which by a two to one vote set aside the Commission's order.[13] Then came review in the Supreme Court of the United States. In June 1961, five and a half years after PRDC applied to the Commission, the Supreme Court reversed the Court of Appeals and upheld the AEC's view that it could "defer a definitive safety finding until operation is actually licensed."[14] The Court held both statute and regulations were satisfied by the Commission's finding that there "was reasonable assurance in the record, for the purposes of this provisional construction permit, that a utilization facility of the general type proposed . . . can be constructed and operated at the location proposed without undue risk to the health and safety of the public."[15]

Since the review did not stay construction, the reactor was nearing completion when the Supreme Court spoke. Yet the fruits of the legal victory are still to be enjoyed. The PRDC's creation, the Enrico Fermi Reactor, experienced repeated technological setbacks. The pursuit of an operating license had to proceed by gradual stages. A provisional license to operate at low power was granted in May, 1963. Only last summer, more than four years after the Supreme Court had cleared the way, the AEC was holding hearings prior to licensing full-power operation. The UAW, though still technically a contestant, had withdrawn from active participation. The license was granted only after the date of these lectures.[16]

The First Revision of the Licensing Process

The PRDC may have produced the largest white elephant in the history of American technology,[17] but it was the stimulus to the

[12] For the AEC proceedings, see In the Matter of Power Reactor Dev. Co., 1 AEC Rep. 1, 9, 10 (1956), 16, 18 (1957), 65 (1958), 128 (1959). The intervenors offered no expert witnesses of their own, relying instead on cross-examination. Expert witnesses exchanged their testimony in writing in advance of the hearing, a tactic calculated to further understanding, perhaps consensus. It has become the regular practice in facility licensing proceedings, and provision is made for it in AEC Rules of Practice, 10 C. F. R. § 2.743(b).

[13] *International Union of Elec. Workers v. United States,* 280 F. 2d 645 (D. C. Cir. 1960).

[14] *Power Reactor Dev. Co. v. International Union of Elec. Workers,* 367 U. S. 396, 407 (1961).

[15] See footnote 14 at 403.

[16] A decision directing the issuance of an operating license was reached by an Atomic Safety and Licensing Board Dec. 7, 1965 and became effective 45 days thereafter. 3 CCH ATOMIC ENERGY LAW REPORTER 17,225-92. The withdrawal of the intervening unions occurred in hearings for the issuance of a provisional (low-power) operating license after the Board had denied their motion for a postponement following the report of a leak and a sodium-water reaction in a PRDC steam generator. See 3 CCH ATOMIC ENERGY LAW REPORTER at 17,225-81.

[17] PRDC believes that, "the most useful . . . role of the Fermil reactor will be to irradiate different types of

(Footnote continued on next page.)

first of a series of reexaminations of the AEC's reactor licensing process.[18] The Congress responded to the revelation that the AEC had concealed scientific doubts as to the adequacy of its safety findings by amending the Act.[19] The Commission was required, before reaching its decisions to give 30 days' notice and to hold a hearing on every application for a construction permit or license for a power or test reactor. Moreover, ACRS review of each application for a permit or license was made mandatory and the ACRS given statutory status. Its report was required to be public "except to the extent that security classification"—long the bugbear of nuclear progress—"prevents disclosure." Secrecy was to come virtually to an end. The application, including the preliminary hazards summary report, would be put on public file, hopefully to be joined there by the staff's hazards analysis. Public hearings were to be the rule, contest or no contest.

Here, one might suppose, was a scheme that should escape criticism. Both the applicant and the public were assured of open hearings. Alas, the Congress's preventive medicine may have been good, but the dosage soon proved excessive.

Chastened by criticism of its handling of PRDC, the AEC was determined that its new procedure should be above legal reproach. Once an application had been noticed for hearing, the Commission separated the hazards evaluation staff from all contact with the rest of the agency, and, when a licensing case reached it for decision, even the Commission itself refrained from consulting with its own experts who had handled the application.[20] Moreover, the AEC interpreted

(Footnote 17 continued.)
fuel . . . to obtain information for future fast reactors," rather than to generate electric power. See 3 CCH ATOMIC ENERGY LAW REPORTER at 17,225-03. How far the reactor exceeded the cost of $44,020,000 projected in 1958, 1 AEC Rep. 80, is not disclosed; plainly the factor of interest during construction and test operation must have gone far beyond original estimates.

[18] Consultants to the JCAE staff in the first of these were two law professors, J. F. Davison of George Washington University and J. G. Palfrey of Columbia University, the latter now an AEC commissioner. See JCAE Staff, cited at footnote 11, at v.

[19] 71 Stat. 579 (1957), 42 U. S. C. §§ 2039, 2232(b), 2239(a) (1958), amending AEA §§ 29, 182.b., 189.a.

[20] The "separated staff" (the Division of Licensing and Regulation, the Division of Compliance, counsel for those divisions, and other portions of the AEC staff aiding in the staff's presentation at the hearing) was denied access to the hearing examiner and to the Commission except on the public record. See 1 JCAE Staff, 87th Cong., 1st Sess., Improving the AEC Regulatory Process 18, 58 (Jt. Comm. Print 1961). The regulation embodying this rule, 10 C. F. R. § 2.734, as late as 1962, excepted "initial licensing," admittedly an error derived from the same exception in § 5 of the Administrative Procedure Act. See Cavers, "Administrative Decisionmaking in Nuclear Facilities Licensing," 110 *University of Pennsylvania Law Review* 330, 341 n. 44 (1963).

the hearing requirement to apply to every proposed amendment to the construction permit during the years that elapsed between the initial hearing and the operating license stage. The Commission also thrust on the ACRS the burden of passing on each one of these amendments before hearing.[21]

An AEC hearing was no informal business but the solemn reading of prepared texts to a hearing examiner, a lawyer whose task it was to make up a record, complete with findings, to be sent up to the Commission. Since the perfection of the reactor's design during construction led to a long series of amendments, frustrating delays were inevitable.[22] Professor Kenneth Culp Davis, the eminent authority on administrative law who was once a member of the West Virginia law faculty, aptly criticized the procedure as suffering from "dueprocessitis."[23]

To make matters worse, the hearing process was essentially meaningless.[24] In the uncontested case, the real decision was made before any hearing by the AEC's staff with the concurrence of the ACRS. If an adverse view of a proposed design change were taken by either body, the reactor applicant had no more incentive to contest this in a hearing than a pharmaceutical house would have reason to contest a finding of failure to provide the FDA's new drug staff with enough data. The company could afford neither the delay in construction nor the risk of adverse publicity that an open contest would create. Ordinarily it would be cheaper to design around the AEC's and the ACRS's objections if, that is, these bodies could not be talked out of their positions in the privacy of pre-hearing "negotiations."

The Role of "Negotiations" in the Licensing Process

I am repeating a term that in my first lecture I borrowed from a scientist who used it to describe informal discussions between drug approval applicants and the FDA staff, but it also has been used to

[21] This resulted from a literal interpretation of the 1957 amendment, combined with the difficulty of making the selection of questions for ACRS consideration. See 1 JCAE Staff Study, cited at footnote 20, at 3, 49, 52.

[22] For summarized chronologies of important permit and license applications, see 1 JCAE Staff Study pt. III; for the chronologies themselves, see 2 JCAE Staff Study 173-304.

[23] See Davis, "Dueprocessitis in the Atomic Energy Commission," 47 *A. B. A. J.* 782 (1961).

[24] See Cavers, cited at footnote 20, at 342-48; 1 JCAE Staff Study, cited at footnote 20, at 50-52. For a detailed description and critique of the licensing process at the hearing stage, see Berman & Hydeman, *The Atomic Energy Commission and Regulating Nuclear Facilities* (1961), reprinted in part in 2 JCAE Staff Study, cited at footnote 20, at 477-89.

describe pre-hearing exchanges concerning construction permits.[25] It may have a sinister sound. It is important enough to deserve analysis. How do a bureaucrat and an industry applicant negotiate? What does each have to offer to the other?

The official, though low in the agency's hierarchy, has the power to hold up the approval or the permit. His view may not ultimately prevail but, by sticking to it, he can at the least protract the proceedings. His position may go only to the need for more data or to involve some change in label claims or warnings or an alteration in the design of some reactor component. The applicant wants him to drop the point or to accept modifications that would render it less objectionable—or less expensive. What can the applicant do to move the bureaucrat?

Perhaps the applicant's most important lever is a shared purpose: presumably in most cases both parties will want to see the application go through, the drug made available to those who need it, the reactor put into operation. Hence, the applicant's experts and counsel may seek subtly to make the staff experts feel like obstructionists, magnifying difficulties that more practical men consider well within a reasonable zone of tolerance. The official who yields to such an argument (which, of course, may be thoroughly sound) can see himself as a broad-gauged, forward-looking man, distinct from the stuffy bureaucratic stereotype. On the other hand, if he holds his ground, the industry negotiators can regretfully intimate that they will have to go higher up, perhaps, if the case is serious, beyond the walls of the agency itself. No doubt the most potent threat would be to withdraw the application altogether and thus place on the official the onus of having stultified progress in science or technology.

The staff man's position would be easier if he could always be sure of his ground, but almost always, of course, the matter at issue is one of degree, of judgment, and rational doubt will be hard to suppress. Moreover, the choice will rarely be between intransigence and surrender. The label claim can be modified, but not as much as was first insisted on; the extra reactor study can be undertaken but on a smaller scale; the design altered but less importantly. Compromises like these are inevitable, and probably are very often in the public interest. Unfortunately, if the staff is weak or its morale low, the

[25] I have seen the term used in this context in print, but, alas, the reference now eludes me. None of the highly knowledgeable persons who have read my manuscript have taken exception to my use of the term; indeed, one gave me some elaboration of the negotiating process.

staff may yield more than the public interest would allow. This risk[26] is one of the main reasons why a need may be felt for an open review of administrative decision-making before the process is completed.

An effective review procedure in an uncontested case is not easily contrived. Suppose, as has almost always been true, the applicant for a construction permit and AEC's hazards evaluation staff are in agreement. The lawyer who sits as hearing examiner will listen to the harmonious testimony of applicant and staff witnesses. What chance is there then that he will penetrate the obscurities of the highly technical evidence and lay bare defects in the reactor's design? The few times in permit hearings that the examiner questioned scientific findings or asked for more evidence, his initiative was greeted with dismay. When, in due course, the examiner produces a set of findings, these are passed on to the Commission for informal review. Though scientists have usually been included among its members, they can scarcely be expected to probe the record of every hearing and to take issue now and then with its staff's conclusions. In actuality, the principal burden of review at the Commission level appears at one time to have fallen on the lawyer assigned to aid the Commissioners in these matters.[27]

The Emergence of the Atomic Safety and Licensing Boards

By 1962, dissatisfaction with this licensing procedure reached the Joint Committee on Atomic Energy—the JCAE—which keeps watch over the AEC's administration for the Congress. It directed its staff to study the problem anew. William Mitchell, former AEC general counsel, and I served as consultants to the staff. The study's recommendations[28] were at variance with those of the AEC's own staff.[29] The latter contemplated little change. The study also rejected the more radical proposal advanced in a University of Michigan Law School study, calling for fission in the Commission itself, proposing a permanent new agency to make regulatory decisions unencumbered

[26] It is mitigated in AEC reactor licensing by the participation of the ACRS, a subcommittee of which will keep in close touch with the AEC staff as the review progresses. Both staff and subcommittee may therefore be involved in separate negotiating processes. Since they frequently meet with the applicant's staff together, a tendency to concession by one may be offset by inflexibility on the part of the other. In this process, the subcommittee is reinforced by the fact that its positions will be reviewed by the entire ACRS.

[27] See Cavers, cited at footnote 20, at 347.

[28] See 1 JCAE Staff Study, cited at footnote 20, at 66-75.

[29] See AEC, *Report on the Regulatory Program of the Atomic Energy Commission* in 2 JCAE Staff Study, cited at footnote 20, at 399-400, 413-20.

by the AEC's promotional obligations to the budding nuclear power industry.[30]

Looking at the AEC's licensing machinery from the vantage point of the JCAE, we felt that both its hazards evaluation staff and the ACRS had been doing good work and that they could do even better work if the staff did not have to hold hearings on every proposed amendment to a construction permit and if the ACRS could operate on a more selective basis. Relief from these burdens could be achieved rather simply by statutory change. The really difficult problems in the regulatory process emerged only as one looked ahead to the time when the volume of license applications had multiplied and when the busy members of the ACRS could no longer scrutinize every new reactor. Perhaps by then, too, the best of the AEC's hazards evaluation staff would have been wooed away by private employers. What further safeguard, if any, was needed against these contingencies?

Separation of the Commission into two bodies did not seem called for by the pressure of business then foreseeable. Moreover, some feared that a body whose only duty was to assure safety might grow so biased as to be unreasonably demanding. They saw the fact that the AEC's promotional duties clashed on occasion with its regulatory mission as a virtue, making for balance in its judgments. The hearing seemed to be the final line of defense, yet the lawyer-examiner could hardly be relied on to man that bastion alone.

Groping for a solution, the JCAE staff came up with a proposal to create an Atomic Safety and Licensing Board comprised of a hearing examiner or other lawyer and two "technically qualified" persons —engineers or scientists.[31] The presence of the latter would give assurance that the hearing would not be *pro forma,* that the case made by the applicant and by the AEC could be subjected to critical scrutiny. Legal and scientific techniques of inquiry and evaluation were to work in harness. The JCAE staff even proposed that decisions of the Atomic Safety and Licensing Board, as the new body was called, should not be subject to Commission review.[32] This the

[30] See Berman & Hydeman, cited at footnote 24, at 319-36, reprinted in 2 JCAE Staff Study, cited at footnote 20, at 545-57.

[31] See 1 JCAE Staff Study, cited at footnote 20, at 69-75. The proposal did not specify a lawyer, merely "a person knowledgeable in the conduct of administrative proceedings." 1 JCAE Staff Study at 69. Though obviously this criterion which the Congress adopted (substituting "qualified" for "knowledgeable"), points to members of the legal profession, the JCAE report on the bill expressly noted that non-lawyers might be used. See SEN. REP. No. 1677, 87th Cong., 2d Sess. 5 (1962).

[32] See 1 JCAE Staff Study, cited at footnote 20, at 70. The Commission would retain rule-making authority.

Congress rejected in adopting the board idea.[33] Moreover, Congress authorized the Commission to establish *ad hoc* boards to be drawn from a panel to be appointed by it,[34] and this is the plan the AEC has actually followed.[35] Congress also relieved the AEC and ACRS of their mandatory jurisdiction over an applicant's amendments and left the holding of public hearings at the operating license stage to the AEC's discretion.[36] Finally, in reporting the amendments, the JCAE encouraged informality in licensing hearings "to the maximum extent permitted by the Administrative Procedure Act."[37]

Professor Davis, I should report, did not view these proposals with favor. Absent a contest, he saw no reason for a hearing whatever; he proposed instead that a public proceeding in the nature of a press conference be held in the vicinage of a proposed reactor. There AEC officials could defend their decision and answer the questions of interested citizens.[38] This position, which bespoke great confidence in the long-term adequacy of unchecked AEC staff decisions,[39] has since been adopted in one respect: hearings before the Atomic Safety and Licensing Boards are now held near to the proposed reactor sites.

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[33] The 1962 amendments provided, among other things, for the creation by the Commission of "one or more atomic safety and licensing boards," composed as had been proposed, "to conduct such hearings as the Commission may direct and make such intermediate or final decisions as the Commission may authorize with respect to the granting, suspending, revoking or amending of any license . . . ." AEA § 191.a., 76 Stat. 409, 42 U. S. C. § 2241(a).

[34] See footnote 33.

[35] The Commission has recently enlarged the panel to 18 members and proposes to adopt a suggestion, recently advanced in the report of a Review Panel, below at footnote 58, that an alternate technical member be appointed to each board. See AEC, Notice of Proposed Rule Making, Amendment to 10 C. F. R. § 2.721(b), 31 Fed. Reg. 832, 833 (January 21, 1966).

[36] For the amendment affecting ACRS review, see AEA § 182.b., as amended, 76 Stat. 409, 42 U. S. C. § 2232(b); for the amendments relating to hearings, see AEA § 189.a., as amended, 76 Stat. 409, 42 U. S. C. § 2239(a).

[37] See SEN. REP. No. 1677, 87th Cong., 2d Sess. 6 (1962). In a proposed AEC Statement of General Policy, informality in uncontested hearings is invited. See AEC, Notice of Proposed Rule Making, app. A, § 111(6), cited at footnote 35, at 835.

[38] See JCAE Staff, 87th Cong., 1st Sess., Views and Comments on Improving the AEC Regulatory Process 25 (Jt. Comm. Print 1961). For an exchange of views on the relative merits of Professor Davis' plan and the JCAE staff proposals, see Cavers, cited at footnote 20; Davis, "Nuclear Facilities Licensing: Another View," 110 *University of Pennsylvania Law Review* 371 (1962); Cavers, "Nuclear Licensing Facilities: A Word More," 110 *University of Pennsylvania Law Review* 389 (1962).

[39] Of course, as long as the ACRS can continue an active surveillance of staff decisions, the latter do not go "unchecked." However, the assumption underlying proposals for procedural change has been that the ACRS would before long find it impossible to continue its case-by-case review.

Once more a new procedure seemed to have solved AEC's problem of how best to administer its ounce of prevention. The applicant still could work out its problems informally with the hazards evaluation staff and the expert members of the ACRS, getting the kind of high-level evaluation that the drug industry has been pining for. To be sure, unfavorable judgments by these two official bodies could not readily be opposed. Yet, if the issue were not dramatic enough to arouse public opposition to this public-relations-conscious industry, an applicant might try to persuade a Board that both staff and ACRS had erred.

As a means of assuring the public that a disinterested and competent body has not only scrutinized the AEC's staff work but is ready to listen to informal objections from persons lacking the preparation, standing or funds needed to intervene,[40] the Boards represent a marked improvement over hearing examiners. And whenever the intervention of an "affected person" gives rise to a contested proceeding, a Board's relative independence should increase public confidence in its decision.

New Troubles Arise: The Siting Problem

Unfortunately, the AEC's actual experience is again disappointing these satisfactions. A series of difficult cases has arisen. However, not all the difficulties can be laid at the door of the licensing process. Some grow out of siting problems where the issue is less the intrinsic safety of the reactor and more the suitability of its proposed location. Though scientific and technological data and opinions are essential to gauging the dimensions of a site's risk, the question whether a given risk is worth taking is one which deeply engages community values. The three cases which I shall report briefly below are atypical, but they cast a shadow into the future.

The first case, one that promised to provide a dramatic example of citizenry rising to oppose a nuclear reactor, began with the filing late in 1962 of an application by the Consolidated Edison Company of New York to construct a million kilowatt nuclear power plant in Ravenswood, across the East River from mid-Manhattan.[41] Not only

[40] In addition to providing for the intervention of persons adversely affected, the AEC's Rules of Practice permit "limited appearances," on due notice to the parties, by persons lacking standing or not wishing to assert their adverse interests formally. Such an appearance is limited to the making of "oral or written statements on the issues involved in the proceeding." See 10 C. F. R. § 2.731. The statements may, of course, raise questions.

[41] See "Nuclear Plant in New York City?," 9 *Forum Memo*, Dec. 1962, p. 11. Various facets of the problem posed by the Consolidated Edison proposal were surveyed for the Citizens' Committee on Radiation Information (a New York group) in Herber, *The Ravenswood Reactor* (undated).

was this the largest reactor ever proposed but the sites of other power reactors were all remote from populous communities. Distance affords a protection that the AEC has viewed as even more reliable than multiple engineered safeguards. Distance, however, adds to cost, and Consolidated Edison contended that it could design a reactor which, as H. C. Forbes, Chairman of the Board, put it, would be "absolutely safe."[42]

New York's reception to this proposal was preponderantly hostile. A motion was made in the City Council to exclude any reactor within the city limits, research reactors excepted.[43] Public concern began to build up. The AEC declared the subject of reactor-safety pre-empted by the federal government and denied New York City jurisdiction to bar an approved reactor.[44] The crisis was reaching a peak when Consolidated Edison abandoned its plan, asserting a sudden preference for bringing hydroelectric power from Labrador. Though this rendered the issue of jurisdiction moot, I cannot resist repeating a position I have previously asserted.[45] I believe the act pre-empts for the United States the power to determine a reactor's safety, but I do not see in that pre-emption any barrier to a city's deciding that, to protect the amenities of life, it wishes no such mechanism within its bounds, however safe it may be and however unreal may be the forebodings of its anxious citizenry. If Congress wants to take away that privilege, it should pay the political price of doing so explicitly.[46]

The next instance of active public opposition came when the Pacific Gas & Electric Company proposed to build a reactor of medium size at Bodega Head, a picturesque spot on the California coast

[42] *N. Y. Times,* May 21, 1963.

[43] New York City Council Majority Leader Treulich introduced a bill that would bar all reactors within the city limits, later amended to except research reactors. After a tumultuous hearing, Treulich indicated his intention to press his bill and predicted its passage. For reports of these developments, see 10 *Forum Memo,* May 1963, p. 10, July 1963, p. 8, and Aug. 1963, p. 28.

[44] Robert Lowenstein, director of AEC's Division of Licensing and Regulation, appeared at the hearing to assert exclusive federal authority. This position also was declared by AEC Chairman Seaborg in a letter to the president of the New York City Council. See 10 *Forum Memo,* July 1963, p. 9.

[45] See Cavers, "Legislative Readjustments in Federal and State Regulatory Powers over Atomic Energy," 46 *California Law Review* 22, 36 (1958); Cavers, "State Responsibility in the Regulation of Atomic Reactors," 50 *Kentucky Law Journal* 29, 50 (1961).

[46] Advocates of exclusive federal authority point to the possibility that restrictive state and municipal laws would cripple the development of nuclear power. If this fear ever began to be realized, doubtless the Congress would assert federal power—unless the Congress had come to share state and local anxieties.

north of San Francisco.[47] At first the opponents were conservationists who would have opposed a fossil-fuel power plant in that location with equal fervor. However, when their opposition on this score seemed unlikely to prevail, they turned to the site. This lay within a quarter mile of the great San Andreas fault, the line along which California earthquakes are most likely to occur. The views of geologists, especially seismologists, were sought. Did the fault lines extend into the site itself, was there a genuine risk of a shearing or shifting of rock so severe as to destroy the carefully engineered containment? The problem never reached an Atomic Safety and Licensing Board. The AEC staff reported adversely on the site though the ACRS had given its approval. Confronted by this division and a hostile public as well, the company withdrew its application.[48]

Today still another siting controversy is in process. The municipal power authority of Los Angeles, the Department of Water and Power (LADWP), wishes to build a large power reactor to add to its electric capacity without adding to the smog. The site is near a fault line, and intervenors allege an earthquake hazard. An Atomic Safety and Licensing Board is now trying not merely to assess the intrinsic safety of the reactor design but also to decide whether even a well-designed reactor at that location would create "an undue risk to the public health and safety," to quote the relevant standard in the AEC regulation.[49]

The site over which the controversy rages is Corral Canyon in the famous Malibu Beach area a little west of Los Angeles. Residents of the area, who include a number of the movie colony, have formed a citizens' group to intervene. An individual intervenor is an estate owner who would lose 200 of his acres to the project. His name is Hope, Bob Hope. A third intervenor is a land company whose acreage would either be taken or suffer a loss in value. In challenging the safety of a reactor built close to a fault line, the intervenors note the exposure of bathers who throng nearby beaches on weekends. They point to the many users of the coastal highway between the reactor site and the sea. The Los Angeles County Board

[47] For an account of this controversy by one of the opponents, see Hedgpeth, "Bodega Head — A Partisan View," 21 *Bull. Atomic Scientists* No. 3, p. 1 (1965).

[48] See the "Bodega Bay Debacle: Demolished by Hypothesis," 11 *Nuclear Industry*, November 1964, p. 3.

[49] See 10 C.F.R. § 50.35. To issue a provisional construction permit before all the technical information can be supplied, the Commission must be "satisfied that it has information sufficient to provide reasonable assurance that a facility of the general type proposed can be constructed and operated at the proposed location without undue risk to the health and safety of the public and that the omitted information will be supplied...."

of Supervisors voted unanimously to intervene after having reversed the county planning commission's grant of a zoning exception to the LADWP.[50]

The Board has met for hearings four times since March, 1965. Its concern led the Department to dig a great trench to expose possible fault lines in the rock beneath the site, but the resulting revelations are ambiguous. Seismologists who had testified for the intervenors before the digging remain uneasy. Senator Murphy has suggested the AEC reconsider. The AEC staff position remains unchanged though "subject to modification." Now proposed findings and briefs are scheduled for late April. Rather wistfully the Board asks that the briefs aid it in defining "undue risk."[51]

Evaluating Incomplete Reactor Designs for Safety

These three cases present sensational challenges to the reactor builder's art, but safety problems may be no less real though far less conspicuous. As reactors multiply, economic pressure to build them ever closer to centers of population will surely grow. So too will economic pressure to reduce the capital costs imposed by redundant safety devices and elaborately engineered systems of containment. Today it is urged that the safeguard of distance can be replaced by engineered safeguards; in time, some of these will be attacked as anachronistic relics of the primitive period of nuclear power. How well does AEC's present procedure seem to meet the needs of the trying period of transition that I foresee? Two cases point up a difficulty, one that first manifested itself in the PRDC case.

This difficulty springs from the need to avoid costly delays by issuing a provisional construction permit while the reactor design is far from complete. Two Atomic Safety and Licensing Boards have faced the perplexing problem of evaluating the safety of an incompletely designed reactor, and they have responded in different ways. In December, 1964, a Board reviewed the application of the Jersey Central Light & Power Co. to build and operate a very large boiling-water reactor on the northern New Jersey coast. The Board was willing to grant a provisional construction permit but only on condition that it retain jurisdiction and, within 180 days, receive more

[50] The interventions are reported in 12 *Nuclear Industry,* March 1965, p. 11. The zoning issue has been deferred until the permit issue has been resolved. LADWP does not regard itself as bound to obtain the exception. See 12 *Nuclear Industry,* March 1965, p. 12.

[51] For the Board's request, see 11 *Nuclear Industry,* October 1965, p. 9; for other recent developments in the proceeding, see 11 *Nuclear Industry,* November 1965, p. 20.

data on a rather formidable array of design features as to which "critically important (as regarding safety) design details" were still to be provided. The Board also set a 60-day time limit on submission for *in camera* review of the contract provisions between Jersey Central and General Electric, its turnkey contractor, relating to "their respective safety and design responsibilities."[52]

This position enabled the Board members to square their professional consciences with granting a provisional permit before they were satisfied that the reactor's design gave "reasonable assurance that" unresolved "safety questions will be satisfactorily resolved" by the completion date set for the facility. Their order created a *conditional* provisional permit, and, I need scarcely add, neither the AEC staff nor the applicant and its contractor liked the solution. They appealed to the Commission, contending that the features of the reactor's design for which the Board sought additional information were features which had not previously required specific approval until the operating license stage, and that further hearings were not needed unless, at the latter stage, when all the design options had been taken and the reactor built, a final hearing seemed desirable.

While this case was pending before the Commission, the same problem confronted another Board convened to pass on the application of the Niagara Mohawk Power Corporation to build near Oswego, New York, a boiling-water reactor of about the same size as Jersey Central's. Before this Board had acted, the Commission ruled that the Jersey Central Board had authority to extend its own life beyond its initial decision, though the Commission reserved the question whether the Board's conditions represented an abuse of discretion.[53]

In a thoughtful opinion devoted as much to its procedural predicament as to its findings of fact and conclusions, the Niagara Mohawk Board decided to order the granting of the provisional permit "with no special conditions requiring further . . . review by this Board." However, after noting that "all questions relating to operating safety, except for the suitability of the site . . . , remain for later administrative evaluation," the Board expressed "uneasiness over whether the proper purposes of a statutory hearing are adequately served by the . . . plan which leaves for future administrative action

[52] For the series of decisions and orders in Jersey Central Power & Light Co. Reactor, see 2 CCH ATOMIC ENERGY LAW REPORTER ¶ 11,249. For the order in the Board's initial decision, see 2 CCH ATOMIC ENERGY LAW REPORTER at 17,485.

[53] See 2 CCH ATOMIC ENERGY LAW REPORTER at 17,485-3 (February 18, 1965).

the making of judgments upon important safety questions which probably will not have been reviewed in a public forum."[54]

New Recommendations: The Staff Analysis Rises and the Hearing Declines

A month later the Commission absolved the Jersey Central Board of having abused its discretion[55] but noted that the staff, aided by a panel, had embarked upon still another procedural study.[56] The seven-man Regulatory Review Panel, comprised of industry and university experts chaired by Mr. Mitchell, reported in mid-July.[57] The Panel recommended that responsibility for reactor safety continue to be reposed in the AEC's regulatory staff, the ACRS, and the Atomic Safety and Licensing Boards. However, it was emphatic in declaring that the staff's responsibility should be primary. The prospect that the ACRS would be overburdened by mounting applications led the Panel to urge that the ACRS be relieved of routine reviews and devote itself to novel safety problems and basic questions. Voicing concern at the layering of safety reviews, the Panel would have the Atomic Safety and Licensing Board in any uncontested case hold a single hearing to determine "whether or not the . . . Staff has made a thorough and complete safety analysis supporting its conclusions. . . ."[58] The Board's duty should be simply to "test and demonstrate for the record the adequacy of the staff review."[59] If it found gaps in the record, it might insist that they be filled, but, if it should be convinced that an adequate review had led the staff to a conclusion on safety that was dead wrong, the Board's duty would still be to approve the proposed granting of the permit—and to do so promptly.[60] In other words, the Board's role would be rather like an appellate court's. The court searches the record below for errors of law or

[54] Niagara-Mohawk Power Corp. Reactor, 2 CCH ATOMIC ENERGY LAW REPORTER ¶ 11,250, at 17,487-15.

[55] See 2 CCH ATOMIC ENERGY LAW REPORTER at 17,485-5 (May 6, 1965). The Commission observed, "Whether we would ourselves have required every item of information requested is not in question." 2 CCH ATOMIC ENERGY LAW REPORTER at 17,485-6.

[56] See 2 CCH ATOMIC ENERGY LAW REPORTER at 17,485-5. For the appointment of the Panel by AEC Chairman Seaborg, see *AEC News Release* H-17, January 25, 1965.

[57] The Panel submitted its report, a 68 page typed document, on July 14, 1965. *AEC News Release* H-165, July 21, 1965

[58] Regulatory Review Panel Report 38.

[59] Regulatory Review Panel Report 37. The Panel adds, "it would *not* be the hearing board's function to conduct *de novo*, its own independent safety review."

[60] Probably a Board so dissatisfied would find some basis for challenging the sufficiency of the information or the adequacy of the staff's review; at the least, it could cast such doubt on the staff's conclusions as to assure careful review by the Commission itself.

procedure but declines to substitute its own judgment on questions of fact for that of the jury or the trial judge.

It may be asking too much of the scientific mind to expect it thus to approve what it considers error, even though that error is the fruit of careful study. It may seem that the Boards are being asked to "play charades" for the benefit of the public, as one knowledgeable skeptic suggested to me. The Panel flatly declared that, "the public hearing is not a proper instrument for the solution of complex technical problems bearing on reactor safety."[61] Yet whenever an intervenor seizes the opportunity afforded by the notice of hearing to attack the staff's proposal, the case becomes contested. Thereupon, for good or ill, the public hearing has to be the instrument for solving "complex technical problems bearing on reactor safety."

The Commission has recently proposed to accept the Panel's recommendations for the procedure to be followed in uncontested cases. In proposed amendments to its Rules of Practice, published on January 20, 1966, it would have the Board, "without conducting a *de novo* review of the application, determine whether the application and the record of the proceeding contain sufficient information, and the review of the application by the Commission's regulatory staff has been adequate, to support" the findings which would be required to sustain the issuance of a construction permit in a contested case.[62]

A proceeding conducted with these objectives would seem to me to satisfy the statutory requirement of a hearing. The findings as to the sufficiency of information and the adequacy of the safety review would ordinarily sustain the inference—and so the substantive conclusion—that the "proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public." If, however, this attenuated hearing had been diluted still further as had been urged in some quarters, if the Board —or a hearing examiner—had only to accept for the record a recital

[61] Regulatory Review Panel Report 37.

[62] AEC, Notice of Proposed Rule Making, Amendment to 10 C.F.R. § 2.104(b)(2), cited at footnote 35, at 833. To the amended Rules of Practice there is proposed to be added, as Appendix A to 10 C.F.R. pt. 2, a proposed "Statement of General Policy: Conduct of Proceedings for the Issuance of Construction Permits for Production and Utilization Facilities for which a Hearing is Required . . . ." Cited at footnote 35 at 833. The Statement spells out the requirements of the Rules of Practice and adds certain matters drawn from the Panel's recommendations which "do not require or lend themselves, to inclusion as formal rules . . . ." Cited at footnote 35 at 832.

of the information at hand and a report of the staff's operations without passing on the adequacy of either, then the proceeding would have been reduced to an essentially ceremonial status. Such a "hearing" would have complied less with the statute than with Professor Davis' proposal that the AEC simply hold a press conference near the reactor site in uncontested cases.[63]

Of course, the Atomic Energy Act could be amended to do away with any hearing in the absence of a contest, thereby completing the cycle by restoring internal decision-making as the accepted practice and reducing public decision-making to the position it had held before the PRDC case—except for the publication of the ACRS report, if any, and the applicant's and the staff's "safety analyses."[64] In that event, whenever a more searching check could not be assured by a well financed and sophisticated intervenor, the exposed communities —and the whole power reactor industry whose very life depends on avoiding any atomic disaster anywhere—would have to rely on the effectiveness of the staff's review. If the Panel's recommendations were to be accepted by the AEC and the Congress, this review would seldom be reinforced by the second layer of review that the ACRS now provides, although, hopefully, the ACRS would be called on to review the "more difficult and novel reactor safety problems."

Perhaps this is enough. The staff may well continue to merit the praise that the Panel bestows upon it, even after an increased volume of reactor construction has begun to lure its experts back to industry. The design criteria that the AEC is now publishing for comment, as elaborated and supplemented over time, may provide important safeguards.[65] Moreover, as the Niagara Mohawk Board's

[63] The statutory requirement of a hearing was continued when the act was amended in 1962 with full knowledge that most AEC permit proceedings were uncontested. Absence of a contest does not of itself remove the need for compliance with a hearing requirement, as our divorce courts daily bear witness. Even in the uncontested divorce case, the judge must decide that statutory criteria have been satisfied. Lack of a contest does alter the purpose of the hearing from the more usual one of resolving a dispute to that of public scrutiny of official action. See Cavers, cited at footnote 20, at 359.

[64] Among the proposed amendments to regulations for the licensing of reactors (and authorizing of Commission reactors not subject to licensing) are changes in nomenclature which the Commission proposes as "more accurate." AEC, Notice of Proposed Rule Making, Facility Licensing Procedure, cited at footnote 35, at 832. The amendments to parts 50 and 115 would substitute "safety analysis report" and "safety analysis" for "hazards summary report" and "hazards analysis." Cited at footnote 35, at 837. The public relations gain is obvious.

[65] General Design Criteria for Nuclear Power Plant Construction Permits, AEC Press Release H-252 (Nov. 22, 1965). The 27 criteria are very general, as is evidenced by the fact that they absorb less than nine pages of double-space typescript.

opinion makes plain,[66] the present scheme assures a public review of no more than the incomplete design and so leaves virtually all the safety questions without final answers. The tactic which the Board in the Jersey Central case employed to meet this problem—the issuance of a provisional permit conditioned on the receipt of further satisfactory evidence of safety as the design progressed—appears to have been negatived by the Commission's proposed amendments.[67] A Board which is dissatisfied with the information presented to it can, of course, request more and recess the hearing until it is provided. However, this delays the construction permit's issuance and so prevents virtually all work on the reactor, a consequence the Jersey Central Board was seeking to avoid.

Probably it is unrealistic to hope to meet the problem posed by the gradual evolution of a reactor's design by means of a system of public review which has to depend on *ad hoc* boards. The experts who staff them are subject to many competing demands and could seldom expect to maintain surveillance during the months—and sometimes the years—in which answers were being reached for the safety questions that the first public hearing had to leave open. If it should be decided that public scrutiny of internal decision-making in reactor licensing is in the public interest, then the only realistic means of achieving this may be the creation of a full-time Atomic Safety and Licensing Board, perhaps reinforced on occasion by co-opted experts, aided by a staff of its own, and having authority to review proposed permit and license actions by public hearing when these are contested or whenever it judges that the importance of the safety issues in an uncontested case warrants its interposition. In 1962, doubtless this solution seemed premature;[68] today I believe it merits renewed consideration, not for this year or the next, but for a not distant future.

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[66] See text at footnote 54.

[67] The Commission's action has taken the form of a proposed amendment to its Rules of Practice, 10 C.F.R. § 2.717 (a), providing that the jurisdiction of the presiding officer (and hence of a Board) terminates upon the expiration of the period within which a record may be certified to the Commission for final decision or when the Commission reaches a final decision. See AEC, Notice of Proposed Rule Making, cited at footnote 35, at 831. The issuance of a conditional provisional permit would appear to call for a final decision which would terminate the Board's jurisdiction before the condition could be complied with.

[68] The JCAE staff proposed a full-time board within the framework of the AEC and rejected proposals for a full-time independent board, for example, in Berman & Hydeman, cited at footnote 24, arguing in part that its proposal would "provide a foundation for the creation of an independent agency when large-scale development of atomic power makes such a move desirable." 1 JCAE Staff Report, cited at footnote 20, at 67.

This hesitant look into the future which I ventured in my lecture has been followed by another look in more specific terms and from a high official source—in a speech entitled "Looking Ahead at the AEC Regulatory Program" by AEC Commissioner James T. Ramey on January 20, 1966. After reviewing the AEC's past reactor licensing procedures and its proposed amendments to its Rules of Practice, Commissioner Ramey said:

> I believe it would be useful to establish a permanent chairman for the licensing boards, and perhaps set up a small permanent staff. Such a chairman could help bring greater consistency to the board system, and he could act as liaison between the Commission and the other board members . . . .
>
> In the next five to ten years, as we gain experience and confidence, and the volume of applications increases, I would expect that the mandatory hearing process might be eliminated, and the licensing board system might evolve into a more permanent full time board with the Commission delegating to it final adjudicatory authority, subject to the rule making power of the Commission. Finally sometime thereafter as further experience is gained, it might be desirable to establish the Commission's regulatory organization as a wholly separate agency, possibly combining with it some of the functions of the Federal Radiation Council and the Department of Health, Education and Welfare (HEW).[69]

Lessons for the FDA from AEC Experience

Though the AEC has not solved its problems of procedure, does its experience in grappling with them have lessons for the FDA? Obviously the tasks set the two agencies differ: power and test reactors are huge, multi-million-dollar affairs, and there are relatively few of them; new drugs, though less costly to discover and develop, are, of course, far more numerous. People are much more aware of the risk from a big reactor to the windward than of a drug that may be dangerous or ineffective. No one really expects to be taking that drug. Yet I suspect you have observed that both agencies' approval processes pose certain basic questions: whether applications should be open or confidential, whether decision-making should be internal or public, which roles in the process should be played by experts and

[69] *AEC News Release* No. IN-661, January 28, 1966, pp. 17-18. The speech was delivered at a Nuclear Power Briefing for Utility Executives held in Oak Ridge, Tennessee. Commissioner Ramey was Executive Director of the JCAE staff at the time of the 1961 JCAE staff study, cited at footnote 20. The AEC's continuing concern with its regulatory procedures has led to the appointment of still another review panel, also under the chairmanship of William Mitchell. It is charged with the study of procedures in contested licensing cases. See AEC Press Release J-86 (April 4, 1966).

which by administrators, and whether an opportunity to be heard should be given to "affected persons" other than the applicant. Some comparisons may have suggestive value.

The Secrecy of Applications. Is the FDA unwise to keep its new drug applications (NDAs) secret in contrast to the AEC's practice of public filing of applications and of safety analyses by both staff and applicant? To be sure, the FDA is not free under the law to disclose "trade secrets" or to disregard professional inhibitions,[70] but even NDAs that had been carefully edited for public filing would reveal much more of the bases of FDA decisions than is now accessible. Closely related to this question of secrecy is the question whether, if the secrecy were to be relaxed and edited NDAs of approved drugs made public, makers of like drugs should be required to duplicate in all respects the investigations and applications required of the pioneer.

FDA's philosophy appears to be that the drug manufacturer should have to make only such disclosure to the FDA of its formulas, research experience and processes as is needed to enable the agency to pass on its product; disclosure to the public can be limited to the information required for the protection of drug users, such as warnings of side effects and contra-indications on labels and in labeling.[71]

[70] Food, Drug & Cosmetic Act § 301 (j), 21 U.S.C. § 331(k) prohibits revealing any information acquired under authority of specified sections "concerning any method or process which as a trade secret is entitled to protection." An effort in 1962 to broaden this provision by striking the quoted clause was defeated in conference. Conference Report to accompany S. 1552, H. R. Rep. No. 2526, 87th Cong., 2d Sess. 26 (1962). For its application to "new drugs," see 21 C.F.R. § 130.32 (1965). Disclosure by a federal official "not authorized by law" of information acquired from investigations or reports which "concerns or relates to the trade secrets, processes, operations, style or work, or apparatus, or to the identity, confidential statistical data, . . . of any person, . . . [or] corporation, . . ." is a federal crime. 62 Stat. 791 (1948), 18 U.S.C. § 1905. Regulations and orders issued under the investigational drug and report-keeping amendments "shall have due regard for the professional ethics of the medical profession and the interests of patients." Food, Drug & Cosmetic Act § 505(i), (j), 21 U.S.C. § 505(i),(j) (Supp. 1964). This provision also authorizes the Secretary to provide where appropriate "for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information" obtained by the FDA. The implementing regulation excludes "information which the Commissioner concludes must be considered confidential." 21 C.F.R. § 130-13 (f) (1965).

[71] Letters to Senator Humphrey by FDA Commissioner Larrick (October 14, 1963) and Deputy Commissioner Harvey (December 17, 1963) describe the FDA's position with respect to confidentiality and to disclosure of otherwise confidential data to protect against significant hazards. *Hearing on Interagency Coordination in Drug Research and Regulation Before the Sub-*

(Footnote continued on next page.)

Among those opposing compulsory disclosure of NDAs to the public,[72] there is fear that this would sharply diminish, if not destroy, the incentive to invest in research for new drugs. This might extend even to patentable products since the secrecy of the NDA may sometimes be more of an impediment to competition than the patent itself. The industry and the agency might find the task of distinguishing between genuine trade secrets and unprotected material in editing NDAs both difficult and time-consuming.[73] If makers of "me-too" drugs were free to ride on the coat-tails of the first company to get approval, the wasteful proliferation of brands would be accelerated.

With these fears goes confidence that, if health needs are sufficiently serious and acute, physicians can get the information they need from the companies or the FDA. Moreover, duplication of investigational work is not seen as unmixed evil; it provides cross-checks on findings, and these the FDA staff, if not the profession, can take full advantage of in making its own evaluations—or can do so when it has been suitably computerized.

Critics of the FDA's present policy of secrecy[74] seem to have had little impact on the medical profession's satisfied acquiescence in it and, given the industry's stout support, there may be little prospect of change. Yet are the legal and practical imperatives so strong? Obviously any change would call for careful study, and I am in no position to prescribe specific remedies. However, I would urge a search in the public interest for workable intermediate positions between full, prompt disclosure on the one hand and secrecy on the other.

To take a different tack, the FDA might be required to accompany each drug approval with a statement of considerations outlining

(Footnote 71 continued.)
committee on Reorganization and International Organization, Senate Committee on Government Operations, 88th Cong., 1st Sess., pt. 4, pp. 1899, 1901 (1963).

[72] For one of the best presentations of this position, see a letter of August 8, 1963 to Senator Humphrey by Dr. R. K. Cannan, Chairman, Division of Medical Sciences, National Academy of Sciences. See footnote 71, at 1895. For a somewhat similar position, see letter of September 10, 1963 to Senator Humphrey by Dr. J. A. Shannon, Director, National Institute of Health. See footnote 71 at 1897.

[73] The category of "trade secret" is not clear-cut. Perhaps the most important information it protects relates to manufacturing processes. In addition, concealing physicians' and patients' identities reported in case histories might be troublesome. However, rules of practice might provide guides to aid the applicant in furnishing an edited version of his NDA.

[74] Several criticisms of the secrecy policy are collected in *Hearings on Interagency Coordination in Drug Research and Regulation,* cited at footnote 71, pt. 4, pp. 1892-95, 1901, 1903, pt. 5, pp. 2527-30. See Mintz, *The Therapeutic Nightmare* 143-6 (1965).

the studies and findings that had led both to the drug's approval and to any warnings that had been called for.[75] The staff would find this burdensome, to be sure, but the FDA could require an applicant to share the burden by submitting a draft statement of considerations with its application. The FDA could provide models, with compact versions for minor variations on established drugs or their uses. Not only would this practice reveal the factual bases of approvals, but out of such documents would almost certainly grow standards to guide internal review and future action, both inside and outside the agency.[76]

The Use of Expert Advisers. The FDA and the AEC are coming closer into line in their resort to expert advisers. The former's use of *ad hoc* committees is increasing as the latter's use of its standing committee, the ACRS, has grown more selective. All these advisers deliberate privately, but the ACRS is required to make its conclusions public. If FDA used statements of considerations of the kind I have just suggested, no doubt the views of *ad hoc* committees could be appended to them.

However, recourse to *ad hoc* advisory committees by regulatory agencies in general and by the FDA in particular has recently been challenged. Dean William C. Warren of the Columbia University Law School sees the administrator who is advised "by a panel of distinguished experts" as, "likely to adopt the recommendation as his decision, without the soul-searching critical analysis to which he would subject the same recommendation from his own official staff . . . ."[77] Not only is the administrator shielded from congressional criticism if he relies on such a panel's advice, but, Dean Warren points out, criticism would be doubled if he disregarded the panel's advice and

[75] Statements of considerations would differ from disclosures as to side effects and contra-indications in prescription drug brochures in that presumably the statements would disclose the factors for and against approval of the drugs they covered and the reasons which had led to their approval and had occasioned any conditions on approval.

[76] The need to give reasons for decisions is a great stimulus to the formulation of premises from which future decisions can be derived. It is easy to underestimate the value of such statements outside the agency by observing that persons desirous of having them do not seem to exist. This overlooks the potentiality of such statements (or of edited NDAs) to create both users and media to disseminate the knowledge thus made available. A like objection was made concerning the disclosure philosophy of the Securities Act. See 1 *Loss, Securities Regulation* 124 (2d ed. 1961). But prospectuses have grown somewhat simpler, 1 *Loss, Securities Regulation* 265, and an expert readership has developed.

[77] "Even," Dean Warren adds, "if that staff consisted of the very same experts." William C. Warren, "Congressional Investigations: Some Observations," 21 FOOD DRUG COSMETIC LAW JOURNAL 40 (January 1966).

events later proved him wrong. Tempted to take the safer course, he "abdicates his official function."[78]

If the voluntary resort to advisory committees by the FDA has aroused Dean Warren's concern—he distinguishes the use of individual consultants[79]—presumably he would view with still greater apprehension the suggested amendment that would make the appointment of an *ad hoc* advisory committee mandatory whenever an applicant requested it.[80] Naturally, such a request would be made only when the FDA staff's position seemed adverse to the applicant. Refusal to heed the advisory committee's counsel would put the FDA Commissioner and staff in the uncomfortable posture of asserting superiority in judgment to disinterested experts without at the same time being able to make full disclosure of the factual bases of the conflicting positions, if at least there were no requirement that statements of consideration be issued and the advisory panel's views be fully disclosed.

I submit that, to handle the hard case where neither the FDA nor the applicant is ready to back down, a public hearing is preferable to a mandatory *ad hoc* advisory committee. However, in providing for such a hearing, the FDA could well take a leaf out of the AEC's book. Let a hearing examiner or other lawyer be the presiding officer of a hearing board to which two or four experts would be appointed, chosen from a panel for the relevance of their expertise.[81] An initial decision by such a board would not, of course, be binding on the Commissioner, but the record before it would provide a public basis for appraising the wisdom of his decision or the lack thereof.

Is Intervention Possible? To turn again to AEC experience, is there a place for intervenors in such a hearing? Obviously the criterion of "persons affected" could scarcely be used to determine standing. One would not expect, say, the child-bearing wives of America to organize and seek representation in hearings involving

[78] See footnote 77.

[79] As to these, Dean Warren observes, "The use of consultants would not seem to have the same pitfalls, although their use does not provide the same 'window dressing'." See footnote 77 at 46. Dean Warren urges that funds be adequate to enable each agency to "employ full-time experts required to accomplish the agency's mission." But in fields such as new drugs and nuclear reactors, no agency, however ample its budget, can employ all the specialized expertise that its decision-making will require.

[80] References to supporters of such an amendment are to be found in my first lecture. See Cavers, "Administering that Ounce of Prevention: New Drugs and Nuclear Reactors," 21 FOOD DRUG COSMETIC LAW JOURNAL 473, footnote 44 (September 1966). Opponents' views appear at 472, footnote 43.

drugs suspected of adverse effects on pregnant women.[82] But professional and scientific societies, research institutes and the like concerned with fields specifically related to the matters at issue might be recognized as entitled to be heard, though perhaps denied standing to appeal.[83]

Might Uncontested Hearings Be Held? Finally, is there any place in the FDA's approval procedure for an analogue to the Atomic Energy Act's mandatory hearing in uncontested cases? Might the FDA be authorized to refuse to pass upon an application until a hearing had been held and to call for a hearing even though the applicant did not wish it? Needless to say, apt cases for exercising this authority would be few. These might arise most often in difficult withdrawal cases where the manufacturer preferred to remove a questioned drug quietly from the market rather than to seek its vindication in a public hearing. Perhaps the authority would be most valuable when the FDA was considering, either for approval or withdrawal, a group of related drugs whose safety or effectiveness would stand or fall on the basis of the same findings.[84] Its recent action against throat lozenges containing antibiotics may provide such a case;[85] possibly the oral contraceptives will someday give rise to another. Such a hearing would be hard to conduct;[86] its conduct and the representation of the parties would make heavy demands on lawyers' skills. Badly run, it could wind up in a shambles. Is the risk worth taking? Indeed, are any of these burdensome procedures that I have been canvassing really worth while?

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[81] To select experts for service on the hearing board would not be easy; conflicts of interest would create problems. However, the AEC seems to have surmounted this barrier in recruiting panel members for its Atomic Safety and Licensing Boards.

[82] But when I read this sentence to my wife, she asked, "Why not?"

[83] *Cf.* the provision for "limited appearances" in AEC reactor licensing hearings, see footnote 40.

[84] The FDA has not yet had to deal with the procedural complexities that seem destined to arise when it wishes to challenge at one time a substantial number of related drugs which, though distinct products, are open to the same objection on the score of efficacy or safety.

[85] See *N. Y. Times,* March 9, 1966, p. 1; *29 Fed. Reg.* 7728 (June 1964).

[86] The difficulty has led to some speculation that the resort to regulations might be necessary. The new drug provisions, unlike those authorizing withdrawal of certification to antibiotic drugs, Food, Drug & Cosmetic Act § 507(a),(f), 21 U.S.C. § 357(a),(f), do not authorize the issuance of regulations to ban drugs that are found unsafe or ineffective, but query whether use might be made of the FDA's general rule-making authority, see § 701 (a), 21 U.S.C. § 371(a), to promulgate a finding applicable to all previously approved drugs having a specified composition or use, withdrawing approval therefrom, subject to the right of the manufacturer of any drug within the category to contest the Secretary's finding as to it.

An Uncomfortable Conclusion

Here at the end of our long quest for a satisfactory procedure for administering the ounce of prevention, this question brings us back face to face with the dilemma I noted at the close of the previous lecture. Let me restate it here, not merely for the FDA and the AEC but for any agency charged with comparable responsibilities. On the one hand, we have to allow the government experts and their expert advisers enough freedom from legal formalities and restraints in reaching their judgments that good men can be attracted to this task. Experts in official posts will usually yield to contrary judgments of the best men in their guild, but their morale will ebb if their own processes and judgments are often overridden by what seem to them unscientific processes and nonscientific considerations. On the other hand, sooner or later the public will reject expert judgments on which hang the safety of many people unless at least some of these judgments can be and are validated by public processes, however unscientific. One way to provide public validation is resort on occasion to a public hearing before a tribunal manned by knowledgeable people of demonstrated independence whose conclusions can be rejected by the final decision-makers in the agency only on the basis of reasoned opinions, themselves subject to public appraisal.

If this or some comparable check is not available, if the staff's work is done and reviewed in secret, the agency, its staff and its processes will all risk becoming the object of suspicion, perhaps not from the public at large but from a relatively small but concerned and articulate group of independent experts and laymen. If there is no effective way for these critics to take part in the process of decision or to evaluate the judgments it yields, they will exploit whatever agency errors hindsight has laid bare and turn to political processes. The most available of these are appeals to congressional committees and to the citizenry at large, ranging from indignant letters to the editor to the hair-raising best-seller. Secrecy is not likely long to survive these assaults, nor will public and professional confidence in the agency.[87]

This is not a comfortable conclusion, but I do not quarrel with it. When government undertakes to administer the ounce of prevention, it is asserting that the problems which the hazard creates are

[87] A possible response by the agency might be to "avoid future trouble by always refusing clearance" or to use "the official escape of saying that there is inadequate data." H. Thomas Austern, "Drug Regulation and the Public Health," 19 Food Drug Cosmetic Law Journal 259 (May 1964). This too would destroy confidence, although, for a time, in a different quarter.

affected with a public interest, a vital public interest. Accordingly, its administration must be such as to achieve and maintain public confidence.

Addendum: Since I delivered the Donley Lectures six months ago, the FDA has experienced a dramatic change. A new Commissioner, a physician, Dr. James L. Goddard, has launched vigorous enforcement programs aimed at prescription drugs. He has sharply criticized the pharmaceutical drug industry and some drug investigators. The FDA has seized approved drugs for exaggerated advertising claims of efficacy, has terminated the investigational drug exemption for the widely-publicized dimethylsulfoxide (DMSO) and has initiated the withdrawal of a new drug's approval because the investigator's report supporting it contained untrue statements. Dr. Goddard has been warmly applauded in the press. Dr. Sadusk, after resigning as head of FDA's Bureau of Medicine, has raised a dissenting voice, warning that the FDA may be assuming too many of the medical profession's responsibilities. If the present activist policies continue, probably the FDA's administrative actions will be challenged more often in the future than heretofore. **[The End]**

FDA PROPOSES REGULATIONS FOR NEW DRUG APPLICATIONS AND ADVERSE EXPERIENCE REPORTS

Proposed Regulations which would speed up and tighten up procedures for evaluating new drug applications have been issued by the Food and Drug Administration. The proposals would require the new drug applications to have a summary of the essential elements, a table of contents, and a summary and evaluation of the evidence of safety and effectiveness for each therapeutic claim made for the drug. Requirements for binding, assembling and numbering pages and volumes of applications would also be provided. Only one copy of individual patient case reports would be submitted instead of the three required now.

The FDA has also proposed (1) that all adverse experience reports be submitted on a standard form (FD-1639) regardless of whether the drug is on the market or still under evaluation, and (2) that all new advertising and promotional labeling on drugs be submitted at the time the promotions are introduced. 31 F.R. 13,347.

Some Recent Legal Developments in the Food, Drug and Cosmetic Field

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THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) PLAYS A CRUCIAL ROLE in our economy. Under a complex system of law it must determine the safety of drugs, cosmetics, food additives, color additives and "hazardous substances." In addition, it must determine that all new drugs are effective for their intended purposes, and that antibiotics conform to their required standards. FDA even has the authority to declare which ingredients shall be permitted in foods for which standards have been promulgated under the law. Furthermore, all of these difficult duties are carried on in a framework of laws and regulations so complex and interwoven that one judge, perhaps out of despair, recently described the entire Act as "monstrous."[1] Such a situation does not lend itself to harmony and repose, and this article will trace some recent successes and failures of the FDA, the industries, and the courts in facing these complexities.

Administrative Regulations

The area in which the regulated industries have felt the greatest impact, and FDA has faced its most determined challenge, has been in the promulgation of administrative regulations. Since 1958 Congress has passed five separate laws, each one of which entrusts to FDA the authority and duty to publish administrative regulations (1) serving to interpret the laws and (2) setting down detailed en-

[1] *United States v. 856 Cases . . . "Demi,"* 254 F. Supp. 59 (N.D. N.Y., 1966).

forcement guidelines for the industries to obey.[2] Each one of these laws is detailed in the extreme and contains undefined or vaguely defined scientific, medical, or technological terms, and therefore each law requires FDA to publish regulations filling in the details and making specific the very general and broad statutory statements.

FDA has done this job and, in the main, has tried to do it well. Unfortunately the problem is so large and the reasoning often so one-sided that the effort has resulted in creating more important problems and more court challenges by industry than had ever before been instituted. The problem facing the regulated industry is that it must either comply with FDA's detailed requirements or risk enforcement proceedings in the federal courts. But the industries, by their very nature, are sensitive to the adverse publicity which always results from any FDA action. The mere bringing of a suit by FDA against a regulated product, especially a drug product, can be enough to destroy that product's usefulness in the market place.

However, this problem could be solved if a means were devised for testing FDA regulations in advance of enforcement activity. In three recent suits the means chosen was for trade associations and member companies to seek a declaratory judgment that certain regulations were illegal because they were in excess of statutory authority. The result has not been entirely successful.

In the first suit the Pharmaceutical Manufacturers Association (PMA) and 44 member companies sought a declaratory judgment on the validity of regulations implementing a portion of the 1962 Drug Amendment Act.[3] The relevant section of the Act requires the "established" or generic name of prescription drugs to be printed "prominently and in type at least half as large as that used thereon for any proprietary name thereof."[4] The regulations added specificity to the Act by requiring that the established or generic name must appear "each" time the trade name is used on labels, labeling or in advertising.[5]

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[2] "Food Additives Amendment of 1958," Pub. Law 85-929, 72 Stat. 1784 21 USC 348; "Color Additive Amendments of 1960," Pub. Law 86-618, 74 Stat. 396, 21 USC 376; "Federal Hazardous Substances Labeling Act," Pub. Law 86-613, 74 Stat. 372, 15 USC 1261 et seq.; "Drug Amendments of 1962," Pub. Law 87-781, 76 Stat 780; and the "Drug Abuse Control Amendments of 1965," Pub. Law 89-74, 79 Stat. 227, 21 USC 360a (1965 edition).

[3] *Abbott Laboratories, et al. v. Celebrezze*, 228 F. Supp. 855 (D. Del., 1964), Reversed in part, aff'd in part 352 F. 2d 286 (3 Cir. 1965), Cert granted, under the name of *Abbott v. Gardner*, 383 U.S. 924 (1966).

[4] "Drug Amendments of 1962," sec. 131 (a); 21 USC 352 (n) (1965 edition).

[5] 21 CFR 1.104 (q) (1), pub. 28 F.R. 6375, eff. June 20, 1963.

In the second suit, also brought by PMA and member companies, the plaintiffs challenged FDA regulations requiring companies to submit detailed reports concerning all drugs for which new drug applications (NDA) have been filed.[6] From 1938 to 1962 the law required that such NDAs be submitted to and approved by FDA for all drugs ("new drugs") which were not generally recognized as safe for their intended uses.[7] In 1962 the law was amended to require that "in the case of any drug for which an approval of an application" is in effect, the owner of such drug shall keep certain specified records.[8] The FDA contends, in the challenged *regulations,* that such record-keeping is required for all drugs which have gone through the new drug application procedure. The industry contends that the *law* states that such records need only be kept for those drugs which are still, in fact, "New Drugs"; that is, drugs which are not generally recognized as safe. It is the industry's position that once a drug is generally recognized as safe there is no requirement in the law to keep such records.

The third suit challenging FDA regulations was brought by the Toilet Goods Association (TGA) and 39 cosmetic manufacturers.[9] The plaintiffs sought a declaratory judgment that certain regulations implementing the Color Additive Amendments of 1960 are invalid. These regulations state that all cosmetics which impart color to the human body are color additives within the meaning of that law and require premarket clearance by the FDA before their sale in interstate commerce.[10] Since such regulations would make all current color cosmetics illegal and since premarket clearance is extremely slow, expensive, and may result in the disclosure of trade secrets, the cosmetic industry felt compelled to challenge these regulations prior to enforcement.

It is obvious that each of these three suits concerns matters of great substance to the industry affected. The first suit involves the labeling and advertising for every prescription drug in the United States; the second, the legal status of over 1,000 drugs now being

[6] *Abbott Laboratories, et al. v. Celebrezze,* cited at footnote 3.

[7] 21 USC 355, 52 Stat. 1040, Sec. 505.

[8] "Drug Amendments of 1962," Sec. 103 (a), 21 USC 355 (j) (1), (1965 edition).

[9] *Toilet Goods Association et al. v. Gardner,* 235 F. Supp. 648 (S.D. N.Y., 1965); aff'd in part, reversed in part 360 F. 2d 677 (2 Cir., 1966).

[10] 21 CFR 8.1 (f), 28 F.R. 6439 eff. June 22, 1963. Three other regulations are also challenged in this suit: 21 CFR 8.1 (m) which defines "diluents"; 21 CFR 8.1 (u) which restricts an exemption given to hair dyes under an older law to certain sensitizing products, and; 21 CFR 8.28 (a) (4) which purports to expand FDA's authority in the inspection of cosmetic manufacturing plants.

sold; the third suit, if lost, would place the cosmetic industry among the most intensely regulated. In spite of these potentialities, however, FDA moved to dismiss each suit upon the grounds that the regulations involved were interpretive; that they had not been enforced; and that there was no actual controversy within the meaning of the Declaratory Judgments Act. FDA also contended that each of these regulations was reasonable and in accordance with the law.[11] Basically, FDA contends that such regulations cannot fairly be tested in the abstract without a concrete factual situation to make the regulations meaningful.

Two of these three cases have now progressed through their respective Courts of Appeals.[12] These are the first PMA case and the TGA case, and in these two cases the Second and Third Circuits have reached diametrically opposite results.

In the PMA case the Third Circuit held that the "each time" regulations were interpretive regulations; that the Declaratory Judgments Act does not provide any means of review for such regulations; and that Congress had provided a variety of other legal remedies under both the Food and Drug Act and the Administrative Procedures Act which the plaintiffs here chose to ignore.

In holding that these regulations were interpretive the Court declared that the regulations did not have the force and effect of law, that they were not "adjudications" and that they were not an order or license under the applicable definitions of the Administrative Procedures Act. The Court also relied upon *Ewing v. Mytinger and Casselberry*, 339 U. S. 594 1950) where the Supreme Court noted that Congress had made numerous administrative proceedings under the Food and Drug Act reviewable by courts, but that it did not make all such proceedings reviewable. The Supreme Court said:

> . . . This highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was the one provided for in the libel suit. Cf. *Switchmen's Union v. Board*, 320 U. S. 297, 305-306[13]

[11] Other defenses of a technical nature were also raised: (1) the plaintiffs had failed to join an indispensable party—the Attorney General; (2) that venue was improper as to all corporations not incorporated within the forum state; (3) that trade associations have no standing to sue; (4) that, in all events, the United States had not consented to be sued. The District Court in the PMA case granted the motion as to the venue of certain corporations. 225 F. Supp. at 860 (D. Del., 1964) and the Third Circuit affirmed 352 F. 2d at 525 (3 Cir. 1965). Otherwise the FDA lost on all points.

[12] *Abbott Laboratories et al. v. Celebrezze et al.*, 352 F. 2d 286 (3 Cir., 1965) cert granted, under the name of *Abbott v. Gardner*, 383 U.S. 924 (1966); *Toilet Goods Assoc. et al. v. Celebrezze et al.* 360 F. 2d 677 (2 Cir., 1966).

[13] *Ewing v. Mytinger and Casselberry*, 339 U.S. at 600-601.

The Third Circuit apparently deduced from this that unless there is a provision for review of a FDA regulation there can be no review. However, it should be pointed out that in *Mytinger and Casselberry* the parties were already in court in actual lawsuits where there could have been a ruling as to the soundness of the questioned administrative ruling. What the drug company had tried to do in *Mytinger and Casselberry* was to test the ruling in still another forum, thus representing a clearly distinguishable situation.

The Third Circuit also relied upon *Helco Products Co. v. McNutt,* 137 F. 2d 681 (D. C. Cir. 1943) stating that *Helco* was the "closest parallel to the instant case."[14] Unfortunately, it is not a particularly close parallel, for *Helco* did not involve any formal industry-wide regulation at all but merely a letter from the administrative official stating what he felt the law to be. The Court in *Helco* had held that one should not have access to the courts to test such an informal statement of opinion of the law.[15] The Third Circuit has therefore chosen rather dubious authority for its decision.[16] The Supreme Court has granted certiorari in this case and it will be argued in the fall term.[17]

Other writers have suggested that FDA's "interpretive" argument is unsound.[18] These writers are probably correct but this does not mean that it is sound judicial administration to permit the testing of these or other regulations in declaratory judgment suits. For one, there is the matter of effective relief. If, in this PMA case, the District Court ultimately enters judgment in favor of the plaintiffs there is some question as to what value that judgment will have. In fact, Judge Wright of the District Court of Delaware, who did rule in the plaintiff's favor, could do no more than rule that the "each time" regulations were invalid. He did not state how many times the law required the name to appear with the proprietary name and therefore it would have been in order for the FDA to have republished regulations requiring the generic name to be used any number of times just so long as they did not require it to be used "each time." The flaw in these suits is that it gives no guide to the agency and very little effective relief to the industry. No matter what happens in any of

[14] 352 F. 2d at 290.

[15] 137 F. 2d at 683.

[16] The District Court in PMA had also held that the "each time" regulation was invalid, 228 F. Supp. at 864. This, of course, was reversed in view of the Third Circuit's decision.

[17] 383 U.S. 924 (1966).

[18] Sweeney, "The 'Generic Every Time' Case: Prescription Drug Industry in Extremis," 21 FOOD DRUG COSMETIC LAW JOURNAL 226, (April, 1966) and see also 3 Davis, *Administrative Law Treatise,* Sec. 21.08.

these suits, FDA must still publish regulations to fill in the details of the broad statutory grant of authority, and there will always be areas of disagreement as to the scope of new laws.

Such being the case, it is readily apparent that this type of lawsuit can result in administrative chaos for the regulatory agency involved. The agencies must publish regulations if the laws are to be effective. However, if every regulation may be so tested in court prior to enforcement, the agency will function with difficulty and the regulated industry will feel the pinch of its uncertainty. Thus it behooves both the agency and the industry to find a common and mutually respectful ground upon which to come to grips with these problems. The courts seem to be the least effective recourse, but it has obviously been necessary to resort to them in order to show that this historically pliable industry is willing to litigate if forced to it. Perhaps the value will be to bring reasonable men together again to take counsel with one another.

TGA fared somewhat better in its suit than PMA, for the Second Circuit held that the regulations could be challenged prior to enforcement.[19] This case was argued after the decision of the Third Circuit in the PMA case and the Second Circuit, agreeing with the government that the two cases were indistinguishable, stated that

> . . . we must confess, with all respect, our inability to understand why the plaintiffs there [in PMA] should be required to violate the challenged FDA regulation in order to raise the same legal issue as to which the district court had granted declaratory relief. Insofar as the [PMA] decision rested on a negative implication from the limited review provisions of the Food and Drug Act, we have already noted our inability to agree.[20]

This is perhaps as clear a conflict in the circuits as one is ever going to get and both the Plaintiffs and the FDA have filed petitions for certiorari.[21]

In holding that TGA could obtain a declaratory judgment, the Second Circuit noted that there has been a growing recognition that the timeliness of granting judicial review of administrative regulations depends on a broader concept of the substantiality of present or immediate harm. The Court noted that these color regulations would have an immediate impact on the industry "posing the unacceptable

[19] 360 F. 2d at 687.

[20] 360 F. 2d at 687.

[21] 35 LW 3083 and 3097. The Second Circuit did uphold FDA's argument as to one of the challenged regulations—the one authorizing increased inspections of cosmetic manufacturing plants, 21 CFR 8.28 (a) (4). The court pointed out that this regulation only stated what FDA thought it might do in a given situation, not necessarily what it would do. Obviously such a regulation does not pose a serious threat since the FDA still has other options. 360 F. 2d at 687. The Plaintiffs seek certiorari on this ruling.

alternatives of complying or of incurring possible forfeitures and criminal liability . . . ."[22]

Thus, with these two cases, the Supreme Court has the opportunity of resolving long standing opposing concepts of judicial review of administrative regulations: (1) that government agencies should not be put in the position of defending regulations in the abstract and prior to enforcement, and (2) that regulated industries should not be put in the position of either obeying regulations which they believe to be illegal or accepting potential criminal prosecution.

The Grandfather Clause

The review of administrative regulations has certainly not been the only problem facing the regulated industries in the last few years. One problem that has always been with the drug industry has been the question of what can cause a drug, which is already on the market, to become a new drug and therefore illegal until it is removed from the market and has received preclearance from FDA. The recent case of the *United States v. Allan Drug Company* 357 F. 2d 713 (10 Cir. 1966) petition for certiorari filed 35 LW 3090, represents a surprising decision in this area.

FDA does not have the authority to require preclearance of all drugs on the market. From 1938 to 1962 preclearance was required only for those drugs which were not generally recognized as safe for their intended purposes.[23] In 1962 the law was amended to require preclearance for all drugs which were not generally recognized as effective for their intended purpose.[24] In order to provide some protection for drugs then on the market, Congress enacted a "grandfather" clause which exempts from the requirement of proof of efficacy all drugs which were on the market the day the 1962 law went into effect and were also generally recognized as safe for their intended purposes.[25] The drug involved in *Allan Drug*, Halsion, was a drug entitled to such protection.

In *Allan Drug* the FDA had seized Halsion upon the grounds that its labeling contained misleading statements. The District Court agreed with FDA and condemned the drug, providing the drug's owner, however, with an opportunity to bring the drug into compliance with the law.[26] The company attempted to do so but the FDA

[22] 360 F. 2d at 685.

[23] 21 USC 355, 52 Stat. 1040, Sec. 505.

[24] "Drug Amendments of 1962," Sec. 102, 21 USC 355 (1965 edition).

[25] "Drug Amendments of 1962," Sec. 107 (c) (4); See note following 21 USCA 321, "Effective date of 1962 Amendment," (1965 pocket part). The statute became effective October 10, 1962.

[26] 21 USC 334 (d) provides the statutory authority for such a procedure.

would not approve any of the new suggested labels for the product and the company went back to the District Court which entered an order approving certain new labeling. FDA appealed from this order.

The Court of Appeals, noting that the drug in question had been condemned by the District Court, stated that in determining whether such a condemned product could re-enter commerce the Court would look to the fundamental purpose of the 1962 law:

> . . . to tighten administrative control and close up loopholes to the end that the labeling on products affecting the public health and safety shall speak the truth in language that the unsuspecting purchaser can understand.[27]

Having done so, the Tenth Circuit held that the grandfather clause exempts only those drugs which continue to contain the exact *same* representations concerning their use as they contained prior to the 1962 act, and no others. Since the "grandfather" labeling had been condemned under other provisions of law and therefore could no longer be used there would necessarily have to be new labeling, and so Halsion had become a "new drug."[28]

Thus, if a drug having the protection of the grandfather clause is brought into Court by a challenge of misbranding and FDA prevails, not only are the claims which are proven false to be stricken from the labeling but the drug itself must go back through the entire new drug procedure with its many delays and expenses before it can re-enter the marketplace. What is especially disconcerting about this decision is that the revised labeling approved by the District Court actually made fewer claims for the product than had been made before, but the grandfather clause protection was nevertheless lost. Incidentally, of equal concern should be the fact that grandfather protection may be lost unilaterally, as well, by merely making such changes—thereby presenting a unique situation to a company wishing to keep its labeling abreast of scientific developments, yet reluctant to lose the grandfathered position for its drug.

Another interesting case involving the new drug law was *Turkel v. FDA*, 334 F. 2d 844 (6 Cir. 1964) cert. den. 379 U. S. 990. In that case, the plaintiff had been testing a drug, on humans, for 11 years

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[27] 357 F. 2d at 719.

[28] In a strong dissent, Judge Seth stated that the decision nullified 21 USC 334 (d) which provides that a condemned drug may be reclaimed by the owner in order to bring it into "compliance" with the law. 357 F. 2d at 720. Of course, Judge Seth's argument fails, for, if the new drug procedure is the only way to be in "compliance," then that is the way demanded by 344 (d). Judge Seth's argument that a *reduction* in claims for a product is not such a *change* in claims as to deprive the owner of the grandfather protection is sounder. 357 F. 2d 720 et seq.

prior to the 1962 law which contained a provision directly applicable to this product.[29] This amendment provides detailed ground rules for the distribution of such investigational drugs in interstate commerce. In an effort to comply with them, the plaintiff filed the required documents with FDA, but FDA refused to approve these documents and forbade further testing because the plaintiff had not submitted any animal test data as required by FDA regulations. Apparently the plaintiff felt that 11 years of work on humans, without adverse effect, obviated the need for animal work at this time. The FDA, however, stuck to its position and the plaintiff brought the case to enjoin the Commissioner of FDA from terminating his investigational use of the drug. FDA moved to dismiss upon the grounds that the plaintiff could only appeal from an administrative order approving or disapproving the final NDA. The Sixth Circuit agreed with FDA and dismissed the case.

This, of course, left the plaintiff in a strange position. He could no longer test his drug and the only way he could get judicial review of FDA's preliminary refusal would be to go ahead and ask FDA, on the meager record then before it, to approve his product for sale in this country. Obviously FDA would not approve it since there was virtually no test data. The drug's owner was in fact asking permission to conduct further human testing to establish the drug's efficacy. The Court of Appeals recognized this strange result, stating that "it appears that the merits of" the preliminary refusal would be a proper issue at the final administrative hearing level.[30] This is not very strong language and if, at the administrative hearing, FDA counsel would be successful at restricting the issue to FDA's refusal to approve the final NDA application, the plaintiff might be effectively blocked from any means of redress. In all events, the decision forces plaintiff to proceed through a long and futile administrative exercise just to get judicial review of the earlier action.

Technical Improvements and the Law

Another problem facing the regulated industry in the last few years has been that of fitting changing consumer tastes and advancing technological improvements into the statutory framework. A recent case demonstrates the difficulty in doing this. In the *United States v. 856 cases of Demi,*[31] the product involved was a low-calorie margarine

[29] "Drug Amendments of 1962," Sec. 103 (b), 21 USC 355 (i) (1965 edition).

[30] 334 F. 2d at 846.

[31] See footnote 1.

obviously designed to meet the current market for such dietary products. Margarine, however, is a peculiar sort of food, for it is the subject of both statutory definition and administrative standardization.[32] Under the law a food which is the subject of an administrative standard must be made in accordance with the standard, or, in lieu thereof, must be labeled "imitation."[33] Here, the margarine product was labeled "imitation margarine" since it did not comply with the administrative standard.

The government seized the product upon the basis that margarine was *sui generis* for, as the government put it, margarine was the only food product which could not have an imitation. The premise for this was that margarine was defined by Congress as that product made in imitation of butter[34] and that Congress, by having done so, and by having passed some 80 years of other special margarine legislation, had declared that there should be but one imitation of butter, "margarine," which imitation would have to always meet the administrative standard. Thus, by the government's theory, "Demi," since it could not comply with FDA's standard (its fat content was too low), could not be made at all.

Judge Foley did not agree with the government, pointing out that by use of the phrase "imitation margarine" there is no opportunity for anyone being deceived as to what the product was, and that the legislative history of the margarine statutes did not support the government's position. The company thus won the suit but still, to comply with the law, a relatively innocuous product which was designed to achieve a part of the current market for low-calorie products, is able to do so only if it uses the clumsy title "imitation margarine" and then only after protracted court proceedings.

Another "imitation" product faced an even more rocky road in reaching the marketplace, but here, so far, it has not had to adopt the word "imitation." This is the product known as Coffee-Rich. The purpose of this non-dairy product is plainly to be used in place of cream in coffee, and, although the product has not been challenged by

[32] 15 USC 55 (f) (2), 21 CFR 45.1.

[33] 21 USC 343 (c) and (g), *United States v. 62 cases . . . Jam,* 340 U.S. 593 (1951); *United States v. 20 Cases . . . Buitoni 20% Protein Spaghetti,* 130 F. Supp. 715 (D. Del., 1955), aff'd 228 F. 2d, 913 (3 Cir. 1956).

[34] ". . . the term 'oleomargarine' or 'margarine' includes . . . (2) all substances . . . which have a consistency similar to that of butter . . . if made in imitation or semblance of butter," 15 USC 55 (f) (2). See also 21 USC 347 (e). The earliest statutory definition appears at 24 Stat 289, Sec. 1 and defines margarine as those "substances made in imitation or semblance of butter." cf. *Land O'Lakes v. McNutt,* 132 F. 2d 653 (8 Cir. 1943).

the FDA, it has been necessary for the company to bring several state suits for a declaratory judgment in order to have the product declared legal.[35] One state case will serve to demonstrate the problem.

The laws of Massachusetts declare misbranded any food made in imitation of another food unless it is labeled "imitation."[36] Coffee-Rich was not labeled imitation and a declaratory judgment suit was brought to determine whether Coffee-Rich violated this law. The Massachusetts Court, after analyzing the facts, held that the product was clearly made in imitation of cream, but went on to hold that the statutes could not be enforced against the product, basing its opinion upon the fact that the average consumer who buys this product would not be mistaken that it was cream and thus it would be an unreasonable exercise of police power to prohibit such a product from sale in Massachusetts. Such a sensible result has been reached in several other states and there has been no challenge by the FDA.

The Coffee-Rich cases and the imitation margarine case, together, demonstrate a recent tendency of the courts to look at such matters with a reasonable attitude. If there is no likelihood of consumer confusion and if the labeling is otherwise accurate the food should be allowed on the market. The position of the governmental agencies in these cases, while doubtlessly reflecting supportable legal arguments, tend to ignore the realities of consumer purchasing attitudes. And, insofar as the agencies' arguments are sound, they demonstrate the inflexible nature of these laws.

Dietary Supplements

One area of the Food and Drug Industry that has received particular attention from FDA in the last few years is the field of vitamin, mineral and dietary supplementations. For years the FDA has taken the position that the American diet is adequate in supplying vitamins and minerals to the consumer, and that, at best, dietary supplementation is surplusage.[37] This attitude has been reflected in a

[35] *Coffee-Rich Inc. v. Commissioner of Public Health*, 204 NE 2d 281 (Sup. Jud. Ct., 1965); *Coffee-Rich Inc. v. Kansas State Bd. of Health*, 388 P2d 482 (Kan. Sup. Ct., 1964); *Coffee-Rich Inc. v. Mich. Dep't of Agric.*, 135 NW 2d 594 (Mich. Ct. of App., 1965), and others.

[36] Gen. Laws of Massachusetts c.94, Sec. 187.

[37] Although it is beyond the scope of this article, it should be noted that, in general, the courts are responsive to FDA's position, cf. *United States v. An Undetermined Number of Cases . . . Vitasafe*, 226 F. Supp. 226 (D.N.J., 1965), aff'd 345 F. 2d 864 (3 Cir., 1965) cert den 382 U.S. 918; *United States v. Articles of Drug, Foods Plus*, 239 F. Supp. 465 (D.N.J., 1965), aff'd 362 F. 2d 923 (3 Cir., 1966). A notable example to the contrary is *United States v. One Hundred and Nineteen Cases . . .* "Dextra Brand," . . . 231 F. Supp. 551 (S.D. Fla., 1963), aff'd 334 F. 2d 238 (5 Cir., 1964).

series of cases involving either well known dietary products or some of the better publicized, albeit controversial, publicists of dietary supplementation.[38] But, most important, on June 18, 1966, the FDA published a series of strict regulations which will, if allowed to become final, prohibit the making and labeling of claims for certain vitamins and minerals and drastically restrict the use of others.[39] The manner in which these regulations have been promulgated reveals in very clear terms FDA's thinking in regard to such products.

Dietary regulations were first published by the FDA in 1962.[40] At that time the FDA stated that the statutory authority for the promulgation of such regulations was to be found in section 403 (j) of the 1938 act. This statute states that a food shall be deemed to be misbranded

> . . . if it purports to be or is represented for special dietary uses, unless its label bears such information . . . as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.[41]

However, the regulations proposed in 1962 did far more than just "prescribe" the "necessary information." They did, in fact, prohibit the use of certain vitamins and minerals and limited the amounts of other vitamins and minerals.

Following the prescribed procedure many comments were received by FDA concerning these proposed regulations and a considerable amount of the comments pointed out the apparent illegality of dietary regulations which do more than prescribe information.[42]

Apparently the FDA realized the weakness of its position in this regard for, in the June 18th version of these regulations, FDA has added another string to its bow. Now, in addition to the statutory authority found in section 403 (j), the FDA has stated that it intends to establish a food standard for virtually all vitamin and mineral products under the authority granted under section 401. This statute provides that FDA may, if such action "will promote honesty and fair dealing in the interest of consumers," establish standards of

[38] In *United States v. Articles of Drug, Foods Plus,* vitamin products were condemned, as drugs, because of radio broadcasts by Carlton Fredricks. The government demonstrated, to the satisfaction of the Court, that Dr. Fredricks' programs, although allegedly unsponsored, were actually promotions of claimant's products. Dr. Fredricks has been the recipient of FDA's interest before. Cf. *United States v. Articles of Drug . . . Carlton Fredricks,* intervenor, 32 F.R.D. 32 (W.D. Ill., 1963).

[39] 31 F.R. 8521, June 18, 1966, amending 21 CFR 1255, and 80.

[40] 27 F.R. 5815, June 20, 1962.

[41] Sec. 403 (j), 21 USC 343 (j). 52 Stat 1047.

[42] R. D. McMurray, "The Forthcoming Dietary Food Regulations," 20 *The Business Lawyer* 755 (1965).

identity, of quality, and of fill of container of *any* food.[43] Since vitamins are a food, FDA takes the position that it can establish such standards.

Obviously section 401 gives FDA a lot more authority here than it had under 403 (j). The only statutory requirement for section 401 standards is that the standards will "promote honesty and fair dealing." There is no restriction requiring FDA to limit its regulations to "information" only.

But what is peculiar about the FDA June 18th "standard" proposal is that FDA has not followed its own law. Prior to June 18th there had been no proposal by FDA to standardize vitamin products under section 401; the 1962 proposal had been under 403 (j) only. However, section 701 (e) (1), which prescribes the procedure for promulgating such regulations, plainly states that any action for the issuance of any regulation under section 401 "shall be begun by proposal made" by FDA or interested persons.[44] The statute then states that such proposal shall be published and that all interested persons shall be "afforded an opportunity" to present their views thereon orally or in writing. After that, and *only* after that, FDA may act upon such proposal and make its final order public.[45] In the case of the June 18th vitamin standard regulation FDA has not complied with any of these statutory requirements. Apparently FDA takes the position that, having made a proposal under section 403 (j) in 1962, it need not repeat a similar, although not identical proposal, under section 401 in 1966. If this is FDA's attitude it ignores two important factors: (1) The criteria for justifying regulations under section 403 (j) and 401 differs substantially, and (2) four years have passed since the earlier proposal; surely there has been a substantial change in technology in that time which justifies doing what the statutes state must be done, that is, to afford interested persons an opportunity to present their views.

The PMA and 12 of its member firms on September 21, 1966 sued in Federal District for the District of Columbia Court to prevent enforcement of a part of the June 18 vitamin regulations, claiming the government's action was illegal. The court was asked for a preliminary injunction to enjoin FDA from proceeding with an anticipated hearing on the regulations, after which they could be made binding. The argument is that the proper course would have been for FDA to publish them as proposals, thereby giving affected parties an op-

[43] Sec. 401, 21 USC 341, 52 Stat 1046.
[44] Sec. 701, 21 USC 371, 52 Stat 1055.
[45] Sec. 701 (e), 21 USC 371 (e).

portunity to present their views before the actual regulations were published. Other requirements published as proposed regulations in June, 1962, and as final regulations last June, are not contested in the court action.

The contested section (Part 80) establishes formal definitions and standards of identity for dietary supplements and for vitamin and mineral fortified foods, restricts the types of foods to which vitamins or minerals may lawfully be added, and requires a specific label statement which says in part that "except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements." This has never been published as a proposed regulation, and it is on this point that the suit was brought.

Finally, of course, there is the serious question of whether FDA may publish similar regulations covering the same type of products under two separate statutes. Sections 401 and 403 (j) were both enacted as part of the 1938 food and drug law. Senator Copeland, who led the fight for the 1938 Act, stated the purpose of each of these sections in the course of debate on earlier versions of the Act.

As for section 401 he stated that:

> One of the glaring weaknesses of the present law is its failure to provide for definitions of identity for food. Without such definitions all sorts of economic cheat are possible. For example, within recent months the Department, in an effort to protect the consumer's pocketbook, brought action against a shipment of oysters to which a considerable quantity of water had been added, to be sold, of course, at oyster prices. The court held that because there was no legally binding definition of identity for oysters, the Government had not made out a case. Many other similar cheats have had to go unchecked because of this lack of authority.[46]

As for section 403 (j) he was similarly explicit.

> . . . Because of the increasing recognition of the importance of the daily diet in maintaining health there are being offered to the consumer an increasing number of preparations alleged to contain this or that vitamin, or mineral salt, or mysterious combinations of these, with special proteins, carbohydrates, and the like. Every field of nutritional science, in which a vast amount of research work is being done, has been or will be exploited by preparations of this character. It is essential to the well-being of the public that provisions be made to keep abreast of these developments and to require informative labeling to accord with the facts as they are uncovered from time to time. For this reason S. 2800 delegates the power to the enforcing agency to establish regulations requiring fully informative labeling on these special dietary preparations. No provision of this kind occurs in the present law.[47]

Thus, it appears that Senator Copeland, at least, intended 403 (j) to cover fully the problems raised by special dietary products and the question becomes: Did Congress, by enacting a special statutory

[46] 78 Cong. Rec. 8959, May 16, 1934. [47] 78 Cong. Rec. 8960, May 16, 1934.

scheme in section 403 (j) for the control of dietary products, intend to exclude such products from section 401? Presumably this question will be answered before the June 18 regulations become law. At any rate, the fact that FDA can so ignore a statute under which it operates only indicates that it regards expediency as superior to statutory obedience.

Conclusion

We have presented only a few of the highlight problems facing those who have dealt with FDA matters in the last few years. We could not have hoped to cover them all. For instance, discovery under the Federal Rules in food and drug cases has taken a peculiar turn all its own, with the courts permitting the almost unlimited use of interrogatories covering the most detailed sort of scientific and medical technology.[48] Also, we have not discussed the problems of compliance under some of the sections of the new laws which have not yet been litigated and for which there are no judicial guidelines.

Unfortunately too, it has not been possible to discuss FDA's latest attempts to expand its authority. In recent criminal information brought against reputable pharmaceutical manufacturers the government has charged that certain drugs were misbranded because the Physicians' Desk Reference (PDR), a book published by Medical Economics, Inc., did not contain full disclosures of side effects for these drugs. PDR is a standard reference text for drugs commonly used by physicians in this country. The descriptions of the drugs are supplied to the publisher by the companies who pay for the space taken. The publisher controls the distribution of PDR from that point.

In order to sustain its position in these cases, the FDA must demonstrate that PDR constitutes labeling as that term is defined in the Food and Drug Act[49] as "all labels and other written, printed, or graphic matter . . . (2) accompanying such article." Thus FDA must demonstrate that PDR "accompanies" the challenged drug.[50]

Courts have held that the term "accompanying" refers to the fact that the suspect document traveled from the same source to the same destination as the drug involved, but there is no requirement that the document physically accompany the product. It must, however, have

[48] Compare *United States v. Article . . . "Sudden Change,"* 36 *FRD* 695 (E.D. N.Y., 1965) with *United States v. an Article . . . "Sudden Change,"* CCH FOOD DRUG COSMETIC LAW REPORTS, 40, 180. Same case: Court denied claimant's objections to 57 interrogatories filed by the government but later sustained Government's objections to similar interrogatories filed by claimant.

[49] 21 USC 321(m).

[50] Cf. *United States v. 353 Cases Mountain Valley Mineral Water,* 247 F. 2d 473 (8 Cir., 1957).

been employed in the sale of the product and be textually related to it.[51] Here, however, PDR is not sold or distributed by the drug companies involved, the book publisher, an independent business, handles all of this and determines its own distribution. In this connection the recent statement by a Court in instructing a jury as to what is "labeling" is apposite:

> I instruct you, however, that not all advertising, promotional or instructional literature used . . . is labeling. If you are not convinced beyond a reasonable doubt that Government's Exhibit 11, [is] . . . part of the labeling for reasons that some third party rather than the defendants placed or caused the brochure to be placed in the [store] then it is your duty to acquit the defendants on both counts. . . .[52]

It should be interesting to observe what weight this instruction may have in the pending cases. Deeper analysis of the effect of these suits must await further rulings of the Courts upon vigorous defense by the companies involved.

We do hope that this limited discussion has served to point up some of the legally more interesting aspects of this vast and expanding field of practice. If it has done nothing more than to offer the thought that there *are* two sides to FDA regulatory issues and that it is worthwhile to challenge roughshod authority, then it has served its purpose. **[The End]**

DECISION ON COLOR ADDITIVES TO BE REVIEWED BY THE U. S. SUPREME COURT

The United States Supreme Court will review the decision of the Court of Appeals for the Second Circuit in *The Toilet Goods Association, Inc. et al. v. John W. Gardner, HEW Secretary,* U. S. Court of Appeals (CA-2), April 13, 1966, Food Drug Cosmetic Law Reports ¶ 40,225. This decision has been found to be in conflict with a decision made by the Third Circuit Court of Appeals (*Abbott Laboratories, et al. v. Anthony J. Celebrezze, HEW Secretary,* U. S. Court of Appeals (CA-3), November 1, 1965, Food Drug Cosmetic Law Reports ¶ 40,206). The Second Circuit gave cosmetic manufacturers the right to test the validity of certain color additive regulations before they were actually enforced or violated. But the Third Circuit Court of Appeals held that a drug manufacturer could not test the validity of regulations that require the generic name of a prescription drug to appear every time the trade name appears on the labeling prior to the enforcement of those regulations.

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[51] *United States v. An undetermined number of cases . . . (Balanced Foods Claimant)* 338 F. 2d 157 (2 Cir., 1964).

[52] *United States v. R. G. B. Laboratories, Inc.,* CCH Food Drug Cosmetic Law Reports, ¶ 40,168, p. 40,472 (W.D. Mo., 1965) (Instructions to Jury).

The Food and Drug Administration and the Economic Adulteration of Foods

By WESLEY E. FORTE

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Part I: The History of Our Economic Adulteration Law

THE ECONOMIC ADULTERATION OF FOODS is an ancient cheat and scholars have found references to it in the laws of Moses and the early literature of China, Greece and Rome.[1] The reported economic adulterations of foods increased unmistakably in the 1800's and early 1900's[2] and it was in this period of public indignation resulting from reports of milk diluted with water, coffee diluted with chicory and other roasted vegetable products, maple syrup diluted with cane sugar or glucose, and spices diluted with ground wheat and corn that Congress first passed prophylactic legislation preventing the debasement of foods.[3] This legislation was part of the 1906 Food and Drugs Act.[4] The provisions of the 1906 Act dealing with economic adulteration were strengthened in the superseding statute, the Federal Food, Drug and Cosmetic Act of 1938.[5] Section 402 (b) of the Federal Food, Drug and Cosmetic Act covers economic adulteration and this section provides that a food is adulterated:

> (b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.[6]

For footnotes see pages 538 and following.

Additionally, section 402 (d) of the act bars economic adulteration through the use of nonnutritive substances in confectionery.[7] The Food and Drug Administration (FDA), acting under the supervision of the Secretary of Health, Education and Welfare (HEW), has the responsibility of enforcing the provisions of the Federal Food, Drug and Cosmetic Act prohibiting economic adulteration.[8]

In 1914, Congress empowered the Federal Trade Commission (FTC) to stop "unfair methods of competition in commerce."[9] These provisions were also strengthened in 1938 when Congress in the Wheeler Lea Act gave the FTC the additional power to stop "unfair or deceptive acts or practices in commerce."[10] Economic adulteration of foods is an "unfair method of competition" and an "unfair or deceptive act or practice" and therefore the FDA and the FTC have concurrent jurisdiction over this practice.[11] However, with a few notable exceptions which have been largely of historical interest,[12] the FTC has deferred to the FDA in the handling of this matter and economic adulteration is therefore regarded as an FDA problem.[13] Violations of the economic adulteration sections of the Federal Food, Drug and Cosmetic Act can result in either criminal penalties[14] or seizure of the offending food[15] but the statutory provisions in the act are general, vague, complex, and abstruse. There are no regulations clarifying the economic adulteration sections of the act and the courts have been understandably reluctant to impose criminal sanctions on individuals who cannot determine in advance whether their conduct may later be held illegal.[16] The patent need for either a better understanding of our present statute or a revised improved statute makes a review of the prohibitions against economic adulteration both timely and appropriate.

Economic adulteration is of a different gender than most other adulterations of food. Other adulterated foods are generally poisonous, deleterious, filthy, decomposed, or contaminated.[17] Foods which are economically adulterated have none of these "dangerous" characteristics. On the contrary, economically adulterated foods may be and frequently are healthful and nutritious. The problem is primarily one of economic cheat with only incidental dangers to health.[18]

Economic adulteration is the sole economic cheat classified as an adulteration under the Federal Food, Drug and Cosmetic Act. The other economic cheats are classified as misbrandings,[19] which may result in less serious consequences. The primary difference under

For footnotes see pages 538 and following.

the present statute is that the FDA can make multiple seizures of adulterated food immediately whereas multiple seizures of misbranded food are not permitted (except under special circumstances) until the government has secured a judgment that the food is misbranded.[20] This classification of economic adulteration as a more serious offense than the other economic cheats does not have any discernable basis in logic.[21] Economically adulterated foods are generally foods of inferior composition which may be confused with foods of superior composition and economic adulteration is prohibited because of the possibility that the inferior food may be passed off for the superior food at some point in the distribution system.[22] The offense is therefore similar to the offering of a food for sale under another name, or the selling of an imitation food without labeling it "imitation," or the selling of a standardized food which does not meet governmental standards. Yet all of these other "passing-off" type offenses are classified as misbrandings rather than adulterations.[23] The more drastic classification of economic adulteration probably reflects the public indignation aroused by reports of economic adulteration at the time the 1906 Act was passed as well as the revulsion most of us still feel at the thought of any tampering with the composition of our foods.

> The 1906 Food and Drugs Act provided that a food is adulterated:
>
> First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.
>
> Second. If any substance has been substituted wholly or in part for the article.
>
> Third. If any valuable constituent of the article has been wholly or in part abstracted.
>
> Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.[24]

The generality of language in this definition of adulteration was such that, standing alone and interpreted literally, it could have seriously impeded improvements in the composition of fabricated foods.[25] This result was avoided under the 1906 Act by two provisos. The provisos stated that a food which contained no added poisonous or deleterious ingredients was not adulterated if it was either (i) a mixture or compound sold under its own distinctive name, or (ii) a compound, imitation, or blend plainly labeled as such.[26] All fabricated foods could therefore be excluded from the economic adulteration prohibitions

For footnotes see pages 538 and following.

of the 1906 Act simply by labeling the foods in conformity with the provisos.[27] The provisos thus provided the honest manufacturer with the opportunity to continue the development and sale of new and improved foods and the dishonest manufacturer with the opportunity to palm off inferior foods on the public under more or less distinctive names.

Upon the passage of the 1906 Act, the government began a vigorous attack upon economic adulteration in both criminal and civil cases. Convictions were secured in numerous criminal[28] and civil[29] cases. Interspersed among the government's many victories in economic adulteration cases were a considerable number of defeats. Some of these defeats resulted from problems inherent in all litigation (for example, faulty pleadings[30] and adverse findings of fact)[31] but other defeats resulted from problems which were unique to economic adulteration law. These problems included difficulties in proving the standard against which the allegedly debased food was to be judged[32] and problems created by the two provisos.

Litigation under the distinctive name proviso tended to produce bizarre results. Manufacturers frequently adopted names which were more descriptive than distinctive for foods of inferior composition which were then passed off as familiar superior foods on the unsuspecting public. A classic example was a product which looked like, tasted like, and was used for the same purpose as jam but which contained little fruit and was labeled "Bred Spred." Economic adulteration charges against this product were dismissed because the court held that "Bred Spred" was a distinctive name.[33] In like decisions, an imitation grape juice labeled "Grape Smack" was absolved under the distinctive name proviso,[34] as was a product which consisted of calcium acid phosphate and corn starch and was labeled with the initials of its more expensive ingredient, "C.A.P."[35] One court even decided that "Macaroons" was a distinctive name thereby exculpating the defendant-producer (and presumably all other producers of macaroons) from the federal economic adulteration laws.[36] Other decisions were more rational, holding, for example, that "Mapleine"[37] and "Maple Flavo"[38] were not distinctive names for imitation maple flavors. "Grant's Hygienic Crackers" was correctly held to be a distinctive name;[39] "Fruit Puddine" and "Cream Vanilla" were both held to be distinctive names in a more dubious decision,[40] and one misguided judge submitted the question whether "Milk

For footnotes see pages 538 and following.

Chocolate" was a distinctive name to the jury, which ultimately exonerated a defendant who was accused of adulterating his milk chocolate with wheat starch.[41]

Equally absurd results occurred when the courts considered the proviso absolving from economic adulteration charges all products which were compounds, imitations, or blends and were plainly labeled as such.[42] One court held that an imitation cherry juice labeled "Fruit Wild Cherry Compound" was not adulterated because it was labeled "compound,"[43] while another court held that a product called "Compound Ess Grape" was adulterated (despite the word "compound") because it consisted only of imitation grape essence.[44] A product labeled "Compound White Pepper" was held economically adulterated because corn had been intermixed with the pepper, although the court indicated that if the product had been labeled "White Pepper Compound," the economic adulteration charges would have been dismissed.[45] There was a marked difference of opinion concerning whether the ingredients of compounds had to be listed on the labels of these products,[46] and, while the economic adulteration sections of the 1906 Act may have been theoretically workable,[47] in general it was impossible to predict the results of any litigation in which one of the provisos was raised as a defense to an economic adulteration charge. The conflicting decisions, their apparent absurdity, and the certainty that the public was still being defrauded through some of these products brought a demand for legislative reform, and it was in this context that in 1938 the Federal Food, Drug and Cosmetic Act was enacted.

The Federal Food, Drug and Cosmetic Act struck directly at the defenses which manufacturers had raised in economic adulteration cases. First, the new statute permitted the government after notice and hearing to define the composition of each food in regulations called "standards of identity."[48] After a food was defined by the government in a standard of identity the producers of that food either had to comply with the standard, or label and sell their products as imitations.[49] Second, the new statute required all non-standardized foods which were fabricated from two or more ingredients to state each such ingredient on the label.[50] Finally, and most important, the new statute enacted the economic adulteration provisions of the 1906 Act in slightly broader language,[51] repealing at the same time the two provisos which had exonerated from the economic adulteration

For footnotes see pages 538 and following.

laws all fabricated foods which were either labeled with distinctive names or as compounds, imitations, or blends.[52] The repeal of these provisos left the language of the 1906 Act in slightly broadened form standing by itself. This statute, which is so broad that it cannot be taken literally and so ambiguous that it can hardly be interpreted intelligently, became Section 402 (b) of the Federal Food, Drug and Cosmetic Law and is our present law. The statute does not define the standards used to determine economic adulterations and this has been one of the many complex problems faced by the courts in economic adulteration cases. **[To Be Continued in the November Issue]**

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[1] See Hart, "A History of the Adulteration of Food Before 1906," 7 FOOD DRUG COSMETIC LAW JOURNAL 5 (January 1952); see also Kleinfeld, "Legislative History of the Federal Food Drug and Cosmetic Act," 1 FOOD DRUG COSMETIC LAW QUARTERLY 532 n.1 (1946); Kushen, "The Significance of Section 402 (b)," 10 FOOD DRUG COSMETIC LAW JOURNAL 829 (1955).

[2] The increase was probably due to both the industrialization and urbanization of the Western World (with the greater impersonality of commercial relations) and the development of analytical chemistry (which made it possible to discover debased foods). See Anderson, *The Health of a Nation* 69 (1958); Hart, cited at footnote 1, at 13-22; see also Anderson, "Pioneer Statute: The Pure Food and Drugs Act of 1906," 13 *Journal of Public Law* 189 (1964).

[3] See footnote 2; Hart, "Food Adulteration in the Early Twentieth Century," 7 FOOD DRUG COSMETIC LAW JOURNAL 485 (1952). The statute which preceded the 1906 Food and Drugs Act was concerned only with the importation of adulterated food, drugs or liquor. See ch. 839, § 2, 26 Stat. 415 ('890). Both before and after passage of the 1906 Act and its superseding statute, the Federal Food, Drug & Cosmetic Act of 1938, Congress passed legislation to prevent the sale of specific adulterated foods within federal jurisdiction. Some of these laws prohibited the sale of specific adulterated foods, see for example, Tea Importation Act, 29 Stat. 604 (1897), as amended, 21 U.S.C. §§ 41-50 (1958); Filled Milk Act, 42 Stat. 1486 (1923), 21 U.S.C. §§ 61-64 (1958); Meat Inspection Act, 34 Stat. 1260 (1907), as amended, 21 U.S.C. §§ 71-91 (1958); Butter Standard Act, 42 Stat. 1500 (1923), 21 U.S.C. § 321(a) (1958); Import Milk Act, 44 Stat. 1101 (1927), as amended, 21 U.S.C. §§ 141-49 (1958), while other laws imposed taxes upon the sale of such foods or similar foods. See for example, Oleomargarine Tax Act, Internal Revenue Code of 1954, §§ 4591-97; Adulterated and Process or Renovated Butter Act, Internal Revenue Code of 1954, §§ 4811-26; Filled Cheese Act, Internal Revenue Code of 1954, §§ 4831-46. However, the 1906 Food and Drugs Act was the first legislation banning adulterated foods in general from interstate commerce and its superseding statute, the Federal Food, Drug & Cosmetic Act of 1938 (which contains adulteration provisions similar to the 1906 Act), is still our basic adulteration law.

[4] Federal Food & Drugs Act of 1906, ch. 3915, § 7, 34 Stat. 768, repealed, 52 Stat. 1059 (1938).

[5] Section 402 (b) of the Federal Food, Drug & Cosmetic Act, 52 Stat. 1046 (1938), 21 U.S.C. § 342(b) (1958), enacted the economic adulteration pro-

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visions of the 1906 Act in slightly broader language and abolished certain provisos in the 1906 Act which had been used as defenses by the manufacturers of fabricated foods. See text accompanying footnotes 48-52.

[6] See statute cited at footnote 5.

[7] 52 Stat. 1046 (1938) as amended, 21 U.S.C. § 342(d) (1958), provides generally that confectionary is adulterated if it contains any nonnutritive substance except flavoring, coloring, and other minor ingredients. This section supersedes a section of the 1906 Act which classified confectionary containing talc and other such substances as adulterated. See Act of June 30, 1906, ch. 3915, § 7, 34 Stat. 768, repealed, 52 Stat. 1059 (1938). The candy industry has objected to § 402(d) of the Federal Food, Drug & Cosmetic Act of 1938 and its predecessor statute as unnecessary in view of the provisions in these acts which prohibit economic adulteration of foods in general. A bill to repeal § 402(d) has twice passed the House of Representatives but has never been acted upon by the Senate. See *Annual Report of National Confectioners Association* 5 (1964-1965). The most current versions of the bill were H.R. 7042, 89th Cong., 1st Sess. (1965) and S. 1839, 89th Cong., 1st Sess. (1965) and the bill died after being favorably reported to the Senate Labor and Public Welfare Committee by a special subcommittee.

[8] The administration of the Federal Food, Drug & Cosmetic Act of 1938 was originally the responsibility of the Department of Agriculture until its transfer first to the Federal Security Administrator and finally to the Secretary of HEW. See 1 CCH Food, Drug & Cosmetic Law Reports 4108.

[9] 38 Stat. 719 (1914), as amended, 15 U.S.C. § 45(a)(6) (1964).

[10] 52 Stat. 111 (1938), 15 U. S. C. § 45(a)(6) (1964).

[11] FDA's jurisdiction is based on § 402(b) of the Federal Food, Drug & Cosmetic Act, 52 Stat. 1046 (1938), 21 U. S. C. § 342(b) (1958). "Economic adulteration" is food and drug law terminology. The FTC does not purport to handle economic adulteration cases, or even to have jurisdiction over this practice as such. However, under § 5 of the Federal Trade Commission Act, 38 Stat. 719 (1914), as amended, 15 U. S. C. § 45(a)(6) (1964), the FTC has the power to prevent "unfair methods of competition" and "unfair or deceptive acts and practices," and, under that authority, the FTC has acted to prevent the sale of debased foods which deceive the public and divert trade from honest competitors. See *Fresh Grown Preserve Corp. v. FTC*, 125 F. 2d 917 (2d Cir. 1942), in which the FTC alleged that it was unfair competition to label as "preserves" a food not containing at least 45% fruit; see also *FTC v. Morrissey*, 47 F. 2d 101 (7th Cir. 1931); *FTC v. Good-Grape Co.*, 45 F. 2d 70 (6th Cir. 1930) ("Good-Grape" soft drink with no natural grape flavor); *cf. FTC v. American Snuff Co.*, 38 F. 2d 547 (3d Cir. 1930); *Royal Baking Powder Co. v. FTC* 281 Fed. 744 (2d Cir. 1922), in which the FTC alleged that respondents' packages were associated with products composed of certain ingredients and that it was deceptive for respondents to use the same style packages after basic changes had been made in the composition of these products. Some of the FTC's cases are virtually indistinguishable from the economic adulteration cases brought by the FDA and predecessor agencies. Compare, for example, *FTC v. Morrissey* and *FTC v. Good-Grape Co.* with *United States v. 88 Cases of Bireley's Orange Beverage*, 187 F. 2d 967 (3d Cir.), *cert. denied*, 342 U. S. 861 (1951) and *United States v. 24⅞ Gallons of Smack*, (E. D. Wis. 1926), a 1906 Act case reported unofficially in White & Gates, Decisions of Courts in Cases under the Federal Food and Drugs Act 1181 (1934) (hereinafter cited as White & Gates). Some of the FTC's trade practice rules also help to prevent economic adulteration of foods. See, for example, Preserve Manufacturing Industry Rules, 16 C. F. R. 114.1 (1960); Tomato Paste Manufac-

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turing Industry Rules, 16 C. F. R. 133.1-.3 (1960); Tuna Industry Rules, 16 C. F. R. 146.1-.2 (1960).

[12] See FTC cases cited at footnote 11.

[13] The FTC and the FDA have a Working Agreement defining their areas of primary responsibility. The Working Agreement is set forth at 3 *Trade Reg. Rep.* ¶ 9850 (1954), and it provides that, unless the agencies otherwise agree, the FTC will exercise sole jurisdiction over all advertising of foods, drugs, devices, and cosmetics and the FDA will exercise sole jurisdiction over all labeling of these products. FTC's cases against the debasement of foods have been on the theory that this appearance (especially their labeling) has permitted them to be "passed off" on the unsuspecting public as foods of more expensive composition. Accordingly, the FTC probably regards economic adulteration of foods primarily as a deceptive labeling problem and, in the Working Agreement, the FTC ceded the responsibility of regulating the deceptive labeling of foods to the FDA.

[14] Violation of the economic adulteration sections of the Federal Food, Drug & Cosmetic Act can result in imprisonment for not more than one year or a fine of not more than $1,000 or both for the first offense, 52 Stat. 1043 (1938), 21 U. S. C. § 333(a) (1958), and imprisonment for not more than three years, or a fine of not more than $10,000 or both, if the violation was committed with intent to defraud or mislead or if the offender had a previous conviction, 21 U. S. C. § 333(b) (1958).

Criminal penalties may be imposed under the Federal Food, Drug & Cosmetic Act even if the defendant has committed no wrongful act and lacks any knowledge of wrong-doing. All that is required is that the defendant stand in a reasonable relationship to the wrong. See *United States v. Dotterweich*, 320 U. S. 277 (1943); *United States v. Parfait Powder Puff Co., Inc.*, 163 F. 2d 1008 (7th Cir. 1947), *cert. denied*, 332 U. S. 851 (1948).

[15] The government can proceed against adulterated or misbranded foods having the requisite connection with interstate commerce by libel and such foods may be condemned and destroyed or required to be brought into compliance with the act. 52 Stat. 1044 (1938), as amended, 21 U. S. C. § 334 (1958). The seizure remedy is more severe in adulteration cases than in misbranding cases for two reasons. First and most important, the government can make multiple seizures of allegedly adulterated food immediately without court action whereas multiple seizures of allegedly misbranded food are not usually permitted until after the government has secured an initial judgment that the foods are misbranded. Second, if the government succeeds in a condemnation action against misbranded food, the claimant generally can recover the seized goods and revise the labeling or otherwise bring the foods into compliance with the act. However, if the government succeeds in a condemnation action against adulterated food, the same opportunity will probably not exist. Because labeling will not usually cure an adulteration, adulterated foods must generally be reprocessed or destroyed if the government is successful. See *United States v. 716 Cases of Del Comida Brand Tomatoes*, 179 F. 2d 174 (10th Cir. 1950), holding that watered tomatoes cannot be released for truthful labeling. There is one possible exception. Some foods which are economically adulterated may comply with the law if they are re-labeled as "imitations." Compare *United States v. 30 Cases of Leader Brand Strawberry Fruit Spread*, 93 F. Supp. 764 (S. D. Iowa 1950) with *62 Cases of Jam v. United States*, 340 U. S. 593 (1951).

[16] See, for example, *United States v. Fabro, Inc.*, 206 F. Supp. 523 (M. D. Ga. 1962); see also *Van Liew v. United States*, 321 F. 2d 664 (5th Cir. 1963).

[17] Adulterated foods are generally those which are either deleterious or have been manufactured with potentially deleterious ingredients or under potentially dangerous conditions. This

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includes foods containing added poisonous substances, unsafe food additives, color additives, or pesticide chemicals, filthy, putrid, or decomposed substances, as well as foods which are packed under unsanitary conditions or are the products of diseased animals. See 52 Stat. 1046 (1938), as amended, 21 U. S. C. § 342 (1958). Some adulterated foods may be fit for human consumption, for example, foods bearing unsafe additives or packed under unsanitary conditions or foods containing some decomposed material, see *Salamonie Packing Co. v. United States,* 165 F. 2d 205 (8th Cir.), *cert. denied,* 333 U. S. 863 (1948); *United States v. 935 Cases of Tomato Puree,* 65 F. Supp. 503 (N. D. Ohio 1946), but such foods are, in general, potentially deleterious. The classification of such foods as adulterated (whether or not they are individually harmful) probably raises the general standards of safety in the food industry.

Economically adulterated foods generally have neither the deleterious characteristics nor the deleterious potentialities of the other adulterated foods. Perhaps the adulteration offense most similar to economic adulteration is found in § 402(a)(3). Section 402 (a)(3) classifies as adulterated those foods which are "otherwise unfit for food" and this has been interpreted as including foods which people would not eat as well as foods which they could not eat. See *United States v. 24 Cases of Herring Roe,* 87 F. Supp. 826 (D. Me. 1949) (herring roe having a tough, rubbery consistency); *cf. United States v. 298 Cases of Asparagus,* 88 F. Supp. 450 (D. Ore. 1949) (asparagus allegedly too woody and fibrous). If this liberal interpretation prevails, § 402 (a)(3) cases may raise the same problem as the economic adulteration cases; the problem of determining when the food varies so far from the norm that the public is defrauded. *Cf.* Steffy, "Otherwise Unfit For Food—A New Concept in Food Adulteration," 4 FOOD DRUG COSMETIC LAW JOURNAL 552, 560-62 (1949) in which the author takes the position that articles otherwise unfit for food are those which offend aesthetic tastes, citing uncontested FDA seizures of foods having abnormal and offensive odors, colors, and flavors.

[18] See, for example, *United States v. 5 Cases of Figlia Mia Brand Vegetable Oils,* 179 F. 2d 519 (2d Cir.), *cert. denied,* 339 U. S. 963 (1950) (involving diluted salad oils); *United States v. 716 Cases of Del Comida Brand Tomatoes,* 179 F. 2d 174 (10th Cir. 1950) (involving diluted canned tomatoes); *United States v. 30 Cases of Leader Brand Strawberry Fruit Spread,* 93 F. Supp. 764 (S. D. Iowa 1950) (involving diluted jam); *United States v. 254 Cases of Baby Brand Tomato Sauce,* 63 F. Supp. 916 (E. D. Ark. 1945) (involving diluted tomato sauce). All of the foods involved in these cases were healthful and nutritious although not as healthful and nutritious as the superior foods they simulated. *Cf. Van Liew v. United States,* 321 F. 2d 664 (5th Cir. 1963) in which the government conceded that defendant's orange drink was just as good and just as palatable and had just as many vitamins as freshly squeezed orange juice. However, the confusion caused by economic adulteration may result in dangers to health in some situations. *Cf.* The 1950 Annual Report of the FDA, Kleinfeld & Dunn, Federal Food, Drug and Cosmetic Act 1953-57 at 564, 569 (1957). [The five volumes under this title for 1938-49, 1949-50, 1951-52, 1953-57, and 1958-60 are hereinafter cited as 1, 2, 3, 4, or 5 Kleinfeld, respectively. The first four volumes of the book were written by Kleinfeld and Dunn and the fifth volume was written by Kleinfeld and Kaplan] in which the FDA suggested that many mothers were being deceived into serving orangeade instead of orange juice, thus impairing the health of small children.

[19] These offenses generally are false or misleading labeling, sale under the name of another food, sale of an imitation food not prominently marked as such, deceptive packaging, failure to state certain mandatory information prominently on the label, and failure

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to conform to the standards of identity, quality, or fill of container. See 52 Stat. 1047 (1938), as amended, 21 U. S. C. § 343 (1958).

[20] Generally, the FDA can only make one seizure of a misbranded food until it has secured a judgment in its favor. See 52 Stat. 1044 (1938), 21 U. S. C. § 334(a) (1958). However, if the Secretary has probable cause to believe that the misbranded article is dangerous to health, or that its labeling is fraudulent or that it would be in a material respect misleading to the injury or damage of the purchaser or consumer, multiple seizures may be made immediately.

The claimant has no right to a hearing on the facts which are the basis for seizures and the Secretary's findings of facts are not subject to judicial review even if they are arbitrary and capricious. See *Ewing v. Mytinger and Casselberry*, 339 U. S. 594 (1950).

[21] If logic were the test, the offenses could appropriately have been divided into more or less serious categories, depending upon whether the offense resulted in a danger to health or merely an economic violation. Alternatively, the offenses could also have been appropriately divided into more or less serious categories depending on whether the offense related to the composition of the food itself or merely to its label or container or the information printed thereon. The classification of offenses in the present statute is not supported by either rationale.

[22] Foods may be economically adulterated although there is no immediate danger of passing-off. Truthful labeling is, in general, therefore no defense to an economic adulteration charge. See *United States v. 36 Drums of Pop'N Oil*, 164 F. 2d 250 (5th Cir. 1947); *United States v. Two Bags of Poppy Seeds*, 147 F. 2d 123 (6th Cir. 1945).

[23] See 52 Stat. 1047 (1938), as amended, 21 U. S. C. § 343 (1958).

[24] Act of June 30, 1906, ch. 3915, § 7, 34 Stat. 768, repealed, 52 Stat. 1059 (1938).

[25] The broadest and most restrictive section of the 1906 Act prohibited substituting any substance in whole or in part for the food. Since most improvements in fabricated foods are made by substituting one ingredient for another, this provision (without the provisos) could have imposed serious limitations on the food industry. Other provisions could have raised similar if less serious problems. The section of the 1906 Act prohibiting abstracting of valuable constituents of foods could have prevented the development of dietary foods. The section of the 1906 Act prohibiting coloring a food to conceal inferiority could have impeded the expanding use of artificial colorings. (Consider, for example, whether artificial coloring in oleomargarine or orange soda merely makes those foods more visually attractive or conceals their inferiority.) However, the most serious problems were those raised by the prohibition against substitution of ingredients under the 1906 Act, and this problem was solved by the provisos which provided fabricated foods were not adulterated if they were sold under distinctive names or as compounds, imitations or blends.

[26] See statute cited at footnote 24, at § 8.

[27] Fabricated foods are foods which are made by combining two or more ingredients. *Cf.* 52 Stat. 1047 (1938), 21 U. S. C. § 343(i)(2) (1958).

[28] See, for example, *Union Dairy Co. v. United States*, 250 Fed. 231 (7th Cir. 1918) (milk diluted by water); *Frank v. United States*, 192 Fed. 864 (6th Cir. 1911) (pepper diluted by corn); *United States v. Frank*, 189 Fed. 195 (S. D. Ohio 1911) (lemon extract diluted by alcohol and water); *United States v. South Hero Creamery Ass'n*, White & Gates 1142 (D. Vt. 1925) (butter with less than 80% milk-fat); *United States v. Atlantic Macaroni Co.*, White & Gates 793 (E. D. N. Y. 1917) (macaroni dyed yellow to conceal inferiority); *United States v. German American Specialty Co.*, White & Gates 459 (S. D.

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N. Y. 1913) (eggs diluted by skim milk); *United States v. Libby, McNeill & Libby*. White & Gates 442 (E. D. Va.), *aff'd*, 210 Fed. 148 (4th Cir. 1913) (condensed skimmed milk diluted by sugar).

[29] See, for example, *United States v. 60 Barrels of Wine*, 225 Fed. 846 (W. D. Mo. 1915) (claret wine diluted by pomace wine); *William Henning & Co. v. United States*, 193 Fed. 52 (5th Cir. 1912) (catsup diluted by pumpkin); *United States v. 100 Barrels of Vinegar*, 188 Fed. 471 (D. Minn. 1911) (cider vinegar diluted by distilled vinegar); *United States v. 420 Sacks of Flour*, 180 Fed. 518 (E. D. La. 1910) (flour bleached to conceal inferiority), But see, *Lexington Mill & Elevator Co. v. United States*, 202 Fed. 615 (8th Cir. 1913), *aff'd*, 232 U. S. 399 (1914).

[30] The generality of the statute invited vague pleadings but the courts insisted that the defendant be informed with sufficient particularity or certainty of the charge against him to enable him to prepare his defense. See, for example, *United States v. Krumm*, 269 Fed. 848 (E. D. Pa. 1921); *United States v. St. Louis Coffee & Spice Mills*, 189 Fed. 191 (E. D. Mo. 1909); *United States v. 154 Cases of Tomatoes*, White & Gates 967 (W. D. Pa. 1920).

[31] See *United States v. Lexington Mill & Elevator Co.*, 232 U. S. 399 (1914) (*affirming* a court of appeals' decision which reversed a verdict because there was no substantial evidence that the bleaching of flour concealed inferiority); *Hall-Baker Grain Co. v. United States*, 198 Fed. 614 (8th Cir. 1912) (holding that there was no evidence to support a verdict that No. 2 wheat had been adulterated by inferior wheat); *United States v. 3998 Cases of Canned Tomatoes*, White & Gates 1213 (D. Del. 1928) (jury failed to find that excess water had been added to canned tomatoes); *United States v. 200 Sacks of Wheat Middlings*, White & Gates 1189 (E. D. Mich. 1926) (the court, sitting without a jury, failed to find that the grinding of wheat middlings into powder concealed their inferiority); *United States v. 4½ Cases of Creme De Menthe*, White & Gates 1191 (E. D. Mo. 1926) (jury failed to find that caffeine had been substituted in part for creme de menthe flavor non-alcoholic cocktail); *United States v. South Peacham Creamery Co.*, White & Gates 1147 (D. Vt. 1925) and *United States v. Barnet Creamery Ass'n*, White & Gates 1149 (D. Vt. 1925) (juries failed to find butter deficient in butterfat); *United States v. 37 One Pound Packages of Colors*, White & Gates 1165 (E. D. Pa. 1925) (jury failed to find that food colors had been diluted by paste); *United States v. Marmarelli*, White & Gates 1122 (S. D. N. Y. 1924) (jury failed to find that defendants had diluted olive oil with cottonseed oil); *United States v. Potter*, White & Gates 409 (E. D. N. C. 1912) (jury failed to find that excess water was used in canning oysters); *United States v. Heide*, White & Gates 325 (S. D. N Y. 1911) (jury failed to find that 5% glucose reduced the quality of almond paste); *United States v. St. Louis Coffee & Spice Mills*, 189 Fed. 191 (E. D. Mo. 1909) (directed verdict for the defendant because there was no evidence that vanilla extract and vanilla flavor were the same foods).

[32] The government did not have the authority to fix standards of identity having the effect of law under the 1906 Food and Drugs Act. See Crawford, "Ten Years of Food Standardization," 3 FOOD DRUG COSMETIC LAW QUARTERLY 243, 244-45 (1948). It was therefore necessary to prove in each case both the composition of the adulterated food and the ordinary or standard composition of the food alleged to be economically adulterated. Even when regulations had been promulgated by the Department of Agriculture defining the ordinary composition of foods, they were usually not given any weight. See, for example, *United States v. Swift & Co.*, White & Gates 1146 (D. Ore. 1925) (no standard of butterfat for butter); *United States v. St. Louis Coffee & Spice Mills*, 189 Fed. 191 (E. D. Mo. 1909) (no standard for vanilla flavor). But see, *United States v. Frank*, 189 Fed. 195 (S. D.

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Ohio 1911) (accepting USDA standards for lemon extract). Difficulties in determining the standard against which the adulterated food was to be judged confounded the courts and resulted in judgments against the government in some cases. See *United States v. Swift & Co.; United States v. St. Louis Coffee & Spice Mills;* and *United States v. Rinchini,* White & Gates 318 (D. Ariz. 1911) (no standard of butterfat for ice cream); *W. B. Wood Mfg. Co. v. United States,* 286 Fed. 84 (7th Cir. 1923) (no standard for salt in food colors); *United States v. 30 Cases of Grenadine Syrup,* 199 Fed. 932 (D. Mass. 1912) (no standard requiring pomegranate juice in grenadine syrup). See "1933 Report of the Food and Drug Administration," p. 14, which is reprinted in Dunbar, *Federal Food, Drug & Cosmetic Law, Administration Reports* 1907-49, 800 (1951). However, the government was "fairly successful" in proving the composition of foods in judicial proceedings although it objected to the expense and complexity of that procedure. See "1931 Report of the Food and Drug Administration," pp. 5-6, which is reprinted in Dunbar, at 742-43.

[33] "Bred Spred" was the subject of three reported seizure actions, all of which ended unhappily for the government. In the first case (which ended in an informal and ambiguous opinion by the district court), the judge apparently concluded that a food which was not labeled with the distinctive name of another food was exempt from the economic adulteration laws under the distinctive name proviso. *United States v. 49½ Cases of Bred Spred,* White & Gates 1204 (E. D. Mich. 1927); see Markel, "The Law on Imitation Food," 5 FOOD DRUG COSMETIC LAW JOURNAL 145, 154 (1950). The second case was dismissed because it involved the same issues as the first Bred Spred case and the first case therefore operated as a collateral estoppel against the government. *United States v. 15 Cases of Bred Spred,* 35 F. 2d 183 (7th Cir. 1929). In the third case, the circuit court held that there was no proof that Bred Spred was economically adulterated because of concealed damage or inferiority. The court reasoned that the ingredients in Bred Spred were not of low quality and that the only allegation was that Bred Spred contained less fruit than ordinary jam. *United States v. Ten Cases of Bred Spred,* 49 F. 2d 87 (8th Cir. 1931). The comparison of Bred Spred with ordinary jam was inappropriate, according to the court, because there was no proof that Bred Spred was being palmed off on the public as jam. A misbranding charge grounded on the theory that Bred Spred was an imitation jam (not labeled as such) was defeated because the government had, incredibly, failed to make the exhibit-jars of Bred Spred and the exhibit-jars of jam part of the record on appeal. The Circuit Court was therefore unable to compare Bred Spred against jam to determine the imitation issue.

The Bred Spred cases provided much of the stimulus for the strengthening of the economic adulteration laws of the 1906 Act in the later Federal Food, Drug & Cosmetic Act. See *62 Cases of Jam v. United States,* 340 U. S. 593 (1951) and *United States v. 30 Cases of Leader Brand Strawberry Fruit Spread,* 93 F. Supp. 764 (S. D. Iowa 1950), in which the courts alluded to the effect of the Bred Spred case on Congress. See also Kleinfeld, "Legislative History of the Federal Food, Drug and Cosmetic Act," 1 FOOD DRUG COSMETIC LAW QUARTERLY 532, 548, 559 (1946), summarizing some of the testimony concerning Bred Spred during the hearings on the bills which later became the Federal Food, Drug & Cosmetic Act.

The irony is that the government might have won the third Bred Spred case under the 1906 Act thereby ending the fraud perpetrated on the public by that product, if the government had proved that Bred Spred was being passed off as jam or made the jars of Bred Spred and jars of jam part of the appellate record so that the

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court could decide whether or not Bred Spred was an imitation.

[34] *United States v. 24⅞ Gallons of Smack,* White & Gates 1181 (E. D. Wis. 1926).

[35] *United States v. 100 Barrels of Calcium Acid Phosphate,* White & Gates 58 (N. D. Cal. 1909).

[36] See *F. B. Washburn & Co. v. United States,* 224 Fed. 395 (1st Cir. 1915), *reversing* a judgment of adulteration on this and other grounds, but *affirming* a judgment of misbranding.

[37] *United States v. 300 Cases of Mapleine,* White & Gates 39 (N. D. Ill. 1909).

[38] *United States v. S. Gumpert,* White & Gates 182 (S. D. N. Y. 1910).

[39] *United States v. Hygienic Health Food Co.,* White & Gates 259 (N. D. Cal. 1911).

[40] "Fruit Puddine" was held to be a distinctive name for a pudding without fruit on the theory that the name had acquired a secondary meaning. "Cream Vanilla," a flavor of Fruit Puddine that contained vanillin rather than vanilla, presented more difficult problems. The government suggested that Cream Vanilla implied that the pudding was flavored with the best vanilla (cream of the vanilla) but the claimant persuaded the court that Cream Vanilla was an arbitrary designation. Fruit Puddine was, however, held to be misbranded because it was falsely labeled "Fruit Flavored." *United States v. 150 Cases of Fruit Puddine,* 211 Fed. 360 (D. Mass. 1914).

[41] *United States v. Auerbach & Sons,* White & Gates 357 (S. D. N. Y. 1912).

[42] Act of June 30, 1906, ch. 3915, § 8, 34 Stat. 768, *repealed,* 52 Stat. 1059 (1938).

[43] *Weeks v. United States,* 224 Fed. 64 (2d Cir. 1915), *aff'd on other grounds,* 245 U. S. 618 (1918).

[44] *United States v. Schider,* 246 U. S. 519 (1918).

[45] *Frank v. United States,* 192 Fed. 864 (6th Cir. 1911). The Court reasoned that the ordinary purchaser would believe that White Pepper Compound was white pepper plus another ingredient but that the ordinary purchaser would believe that Compound White Pepper was white pepper with added strength.

[46] There was no provision in the 1906 Food and Drugs Act expressly requiring the labeling of ingredients of compounds. However, the Department of Agriculture's regulations required a clear statement of the principal or essential ingredients of such foods and at least one economic adulteration case supported this type of requirement. See Rules and Regulations for the Enforcement of the Federal Food and Drugs Act (Ninth Revision) § 20(a) (1927) reprinted at I *Dunn's Food and Drug Laws* 14 (1927), (hereinafter cited as *Dunn*); *William Henning & Co. v. United States,* 193 Fed. 52 (5th Cir. 1912). *Contra United States v. Weeks,* White & Gates 519 (S. D. N. Y. 1913), *rev'd on other grounds,* 224 Fed. 64 (2d Cir. 1915), *aff'd,* 245 U. S. 618 (1918); *United States v. One Carload of Corno Horse and Mule Feed,* 188 Fed. 453 (M. D. Ala. 1911); *cf. United States v. Goodman,* White & Gates 484 (E. D. N. Y. 1913).

[47] The government's principal problems with economic adulteration cases under the 1906 Act were the problems of proving the standard composition of the food which was allegedly adulterated and the problems raised by the two provisos. Proof of the standard composition of a food is merely a question of fact and probably no more difficult than many other questions of fact decided in connection with ordinary negligence or patent cases. In general, the government was not losing many cases on the "standard" problem, see footnote 32, and it is likely that if the government continued to prepare its cases carefully and the appellate courts reviewed the record fairly, proof of the standard would not have been a major problem.

The problems raised by the provisos could have been resolved through a different interpretation of their language.

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The distinctive name proviso exempted mixtures or compounds sold under their own distinctive name "and not an imitation of or offered for sale under the distinctive name of another article." It could therefore be argued that a food which was an imitation was not exempted by the distinctive name proviso and, indeed, some courts so held, although others held contra. See *United States v. Five Cases of Champagne*, 205 Fed. 817 (N. D. N. Y. 1913); see also *Hudson Mfg. Co. v. United States*, 192 Fed. 920 (5th Cir. 1912); *cf. United States v. 9 Cases of Sparkling White Seal*, White & Gates 1023 (E. D. Pa. 1921), *aff'd*, 285 Fed. 737 (3d Cir. 1923). *Contra United States v. 24⅞ Gallons of Smack*, White & Gates 1181 (E. D. Wis. 1926). See also Markel, "The Law on Imitation Food," 5 FOOD DRUG COSMETIC LAW JOURNAL 145, 154-64 (1950). The Department of Agriculture regulation interpreting that proviso also stated that foods sold under distinctive names could not be imitations of other articles. See Rules and Regulations for the Enforcement of the Federal Food and Drugs Act § 19(b) (1927) (reprinted in *Dunn* 13).

The second proviso exempted compounds, imitations, and blends, if the word "compound," "imitation," or "blend" was stated plainly on the label. The Department of Agriculture regulations interpreting this proviso stated that an imitation food must be labeled "imitation" and that compounds and blends must be labeled "compounds" and "blends." See Rules and Regulations for the Enforcement of the Federal Food and Drugs Act § 20 (1927) (reprinted at *Dunn* 14). Had the courts decided that many of the products challenged by the government were imitations and could only be sold as such rather than as compounds and blends, this proviso also would have offered no refuge for those defrauding the public. *Cf. United States v. Schider*, 246 U. S. 519 (1918).

The remaining problems under the 1906 Act would be little different from the problems which the government has now under the Federal Food, Drug & Cosmetic Act. However, the provisos might under these revised interpretations offer desirable counterparts to the present all inclusive language of § 402(b).

[48] Under § 401 of the act, when such action will promote honesty and fair dealing in the interest of consumers, the Secretary can fix a reasonable definition and standard of identity for a food. See 52 Stat. 1046 (1938), as amended, 21 U. S. C. § 341 (1958). Standards of identity have been promulgated for the following foods: Cacao Products (chocolate, cocoa, etc.), 21 C. F. R. 14 (1955); Cereal Flours, 21 C. F. R. 15 (1955); Macaroni and Noodle Products, 21 C. F. R. 16 (1955); Bakery Products (Bread & Rolls), 21 C. F. R. 17 (1955); Milk and Cream, 21 C. F. R. 18 (1955); Cheeses and Related Foods, 21 C. F. R. 19 (1959); Frozen Desserts (Ice Cream and Related Products), 21 C. F. R. 20 (1965); Food Flavorings (Vanilla Extract and Similar Products), 21 C. F. R. 22 (1963); Dressings for Foods (Mayonnaise, French and Salad Dressing), 21 C. F. R. 25 (1955); Canned Fruits and Fruit Juices, 21 C. F. R. 27 (1955); Fruit Butters, Jellies, and Related Products, 21 C. F. R. 29 (1955); Shellfish (Shrimp and Oysters), 21 C. F. R. 36 (1955); Canned Tuna Fish, 21 C. F. R. 37 (1958); Eggs and Egg Products, 21 C. F. R. 42 (1955); Oleomargarine and Margarine, 21 C. F. R. 45 (1955); Canned Vegetables, 21 C. F. R. 51 (1955); and Tomato Products, 21 C. F. R. 53 (1955).

Foods which comply with standards of identity may still be economically adulterated. FDA's regulations specifically provide for concurrent applicability of the general provisions of the act and the standards of identity for particular foods and one of the examples in the regulations involves economic adulteration: "A provision in such regulations [standards of identity] for the use of coloring or flavoring does not authorize such use under

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circumstances or in a manner whereby damage or inferiority is concealed or whereby the food is made to appear better or of greater value than it is." 21 C. F. R. 10.1(c) (Supp. 1962). Even foods which are labeled "imitation" can probably violate our economic adulteration laws, see Austern, "Ordinary English But Not Ordinary Jam," 6 FOOD DRUG COSMETIC LAW JOURNAL 909, 913 (1951), although there do not seem to be any reported cases involving such a situation.

[49] The classic United States Supreme Court case involving standards of identity is *Federal Security Adm'r v. Quaker Oats Co.*, 318 U. S. 218 (1943). The Quaker Oats Co. had manufactured and sold for ten years a cereal consisting of farina plus vitamin D. The Administrator (who then had the responsibility of administering the Federal Food, Drug and Cosmetic Act) promulgated standards of identity for two farina products—ordinary farina with no vitamins added called "farina," and "enriched farina" with added vitamins B, D, and other ingredients. Since the Quaker Oats product did not comply with either of these standards, it could not be sold as either "farina" or "enriched farina." The company appealed, arguing that the standards were arbitrary and unreasonable. However, the United States Supreme Court (6-3) upheld the standards. In a later case, *62 Cases of Jam v. United States*, 340 U. S. 593 (1951), the government had promulgated a standard of identity for jam requiring 45% fruit in that product while the claimant was manufacturing a product labeled "Imitation Jam" which contained only 25% fruit. The government seized the claimant's product, asserting that it was in violation of the standard of identity and the United States Supreme Court (7-2) held that the product did not violate the standard of identity because it did not purport to be "jam," it purported to be and was "imitation jam." After these two Supreme Court cases, it was generally recognized that when standards of identity for a food have been promulgated, the food must either conform to these standards or, perhaps, be labeled "imitation," or it cannot be sold.

While violations of the standards of identity could be considered a form of economic adulteration, *cf.* Willis, "Preventing Economic Adulteration of Food," 1 FOOD DRUG COSMETIC LAW QUARTERLY 20 (1946), it would seem that the better view is contra. "Farina with Vitamin D Added" may be barred from sale as such because it violates standards of identity, *cf. Federal Security Adm'r v. Quaker Oats Co.*; see also *Libby, McNeill & Libby v. United States*, 148 F. 2d 71 (2d Cir. 1945) (condemning a product labeled tomato catsup with preservative because it did not conform to the standard for tomato catsup), but only under the most liberal definitions can such a product be considered as adulterated or debased food. *Cf. United States v. Cudahy Packing Co.*, 4 Kleinfeld 138 (D. Neb. 1955). But see Anderson, *The Health of a Nation* 69 (1958), stating that Dr. Harvey W. Wiley's view was that adulteration was any purposeful change in the composition of a food whether or not it resulted in debasement. The real importance of standards of identity is that they avoid recourse to the economic adulteration prohibitions in most instances involving foods for which standards have been established. Proof of noncompliance with the standard of identity constitutes a misbranding and the FDA often secures a judgment on that basis without trying the more complex issues of economic adulteration.

[50] See 52 Stat. 1047 (1938), 21 U. S. C. § 343(i)(2) (1958). The ingredients had to be stated with sufficient prominence and conspicuousness and in such terms as would be likely to be read and understood by the ordinary individual under customary conditions of purchase and use. 52 Stat. 1047 (1938), 21 U. S. C. § 343(f) (1958). FDA's regulations prohibited

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the listing of ingredients in misleading order and required the proportion of an ingredient to be disclosed when the proportion became material in the light of representations concerning the ingredient. 21 C. F. R. § 1.10(d)(1) and (2) (1955). The sum of these statutes and regulations gave the intelligent consumer fairly complete information concerning the composition of the food, and this information has probably acted as an indirect deterrent to economic adulteration.

[51] Section 402(b) of the Federal Food, Drug & Cosmetic Act is broader than the economic adulteration provisions of the 1906 Act in the following areas:

(a) Section 402(b)(1) provides a food is adulterated if a valuable constituent has been *omitted* or abstracted. Omitting a valuable constituent was not included under the 1906 Act.

(b) Section 402(b)(3) provides a food is adulterated if damage or inferiority has been concealed *in any manner*. The 1906 Act covered concealment of damage or inferiority by mixing, coloring, powdering, coating, or staining the food; and

(c) Section 402(b)(4) provides a food is adulterated if any substance has been added, mixed, or packed with it to *increase its bulk or weight*, reduce its quality or strength, or *make it appear greater or of better value than it is*. The 1906 Act covered mixing or packing a substance with the food to reduce or lower or injuriously affect its quality or strength. See 52 Stat. 1046 (1938), 21 U. S. C. 342(b) (1958) and Federal Food & Drugs Act of 1906, ch. 3915, § 7, 34 Stat. 768, repealed, 52 Stat. 1059 (1938).

Only § 402(b)(2) was not changed significantly from the language of the 1906 Act. This section provided a food is adulterated if any substance has been substituted in whole or in part for the food, and it was the broadest section in the 1906 Act.

[52] The effect of repealing the provisos was dramatically illustrated in *United States v. 651 Cases of Chil-Zert*, 114 F. Supp. 430 (N. D. N. Y. 1953). Claimant in that case manufactured and sold a product which resembled ice cream but was composed of soy fat and soy protein rather than milk fat and milk protein. The product was seized because it was not labeled imitation ice cream and the claimant defended on the ground that its labeling was truthful. The court granted the government's motion for summary judgment, stating, "The Court is impressed that claimant's argument proceeds as if the distinctive name provision of the 1906 Act is still in force, and claimant seeks to use the fanciful name of Chil-Zert with informative labeling to escape the provisions of the present statute. (The distinctive name provision was eliminated in the 1938 Act)." Cited at 433.

THE TENTH ANNUAL JOINT EDUCATIONAL CONFERENCE TO BE HELD

The Food and Drug Administration and the Food and Drug Law Institute will sponsor the Tenth Annual Joint Educational Conference to be held at Washington, D. C. on November 28, 1966. A series of panels on drug advertising, quality control on drug production, microbiological contamination of foods, and antibiotic residues in foods will be featured, as well as a status report on international food standards. James L. Goddard, M.D., Commissioner of Food and Drugs, will present a "Report from FDA" at the evening banquet. Paul Rand Dixon, Chairman of the Federal Trade Commission, will be the speaker at the luncheon.

Co-chairmen of the one-day conference are Franklin M. Depew, FDLI president, and Fred J. Delmore, Director of FDA's Bureau of Education and Voluntary Compliance.

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