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otterweich Revisited–Criminal Liability Under the Federal Food, Drug and Cosmetic Act

. . . . . DANIEL F. O'KEEFE, JR. and C. WILLARD ISLEY

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REPORTS

TO THE READER

The JOURNAL's first article is an analysis of the *Dotterweich* Doctrine and a followup of an earlier Food and Drug Law Institute-sponsored paper on the same subject. This presentation, beginning on page 69, considers the area of corporate criminal liability under the Federal Food, Drug and Cosmetic Act in light of the important *Park* decision. It was written by *Daniel F. O'Keefe, Jr.*, President of the Food and Drug Law Institute and *C. Willard Isley*, a third-year law student at the University of Virginia School of Law. Titled "*Dotterweich* Revisited—Criminal Liability Under the Federal Food, Drug and Cosmetic Act," the article also discusses the evidence necessary for prosecution and the various possible defenses.

Nineteenth Annual Educational Conference of the FDLI and the FDA. The following papers were presented at the 19th Annual Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration which was held in Washington, D. C. on December 2 and 3, 1975.

"The Cost Effectiveness of Medical Device Standards," beginning on page 81, is an evaluation of the factors involved in the determination of standards for medical devices. The author, *Michael J. Miller*, Executive Director of the Association for the Advancement of Medical Instrumentation, urges the Food and Drug Administration to consider before recommending the use of medical device standards as a regulatory mechanism, citing many reasons such as cost, funding, political considerations and priorities.

Medical devices and the need for well-controlled investigations to regulate them is the subject of *Joel E. Hoffman's* article beginning on page 86. Mr. Hoffman, a member of the law firm of Wald, Harkrader & Ross, points out the disparity between device and drug regulations, especially in regard to premarket approval. Using examples of heart valve and pacemaker experiments, Mr. Hoffman urges careful consideration in establishing standards of safety and effectiveness. "Well-Controlled Investigations and Medical Devices" also explains provisions of device legislation introduced in Congress.

Terry Coleman, Associate Chief Counsel for Food in the Food and Drug Administration, expresses the Agency's attitude toward using regulations to assure safe and sanitary manufacturing practices for cosmetics. Showing that the courts have been hampered in interpreting the Federal Food, Drug and Cosmetic Act because of lack of specifics, Mr. Coleman argues that regulations aid manufacturers by more clearly informing them of their responsibilities. "The Use of Regulations to Enforce Statutory Quality Assurance Requirements" begins on page 96.

John A. Wenninger's article also praises good manufacturing practices for quality assurance as a means of ensuring safe and sanitary foods, drugs and cosmetics. Titled "Quality Assurance Procedures for the Cosmetics Industry—The FDA's Viewpoint," the article outlines the reasons why the Agency favors such standards and the criteria it will use in determining them. Mr. Wenninger, whose article begins on page 101, is Deputy Director of the Division of Cosmetics Technology in the Bureau of Foods in the Food and Drug Administration.

Edward Milardo approaches the subject of quality assurance guidelines for cosmetics from the industry's viewpoint. In an article beginning on page

105, he discusses the preliminary work done by the Cosmetic, Toiletry and Fragrance Association and urges increased cooperation between the Agency and industry for the benefit of consumers. Mr. Milardo is Director of National Quality Control of Avon Products, Inc. His article is titled "Quality Assurance Guidelines — The Industry's Viewpoint."

"Cosmetic Ingredient Labeling—An FDA Chimera" expresses *Walter E. Byerley's* opinion of the Food and Drug Administration's cosmetic ingredient labeling regulations. Mr. Byerley, a member of the law firm of Markel, Hill & Byerley, feels that the regulations place an undue burden on manufacturers without much benefit to consumers. He disputes the argument that the regulations will help consumers avoid allergens or make value comparisons among differing products. Mr. Byerley's article can be found on page 109.

Heinz J. Eiermann is Director of the Division of Cosmetics Technology in the Bureau of Foods in the Food and Drug Administration. His article, "Cosmetic Ingredient Labeling Requirements," beginning on page 115, is an outline of the provisions of the Agency's regulations concerning the labeling of cosmetic ingredients. Among the areas covered by Mr. Eiermann are incidental ingredients, multiunit and multicomponent packages, branded shade lines and trade secret information.

"Status Report on Cosmetic Ingredient Labeling" comprises the title and the contents of *Margaret Gilhooley's* article. As an attorney in the Office of the General Counsel in the Food and Drug Administration, she explains the history and the effective dates of the Agency's cosmetic ingredient labeling regulations. Her article, beginning on page 121, also describes industry lawsuits challenging the requirements.

In his article, "Cosmetic Ingredient Labeling—The Nomenclature Problem," *Murray Berdick* details the problems associated in listing cosmetic ingredients in a manner that is meaningful to the lay person. When the Food and Drug Administration passed its cosmetic ingredient labeling regulations, the Cosmetic, Toiletry and Fragrance Association initiated efforts to compile a compendium listing cosmetic raw materials. Dr. Berdick's article, beginning on page 125, describes the Association's efforts and methods in establishing a suitable system of nomenclature. Dr. Berdick is Director of Regulatory Affairs of Chesebrough-Pond's Inc. and Chairman of the Inter-Industry Color Technical Committee.

In Memoriam.—To many readers of this JOURNAL the name of Professor E. J. Bigwood of Brussels is a familiar one, and they will be saddened to learn that he died on December 11, 1975 at the age of almost 85. He was an outstanding personality in the field of food science and food law with a background of two doctorates in Medicine and Biology. For many years he was active as Professor of Medicine at the University of Brussels, of which he became the Rector. He was also the Founder and Chairman of the Belgian Institute for Food and Nutrition and a member of the Belgian High Council of Hygiene.

After his official retirement, he founded in 1965 the Food Law Research Centre which is part of the Institute of European Studies of the University of Brussels. His main contribution to food law was the first comprehensive study of comparative food law ever made, a four-volume work under the title "Fundamental Principles and Objectives of a Comparative Food Law" under joint authorship with Dr. Alain Gérard (Brussels University Food Law Research Centre) published in 1967-1971 by S. Karger in Basel. Professor Bigwood was editor-in-chief of "Food Additives Tables," a comparative study in loose-leaf form which is being published by Elsevier Scientific Publishing Company in Amsterdam and New York. It is a comparative survey of current legal regulations governing food additives in the 20 most important countries exporting and importing food products.

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Dotterweich Revisited— Criminal Liability Under the Federal Food, Drug and Cosmetic Act

By DANIEL F. O'KEEFE, JR. and C. WILLARD ISLEY

Mr. O'Keefe Is a Member of the Virginia and District of Columbia Bars. He Is President of the Food and Drug Law Institute, and Wishes to Point Out That the Views Expressed in This Paper Are Those of the Authors and Not Necessarily the Views of the Food and Drug Law Institute.

Mr. Isley Is a Third-Year Law Student at the University of Virginia School of Law. His Work on This Paper Was Performed While Employed as a Summer Law Intern with the Food and Drug Law Institute.

I. INTRODUCTION

THE NATURE AND SCOPE of the *Dotterweich*[1] Doctrine, imposing criminal liability upon corporate officers who have a "responsible share" in the furtherance of a transaction which the Federal Food, Drug and Cosmetic Act[2] outlaws, regardless of consciousness of wrongdoing, was the subject of a recent Food and Drug Law Institute

[1] *U. S. v. Dotterweich*, 320 U. S. 277 (1943).

[2] Federal Food, Drug and Cosmetic Act (hereinafter cited as the Act), 21 U. S. C. Sec. 301 (1970).

sponsored article,[3] published on the eve of the review of *United States v. Park*[4] by the United States Supreme Court.

In the Institute's earlier article, it was pointed out that "responsible" persons could be held criminally liable for violations of the Act. The test set forth for criminal liability in *Dotterweich* is that the offense is committed by "all persons who aid and abet its commission," by all who share "responsibility in the business process resulting in unlawful distribution," and "by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws."[5] It was further noted that there exist some judicial dicta to the effect that a corporate president may be held criminally liable solely on the basis of his general authority and responsibility as president for the overall operation and conduct of the business. However, the factual situations in the previously analyzed cases showed that close and immediate supervisory control by the defendant over the operation in which the violative act occurred had always been present when individuals were held criminally liable.[6]

The earlier research posed a number of questions. Need the government prove, in order to convict, more than the fact that the defendant is the president of the offending corporation or otherwise in general charge of all its affairs? If so, does the government have to prove a relationship between the defendant and the specific violative acts? And, if not to the acts, then to the specific operation or plant in which the acts occurred? In short, when does an individual share "responsibility in the business process resulting in unlawful distribution?"[7]

In this paper we will examine the *Park* decision and attempt to assess the degree of light which it sheds on the nature and scope of the *Dotterweich* Doctrine.

II. *PARK*—FACTS AND POSTURE ON APPEAL

Park arose when Acme Markets, Inc., and its president, Mr. Park, were charged with violating Section 301(k) of the Federal Food, Drug and Cosmetic Act [the Act] which prohibits the doing of any act with respect to a food held for sale after shipment in interstate commerce which results in such article being misbranded or adulterated. A five-

[3] O'Keefe and Shapiro, *Personal Criminal Liability Under the Federal Food, Drug and Cosmetic Act—The Dotterweich Doctrine*, 30 Food Drug Cosmetic Law Journal 5 (January 1975).

[4] 421 U. S. 658 (1975).

[5] *U. S. v. Dotterweich*, 320 U. S. 277, 284 (1943).

[6] O'Keefe and Shapiro, *Personal Criminal Liability Under the Federal Food, Drug and Cosmetic Act—The Dotterweich Doctrine, supra* note 3 at 20.

[7] *Id.* at 24.

count information alleged that defendants caused food to be held in Acme's Baltimore warehouse accessible to rodents and to be exposed to contamination by rodents, resulting in unlawful adulteration within the meaning of Section 402 (a)(3) and (4). Acme pleaded guilty to each count, but Park pleaded not guilty.

At trial, evidence showed that, in April of 1970, the Food and Drug Administration (FDA) had advised Park by letter of insanitary conditions in Acme's Philadelphia warehouse. An FDA official testified that he found similar conditions in Acme's Baltimore warehouse during a twelve-day inspection in November and December of 1971, and during a second inspection in March of 1972. Though the FDA inspector found improvement in the 1972 inspection, he testified that there continued to be evidence of rodent activity and rodent-contaminated food. The first four counts of the information alleged violations discovered during the November-December inspection, and the fifth was based upon the inspection in March of 1972. Evidence also showed that Park was informed, by an FDA letter dated January 27, 1972, of the conditions at the Baltimore warehouse after the first inspection there.

Testimony by Acme's Baltimore division vice president, who had responded to the letter on behalf of Acme and Park, described the steps taken to remedy insanitary conditions discovered during both inspections. Acme's vice president for legal affairs and assistant secretary identified Park as president and chief executive officer of the company and read a bylaw delegating to the latter the duty, subject to the board of directors, of "general and active supervision of the affairs, business, offices and employees of the company." The vice president's testimony indicated that Park functioned by delegating "normal operating duties," including sanitation, but that he retained "certain things, which are the big, broad principles of the operation of the company," and had "the responsibility of seeing that they all work together."

Motion for Acquittal

Park's motion thereafter for acquittal, on the ground that "the evidence in chief has shown that Mr. Park is not personally concerned in this Food and Drug violation," was denied by the trial judge, who stated that *United States v. Dotterweich* was controlling.

Park then appeared as the only defense witness. His testimony was that, although all of the company's employees were in a sense under his general direction, Acme had an "organizational structure for responsibilities for certain functions" according to which different phases of its operation were "assigned to individuals who, in turn,

have staff and departments under them." After identifying the individuals responsible for sanitation, Park said that, after receipt of the January, 1972 FDA letter, he conferred with the vice president for legal affairs, who informed him that the Baltimore division vice president "was investigating the situation immediately and would be taking corrective action and would be preparing a summary of the corrective action to reply to the letter." Park testified that he did not "believe that there was anything [he] could have done more constructively than what [he] found was being done."

On cross-examination, Park admitted that providing sanitary conditions for food offered to the public was something he was "responsible for in the entire operation of the company," but that it was one of the many phases of Acme that he assigned to "dependable subordinates." Evidence was admitted over the objection of Park's counsel that he had received an FDA letter in 1970 regarding insanitary conditions at Acme's Philadelphia warehouse. Park acknowledged that the same individuals, with the exception of the division vice president, were responsible for sanitation in both Baltimore and Philadelphia. He also conceded that the Baltimore problem showed that the system for sanitation matters "wasn't working perfectly" and that as the company's chief executive officer he was responsible for "any result which occurs in our company."

Park's renewed motion for a judgment of acquittal at the close of the evidence was denied. The trial judge gave the following instructions to the jury:

"In order to find the Defendant guilty on any count of the Information, you must find beyond a reasonable doubt on each count. . . .

"Thirdly, that John R. Park held a position of authority in the operation of the business of Acme Markets, Incorporated.

"However, you need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets. . . .

. . .

"The statute makes individuals, as well as corporations, liable for violations. An individual is liable if it is clear, beyond a reasonable doubt, that the elements of the adulteration of the food as to travel in interstate commerce are present. As I have instructed you in this case, they are, and that the individual had a responsible relation to the situation, even though he may not have participated personally.

"The individual is or could be liable under the statute, even if he did not consciously do wrong. However, the fact that the Defendant is pres[id]ent and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though, he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case, whether the Defendant, John R. Park, by virtue of his position in the company, had a

position of authority and responsibility in the situation out of which these charges arose."

Park's objection to the instructions on the ground that they failed to reflect fairly the *Dotterweich* decision and to define " 'responsible relationship' " was overruled by the trial judge. The jury found him guilty on all counts, and Park was subsequently sentenced to pay a fine of $50 on each of the five counts.

In the words of the Supreme Court opinion:

"The Court of Appeals reversed the conviction and remanded for a new trial. That court viewed the Government as arguing 'that the conviction may be predicated solely upon a showing that . . . [respondent] was the President of the offending corporation,' and it stated that as 'a general proposition, some act of commission or omission is an essential element of every crime' . . . It reasoned that, although our decision in *United States v. Dotterweich* . . . had construed the statutory provisions under which respondent was tried to dispense with the traditional element of 'awareness of some wrongdoing,' the Court had not construed them as dispensing with the element of 'wrongful action.' The Court of Appeals concluded that the trial judge's instructions 'might well have left the jury with the erroneous impression that Park could be found guilty in the absence of "wrongful action" on his part . . .' and that proof of this element was required by due process. It held, with one dissent, that the instructions did not 'correctly state the law of the case,' . . . and directed that on retrial the jury be instructed as to 'wrongful action,' which might be 'gross negligence and inattention in discharging . . . corporate duties and obligations or any of a host of other acts of commission or omission which would "cause" the contamination of food' . . . .

"The Court of Appeals also held that the admission in evidence of the April 1970 FDA warning to respondent was error warranting reversal, based on its conclusion that, 'as this case was submitted to the jury and in light of the sole issue presented,' there was no need for the evidence and thus that its prejudicial effect outweighed its relevancy. . . .

"We granted certiorari because of an apparent conflict among the Courts of Appeals with respect to the standard of liability of corporate officers under the Federal Food, Drug, and Cosmetic Act as construed in *United States v. Dotterweich* . . ., and because of the importance of the question to the Government's enforcement program."[8]

III. *PARK* BEFORE THE SUPREME COURT

The Supreme Court in a 6-3 decision reversed the Fourth Circuit. The Court set forth in great detail the facts of the case, including the fact that defendant had been informed by letter from the FDA of conditions at the Baltimore warehouse after the first of the two inspections at that facility. This important fact was not mentioned in the Fourth Circuit's opinion.

The Court then reaffirmed *Dotterweich* and other cases upholding criminal accountability of corporate agents for "failure to exercise the

[8] *U. S. v. Park*, 421 U. S. 658, 666-667 (1975).

authority and supervisory responsibility reposed in them by the business organization . . . ," noting with approval, that "the Courts of Appeals have recognized that those corporate agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act bear a 'responsible relationship' to, or have a 'responsible share' in, violations."[9]

Chief Justice Burger, speaking for the majority, said the *Dotterweich* and cases following it reveal that:

". . . in providing sanctions which reach and touch the individuals who execute the corporate mission—and this is by no means necessarily confined to a single corporate agent or employee—*the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.* The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public. . . . "[10] (Emphasis added.)

The Chief Justice continued:

"The Act does not, as we observed in *Dotterweich*, make criminal liability turn on 'awareness of some wrong doing' or 'conscious fraud.' *The duty imposed by Congress* on responsible corporate agents *is*, we emphasize, *one that requires the highest standard of foresight and vigilance, but the Act, in its criminal aspect, does not require that which is objectively impossible. The theory upon which responsible corporate agents are held criminally accountable for 'causing' violations of the Act permits a claim that a defendant was 'powerless' to prevent or correct the violation to 'be raised defensively* at a trial on the merits.' "[11] (Emphasis added.)

Speaking to the concept of "responsible relationship," Chief Justice Burger stated:

". . . the Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."[12] (Emphasis added.)

Finding that the trial court's instruction to the jury, read as a whole, contained no reversible error, the Chief Justice said:

"The record in this case reveals that the jury could not have failed to be aware that the main issue for determination was not respondent's position in the corporate hierarchy, but rather his accountability, because of the responsibility and authority of his position, for the conditions which have risen to the charges against him."[13]

The dissenting opinion, filed by Justice Stewart and joined by Justices Marshall and Powell, argued that the defendant should have

[9] *Id.* at 671-672.
[10] *Id.* at 672.
[11] *Id.* at 672-673.
[12] *Id.* at 673-674.
[13] *Id.* at 675.

been granted a new trial on the grounds that the jury instructions in the case were not consistent with the law as expounded by the majority. The dissent argued that the jury instruction in effect told the jury: " 'You must find the defendant guilty if you find that he is to be accountable for this adulterated food.' In other words: 'you must find the defendant guilty if you conclude that he is guilty.' "[14]

IV. THE LESSONS OF *PARK*

A. *Who is a "Responsible" Person?*—The difficulty of defining "responsibility" was noted in the Institute's earlier article. The test for criminal liability set forth in *Dotterweich* is that the offense is committed by "all persons who aid and abet its commission," by all who share "responsibility in the business process resulting in unlawful distribution," and "by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws." The Institute's earlier article noted that examination of litigated cases since 1943 showed that close and immediate supervisory control by the defendant over the operation in which the violative act occurred had always been present when individuals have been held criminally liable. The questions were raised as to whether it is necessary to show for conviction that defendant bears some relationship to the specific acts which resulted in violation, or to the specific operation or plant in which a violation occurred.

The important question, which *Park* makes clear, is whether a defendant has authority and responsibility to prevent or promptly correct violations of the Act. As the Court stated:

". . . the Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the *defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation* complained of, and that he failed to do so. The failure thus to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute furnishes a sufficient causal link."[15] (Emphasis added.)

Mr. Justice Stewart, in his dissent, stated his understanding of the holding of the Court, that in order to sustain a conviction, "the prosecution must at least show that by reason of an individual's corporate position and responsibilities, he had a duty to use care to maintain the physical integrity of the corporation's food products." He went on to say that "a jury may then draw the inference that when the food is found to be in such condition as to violate the statute's prohibitions, that condition was 'caused' by a breach of the standard of

[14] *Id.* at 679.

[15] *Id.* at 673-674.

care imposed upon the responsible official,"[16] noting his agreement with the basic holding, as he understood it.

Prima Facie Case

Thus, leaving aside for the moment the question of the "duty" or degree of care imposed, it appears that an executive who has the responsibility and authority to prevent or correct a given violation of the Act, and who failed to do so, may be held criminally liable for the violation. His responsibility and authority, in combination with the fact of violation, appear to be sufficient to establish a *prima facie* case. "An omission or failure to act was deemed a sufficient basis for a responsible corporate agent's liability. It was enough in such cases that, by virtue of the relationship he bore to the corporation, the agent had the power to prevent the act complained of."[17]

It should also be noted that the Court made clear that the mere holding of the title of president is not sufficient to sustain conviction.[18] It is necessary for the government also to show his responsibility and authority to prevent or to correct the violation complained of.

Further, the Court made it clear that the sanctions of the Act are "by no means necessarily confined to a single corporate agent or employee,"[19] and thus reaffirmed the point that corporate employees other than senior officials may also be held liable.

B. *The Standard of Care Imposed on Responsible Officials.*—The Chief Justice several times noted that the "duty imposed by Congress on responsible corporate agents is, we emphasize, one that requires the *highest standard of foresight and vigilance.*"[20] (Emphasis added.) He quoted *Morissette v. United States*[21] to the effect that the Act punishes " 'neglect where the law requires care, or inaction where it imposes a duty' " in order to make " 'distributors of food the strictest censors of their merchandise.' "[22]

Indeed, in amplifying the standard of care required, the Chief Justice came close to requiring executives to be insurers of the integrity of their merchandise—with criminal sanctions. The Chief Justice said, "the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, *and primarily*, a duty

[16] *Id.* at 678-679.
[17] *Id.* at 671.
[18] *Id.* at 674.
[19] *Id.* at 672.
[20] *Id.* at 673. See also *U. S. v. Park*, *supra* note 8 at 672, 676.
[21] 342 U. S. 246, 255 (1952).
[22] *U. S. v. Park*, *supra* note 8 at 671, quoting *Smith v. California*, 361 U. S. 147, 152 (1959).

to implement measures that will insure that violations will not occur."[23] (Emphasis added.)

C. *Defenses Available.*—It was noted in the Institute's earlier research that Justice Stewart, in his opinion in *United States v. Wiesenfeld Warehouse Co.*,[24] raised the possibility of a defense of due care. There, Justice Stewart said:

"It is argued . . . that the Government in this case is seeking to impose criminal sanctions upon one 'who is, by the very nature of his business, powerless' to protect against this kind of contamination, however high the standard of care exercised. Whatever truth of this claim, it involves factual proof to be raised defensively at a trial on the merits."[25]

United States v. Park amplifies that statement considerably. The Court, in *Park,* said this:

"The Act does not . . . make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud.' The duty imposed by Congress on responsible corporate agents is, we emphasize, one that requires the highest standard of foresight and vigilance, but *the Act, in its criminal aspect, does not require that which is objectively impossible.* The theory upon which responsible corporate agents are held criminally accountable for 'causing' violations of the Act permits a claim that a defendant was 'powerless' to prevent or correct the violation to 'be raised defensively at a trial on the merits' (citing Wiesenfeld). If such a claim is made, the defendant has the burden of coming forward with evidence."[26] (Emphasis added.)

Later in the opinion of the Court, Chief Justice Burger noted, that in the instant case:

". . . there was no request for an instruction that the Government was required to prove beyond a reasonable doubt that respondent was not without the power or capacity to affect the conditions which founded the charges. . . ."[27]

At trial, Park testified in his defense that he employed a system in which he relied upon his subordinates and that they were "dependable." He tried to persuade the jury that, as president of a large corporation, he had no choice but to delegate duties, that he had no reason to suspect his subordinates were failing to ensure compliance with the Act, and that, once violations were unearthed, acting through his subordinates, he did everything possible to correct them. The government then offered testimony that defendant was on notice that he could not rely on his system of delegation and that he was aware of the deficiencies in the system. In essence, the Court held that evidence offered by the government was proper and necessary rebuttal evidence to rebut the contention that defendant justifiably relied on subordinates to handle sanitation matters.

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[23] *U. S. v. Park, supra* note 8 at 672.
[24] 376 U. S. 86 (1964).
[25] *Id.* at 91.
[26] *U. S. v. Park, supra* note 8 at 673.
[27] *Id.* at 676.

In a footnote, the Court said:

"Assuming, *arguendo,* that it would be objectively impossible for a senior corporate agent to control fully day-to-day conditions in 874 retail outlets, it does not follow that such a corporate agent could not prevent or remedy promptly violations of elementary sanitary conditions in 16 retail warehouses."[28]

In any event, the Court noted that an instruction on defenses was not requested and that the Court need not decide whether the defendant's testimony would have entitled him to an instruction as to his lack of power.

The Court in *Park* made it clear that defenses to criminal liability do exist. The Court stated that "the Act, in its criminal aspect, does not require that which is objectively impossible" and that the Act permits a "claim that a defendant was 'powerless' to prevent or correct" a violation. However, the Court gave little guidance on the kind of factual situations in which the defenses would be valid. There are, of course, a wide variety of factual settings in which the defenses might apply, and courts in coming years undoubtedly will amplify the nature of the available defenses.

Organizational Authority

Certainly the defense that a specific defendant did not have the *organizational* authority or responsibility is available, for example, where a corporate official proves he had no authority over the function of the business which produced the violation (that is, plant sanitation). However, the government has the burden of proving this point in order to establish its *prima facie* case.

A related question is whether a general executive may delegate his authority and responsibility and thereby escape criminal liability. The extent to which this may be done is very unclear. The underlying question remains: who has the responsibility and authority? Certainly one would have to examine the extent of the delegation, particularly the delegation of authority, and the reporting relationship. Such questions as the authority of the delegatee to close an operation or to spend money to prevent or to correct a flaw would have to be explored, as well as the finality of his decisions.

Another interesting question is the extent to which a defendant can justifiably rely on subordinates. The Court, in the footnote quoted above, certainly raised the question as to the degree of detail for which a general executive can be held criminally responsible. It would seem that a general executive would be entitled to a jury instruction

[28] *Id.* at 677, footnote 19.

on objective impossibility and powerlessness where he had established a system to prevent a violation of law, had provided qualified personnel to implement the system, had established a monitoring system to keep informed of how it was working, and had no reason to think his system was not working.

Does the defense permit a defendant to argue that he exercised the highest degree of care and, in spite of that care, a violation occurred? Thus, assuming a defendant clearly has the responsibility and the authority over the function which produced the violation (that is, plant sanitation), and he presents evidence tending to show that it was impossible to totally eliminate rats from the food plant and that he had taken extensive measures to eliminate the problem, assuming that the food was adulterated under the Act, is the defense discussed in *Park* available? The answer is not clear.

Absolute Liability

On the one hand, the Court interprets the Federal Food, Drug and Cosmetic Act as imposing a duty to implement measures that *will insure* that violations will not occur. This is the language of "absolute liability," which permits no such defense when a violation occurs.

On the other hand, the Court states that, while the Act requires the highest standard of foresight and vigilance, it does not "in its criminal aspect . . . require that which is objectively impossible." Thus, the Court raises the possibility of a defense that it would be "objectively impossible" to prevent a violation and, therefore, though one occurred, *criminal* conviction could not be sustained.

A case currently before the Ninth Circuit may prove instructive on this point. In that case, *United States v. Y. Hata*,[29] a corporation and its president were found guilty by a jury of holding food in a warehouse under conditions whereby it could have become contaminated in violation of the Act. The case was tried prior to the Supreme Court's resolution of the *Park* case, and defendants, in appealing the verdict, are stressing their position that they did all they reasonably could to prevent the violation, that is, that it was "objectively impossible" to do more.

Another case currently before the Ninth Circuit is *United States v. Starr*.[30] In this case, a corporate official of a wholesale food distributorship was found guilty of holding food under insanitary condi-

[29] Appeal docketed, No. 75-1680, (CA-9).

[30] Appeal docketed, No. 74-3173, (CA-9).

tions. This case, too, was tried prior to the final resolution of the *Park* case. Defendant, in the appeal, is stressing the contention that he cannot be convicted because of the acts of a disgruntled employee who intentionally caused sanitary violations when an FDA inspector was aware of the facts and did not report them to the defendant. This is a version of a "powerless" argument.

The opinions of the Ninth Circuit on these cases may be helpful in offering some guidance in these areas.

It also should be noted that, as a practical matter, many of the points of defense discussed here will arise at a Section 305 hearing at the FDA. And the government may well conclude not to prosecute criminally where it believes that a given defense is valid in fact even though it may take the position that a given defense is not valid as a matter of law. In other words, the government may not prosecute criminally an individual who it believes is really not culpable even though it thinks it could prevail in court.

IV. SUMMARY AND CONCLUSION

In summary, in order to successfully prosecute an individual for criminal violation of the Federal Food, Drug and Cosmetic Act, the government must prove the fact of violation and introduce evidence sufficient to warrant a finding by the trier of fact that the defendant had the responsibility and authority to prevent or to correct the violation. This establishes a *prima facie* case for the government.

Defendant may then come forward with evidence that he was "powerless" to prevent or to correct the violation, that it was "objectively impossible" for him to do so. The existence of this defense is clear; its nature, unfortunately, is not, although the standards of "powerless" and "objectively impossible" are indeed tough.

The desirability of the policy of *Dotterweich* and *Park* is currently before Congress. The Court has interpreted the will of Congress in enacting the Federal Food, Drug and Cosmetic Act. As the Court has said:

"Congress has seen fit to enforce the accountability of responsible corporate agents dealing with products which may affect the health of consumers by penal sanctions cast in rigorous terms, and the obligation of the courts is to give them effect so long as they do not violate the Constitution."[31]

The pros and the cons of the policy were discussed at length in the Institute's earlier article. **[The End]**

[31] *U. S. v. Park, supra* note 8 at 673.

The Cost Effectiveness of Medical Device Standards

By MICHAEL J. MILLER, J.D.

Mr. Miller Is Executive Director of the Association for the Advancement of Medical Instrumentation.

THE TRUE COST OF MEDICAL DEVICE STANDARDS can be measured in terms of the professional, industrial and governmental resources that are diverted from health care during the development of and compliance with standards. It is important to remember that the patient ultimately bears the cost of resources expended for standards.

The following are some of the major cost factors that may determine whether or not resources will be utilized effectively during the development of and compliance with standards and whether or not resources will be utilized effectively in a way to maximize device safety and effectiveness without undue loss of innovation.

1. *The objectives.* The Food and Drug Administration (FDA) and standards organizations must clearly set their objectives prior to the development of a standard. This includes a clear identification of major device characteristics that should be subjected to safety and performance requirements. Device characteristics which are not essential for safety and performance should not be included in standards. The FDA and standards organizations should rely on expert panels to determine these characteristics of medical devices.

2. *Priorities.* There are a limited amount of resources for standards development and compliance. The FDA and standards organizations must set priorities carefully, in such a way that resources are utilized first to set standards for critical care devices. Standards for devices that do not pose an unreasonable risk to the patient can be given lower priority on the list of needed standards.

Three-Tier Approach

3. *Maximum utilization of all experts.* The Association for the Advancement of Medical Instrumentation (AAMI) has proposed a three-tier approach for medical device standards. The three tiers consist of the research community, the consensus community and, finally, the regulatory community. Members of the research and academic communities must carefully provide input prior to the development of medical device standards to assure that standards do not impede innovation.

The consensus standards process must provide the means of assuring that all input—industrial, professional and governmental—is available during all stages of standards development. No one group can dominate the standards development process. If this should occur, biased standards will result. The FDA should utilize the resources made available by the voluntary consensus approach.

The third tier of the process is the point at which the FDA determines that the voluntary consensus standards are appropriate for regulatory purposes.

4. *Flexibility of approach.* Organizations which write standards, by FDA contract or otherwise, must be given the flexibility to determine when contemplated standard requirements are not feasible or desirable. During the development of a pacemaker standard for the FDA, AAMI found several areas in which standards were neither feasible nor desirable. Too often, contractors and standards organizations proceed with the development of a standard requirement when its development is not necessary or feasible.

5. *Conflict of interest.* Knowledgeability must not be equated with conflict of interest. If experts with potential conflicts of interest, who are also the most knowledgeable about medical devices, are precluded from participating in the development of standards, resources will be allocated on a highly inefficient basis.

Senate Device Bill

For example, the Senate device bill forbids national standards organizations to write FDA standards, under contract, because they permit industry input. This would preclude the most knowledgeable groups in the country from participating in the development of FDA standards. This carries potential conflict of interest to an extreme.

AAMI has written—and other organizations can write—FDA standards without industry domination of the process. Current FDA regulations preclude industry domination and, therefore, conflict of interest under FDA standards contracts.

The consumer groups which have proposed this restriction have a significant responsibility to the consumer, the industry and the professions to assure that this type of proposal does not cause more harm than good to the patient. We must recognize that *all* experts have a potential conflict of interest in developing standards. The key factor is identification of the potential conflicts, not the elimination of the expert groups which are badly needed to write standards.

6. *Limitations of standards.* In developing standards, organizations and FDA contractors must realize that standards are not panaceas. Many other regulatory mechanisms are envisioned by the medical device bill now pending in Congress. Users and purchasers will also assume safety and effectiveness responsibilities.

Premarketing Scientific Review

Standards should not be written in areas where scientific knowledge has yet to be refined. To attempt to do by standards that which should be accomplished by premarketing scientific review or other mechanisms distorts the true purpose of standards.

7. *Political factors.* Standards should be written based on a determination of scientific need, not on the basis of political need. It is very easy for a senator or a government official to claim that a medical device should be subjected to a standard when a standard may prove to be of no benefit and may, in fact, impose an unnecessary cost on the patient.

8. *Funding.* It is very difficult to obtain badly needed user input on standards without some form of funding. Fortunately, some medical organizations are providing sources of funding for their standards experts. Under pending medical device legislation, the FDA will provide funding to organizations that write standards. In other cases, the funding will have to come from different sources. In many cases, the industry, the professions and the government will find that the development of and compliance with a medical device standard may be as expensive as premarketing scientific review. This is one of the reasons that AAMI proposed that a manufacturer should always have the legislative option of conforming to a standard or, alternatively, to premarketing scientific review requirements.

Safety and Effectiveness Requirements

9. *Performance standards versus specifications.* In many cases, if not in most cases, safety and "effectiveness" requirements for medical devices can be handled by "performance" requirements. In other words, the manufacturer can be instructed as to what is expected of the device rather than being told how to design it. Many groups strongly advocate specification-type standards because they are, in the short run, easier and less expensive to write. However, in the long run, specifications may be more expensive to all parties concerned, particularly in regard to the patient's well-being, if they inhibit innovation.

10. *Period for development.* The FDA began with the assumption that draft standards for certain critical care devices (such as the defibrillator) could be developed within six months. This proved to be an assumption requiring revision. (The defibrillator document recently went through its fifth draft after a period of almost two years). Reasonable periods of time for the development of medical device standards will do much to reduce the resource consumption involved in medical device standards development and compliance. Many draft standards can be developed within a period of 18 months, if prior work has been undertaken by the standards development body. Where the organization is new to standards work, the time period must be longer.

11. *The FDA's attitude and approach.* The FDA is undergoing a learning process as it seeks appropriate ways to develop medical device standards. Furthermore, there are serious questions as to whether or not the approach outlined in pending medical device legislation is the approach that is most desirable, or even sought by the FDA. Consequently, the FDA should be receptive to all viewpoints and all approaches as it attempts to determine the most effective way to use all available resources to produce good standards.

Limited Resources

With limited resources, the FDA must utilize standards experts where they may be found. In addition, the Agency may have to examine its approach to contracting, which can result in unqualified contractors developing medical device standards. The time is rapidly approaching when the FDA must reach the end of its learning curve

concerning the development of medical device standards and the various approaches involved.

Some FDA officials have been critical of the voluntary consensus standards approach. Hopefully, this criticism will be tempered by their own experience in attempting to develop standards, internally or externally, by contract. I think the voluntary consensus standards approach requires a reasonable opportunity to prove itself. It may be the best approach for optimizing the benefits and reducing some of the costs of the standards.

The effectiveness of or benefit factors derived from medical device standards generally fall into the following four categories:

(1) *Labeling.* Through labeling, the user receives information, presented in a uniform manner, which provides better understanding and use of the device.

(2) *Device identification and classification.* These standards provide the user with an immediate means of identifying different categories and classes of medical devices during routine or emergency situations.

(3) *Performance requirements.* Standards require from the industry a uniform approach to safety and "effectiveness." This does not mean the specification approach. Rather, the standards require the industry, as a body, to approach safety and "effectiveness" considerations in a uniform way during the design and the manufacture of medical devices. This is a positive form of "standardization," not the negative form which may inhibit the industry and professions.

(4) *Basis for referee tests.* Medical device standards will provide the basis for referee test procedures which will determine whether or not a medical device conforms with safety and effectiveness requirements.

At this point in time, an objective review of the costs and the benefits of standards and this country's experience with standards as a regulatory tool shows that there is a serious question as to whether or not medical device standards will be an effective form of regulation in the near future. The relative benefits and costs of medical device standards are unknown. Consequently, the FDA should proceed, as it has, very cautiously in utilizing standards as a regulatory mechanism. **[The End]**

Well-Controlled Investigations and Medical Devices

By JOEL E. HOFFMAN

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THE CORNERSTONE OF DRUG REGULATION under the Federal Food, Drug and Cosmetic Act as it stands today is the requirement that, before a new drug may lawfully be marketed, there must be "substantial evidence" of the drug's effectiveness. "Substantial evidence" is defined to mean "evidence consisting of adequate and well-controlled investigations, including clinical investigations . . . ."[1] Regu-

[1] Federal Food, Drug and Cosmetic Act, Sec. 505(d), as amended, 21 U. S. C. Sec. 355(d). The provision applies to "new drugs" as defined by the statute, *i.e.*, "any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ." Sec. 201 (p)(1), as amended, 21 U. S. C. Sec. 321(p)(1).

It is unlawful to market such a "new drug" "unless an approval of an application . . . is effective with respect to such drug." Sec. 505(a), as amended, 21 U. S. C. Sec. 355(a). Applications for approval are filed with the Secretary of Health, Education and Welfare (Sec. 505(b), as amended, 21 U. S. C. Sec. 355(b)), who has delegated his functions in this regard to the Commissioner of Food and Drugs (21 CFR Sec. 2.120). "If the Secretary finds . . . that . . . evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; . . . he shall issue an order refusing to approve the application." Sec. 505(d), as amended, 21 U. S. C. Sec. 355(d).

"As used in this subsection and subsection (e) [providing for withdrawal of approval previously granted], the term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." Sec. 505(d), as amended, 21 U. S. C. Sec. 355(d).

lations of the Food and Drug Administration (FDA) have particularized what the FDA calls "the essentials of adequate and well-controlled clinical investigations."[2] No less an authority than the Supreme Court of the United States has ruled, in the *Hynson* case, that these regulations "express well-established principles of scientific investigation" whose "strict and demanding standards . . . are amply justified by the legislative history" of the Act.[3]

The statutory requirement that drug effectiveness be demonstrated by "adequate and well-controlled investigations" was not imposed until 1962, in what the Supreme Court in the same case characterized as "an abrupt departure . . . from old norms for marketing drugs."[4] No such requirement was added for medical devices.

This is not surprising, for the subject of devices seemed not to be on anyone's mind. The focus of attention in 1962 was the near tragedy involving the drug thalidomide. There was no deliberate Congressional choice to leave the device category alone. It was merely a failure to address the issue.

But it was inevitable that, at some point, particularly as legitimate medical devices became more numerous and more sophisticated, the elimination or at least the reduction of the disparities between drug regulation and device regulation would be sought. Oversights have a way of being rectified.

Separate Treatment of Drugs and Devices

It was not merely in 1962 that the subject of medical devices escaped serious consideration. In its 1969 decision in the *Bacto-Unidisk* case, the Supreme Court called attention to the fact that the separate treatment of drugs and devices in the original Federal Food, Drug and Cosmetic Act of 1938 had flowed solely from a desire to avoid what the Court called the "semantic incongruity" of describing machines as drugs. The Court noted that the two categories had been separated at a stage of the legislative history when identical regulatory provisions for each were under consideration. At that point, the requirement of an approved application for new drugs had not been added to the pending bill. That, too, had come late in the legislative process in direct response to an earlier dramatic tragedy involving a drug, the Elixir Sulfanilimide affair.[5]

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[2] 21 CFR Sec. 314.111(a)(5)(ii).

[3] *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U. S. 609, 619 (1973).

[4] *Id.* at 619.

[5] *United States v. An Article of Drug * * * Bacto-Unidisk*, 394 U. S. 784, 797, 798, 800 (1969).

And so that is why today there is no explicit legal requirement that the effectiveness of a marketed medical device be shown by "adequate and well-controlled investigations." However, such a requirement figures prominently in important proposals for a comprehensive regulatory scheme to govern medical devices which are nearing enactment by the Congress.[6] The object of this presentation is to review the extent to which this requirement would be applied to medical devices under the pending legislative proposals, and to explore the probable intended nature of the requirement in the device context.

I. When are "Well-Controlled Investigations" Necessary?

A. Under the drug provisions of the Federal Food, Drug and Cosmetic Act, the requirement of "adequate and well-controlled investigations" applies only to those drugs classified as "new drugs," that is, drugs for which premarketing approval must be obtained from the FDA. The device bill passed in April 1975 by the Senate conforms to this pattern. In those cases where premarketing approval by the FDA (euphemistically called "scientific review") would be required, the application for approval would have to show "adequate scientific evidence" of the effectiveness of the device for its intended uses.[7] "Adequate scientific evidence" would in turn be defined to mean:

". . . evidence consisting of sufficient well-controlled investigations, including clinical investigations where appropriate, by experts qualified by scientific training and experience to evaluate the effectiveness of the device involved, on the basis of which it could fairly and responsibly be concluded by such experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof, unless the Secretary determines that other valid scientific evidence is sufficient to establish the effectiveness of the device."[8]

This definition does depart from the drug provision of the Federal Food, Drug and Cosmetic Act in a potentially significant respect. The drug provisions allow no exceptions to the requirement of "substantial evidence," as defined by the statute, in cases involving a "new drug"

[6] S. B. 510, 94th Congress, 1st Session (passed by the Senate April 17, 1975, 121 *Congressional Record* S6153 (daily edition)); H. R. 5545, 94th Congress, 1st Session (introduced March 26, 1975).

[7] S. B. 510, 94th Congress, 1st Session (hereafter S. B. 510), proposed Sec. 514(e)(1)(C).

[8] S. 510, proposed Sec. 514(e)(2). The definition of the term "[a]s used in this subsection [covering approval of applications for scientific review] and subsection (f) [covering withdrawal of approval]" makes no reference to the provision covering product development protocols (proposed Sec. 514(m)(1)). However, it seems reasonable to expect that the standard of "adequate scientific evidence" in the latter provision would be read the same way, especially as product development protocols essentially would be substitutes for post-development scientific review.

which requires premarketing approval. The Senate bill on devices, however, permits the FDA to dispense with the requirement of "well-controlled investigations" meeting the statutory standard where it determines that "other valid scientific evidence is sufficient to establish the effectiveness of the device."

Well-Controlled Investigations

B. This recognition that "well-controlled investigations" may not always be necessary to establish the effectiveness of a medical device is also found in H. R. 5545. That bill would provide that the effectiveness of *every* device (not just those requiring premarket approval):

"is . . . to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling of the device."[9]

But the comprehensiveness of this requirement would be mitigated by a further provision allowing the FDA to authorize reliance upon other "valid scientific evidence" which the Agency decides is "sufficient to determine the effectiveness of a device" and is evidence "from which it can fairly and responsibly be concluded by qualified experts" that the device will be effective for its intended uses.[10] Moreover, even where insufficient information exists "to provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance," only "general controls" (which do not include a showing of well-controlled investigations) would be imposed if the device is not intended:

"(I) . . . for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, and

"(II) does not present a potential unreasonable risk of illness or injury . . . ."[11]

C. As noted above, the Senate bill would impose the requirement of "well-controlled investigations" only where premarket approval of the device is required. The scheme of the bill suggests that such investigations should not even be necessary in every case of so-called "scientific review."

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[9] H. R. 5545, 94th Congress, 1st Session (hereafter H. R. 5545), proposed Sec. 513(a)(3)(A).

[10] H. R. 5545, proposed Sec. 513(a)(3)(B).

[11] H. R. 5545, proposed Sec. 513(a)(1)(A)(ii) (as amended by the Subcommittee on Health and the Environment, House Committee on Interstate and Foreign Commerce, October 22, 1975).

Scientific Review

A device may be classified to receive "scientific review" for either of two reasons: "that . . . such review is appropriate to assure effectiveness or is appropriate to reduce or eliminate unreasonable risk of illness or injury. . . ."[12] If the sole basis for assigning a device to "scientific review" is a need to "reduce or eliminate unreasonable risk of illness or injury," and the effectiveness of the device is not questioned, it would be anomalous for the FDA to deny approval of the device on the ground that "well-controlled investigations" (or other evidence) showing effectiveness had not been presented. To do so would impose unnecessary (by definition) burdens and costs in conducting investigations in an area where the medical profession has been extremely fearful of just such over-regulation and unnecessary experimentation. The classification panels, therefore, should state explicitly in every case whether scientific review is appropriate on effectiveness grounds. This should be done even where safety considerations alone would justify review. In cases where effectiveness is unquestioned, the FDA should not attempt to require well-controlled investigations and should approve the device if safety is properly shown.

II. What is a "Well-Controlled Investigation"?

Like the present provisions of the Federal Food, Drug and Cosmetic Act applicable to drugs, neither S. B. 510 nor H. B. 5545 makes any effort to specify what would constitute an "adequate and well-controlled investigation" of a medical device. The legislative history of the pending bills should counsel strongly, however, against any effort to implant in the device regulatory scheme the principles promulgated by the FDA with respect to drugs. And the resulting need for a thorough but sophisticated answer to the definitional question

[12] S. B. 510, proposed Sec. 514(a)(1)-(A). The first reason is explicitly stated only with reference to the initial classification program to be undertaken by classification panels in the first instance upon enactment of the legislation. The second reason alone is authorized as a basis for classification into "scientific review" on the initiative of the FDA outside the initial program (S. B. 510, proposed Sec. 514(a)(2)(A)). The argument has frequently been advanced in the drug context, however, that an ineffective drug may be unsafe because its use may be in lieu of other effective therapy. This attempt to merge effectiveness into safety had uniformly been rejected by the lower courts, but in *USV Pharmaceutical Corp. v. Weinberger*, 412 U. S. 655, 660, n. 2 (1973), the Supreme Court expressly left the question open. A similar argument might be made in the case of devices which the FDA undertakes to classify, and the Committee report on what later became S. B. 510 seems to approve such an approach. Senate Report No. 93-670, 93rd Congress, 2nd Session, p. 2 (1974).

makes it essential for the FDA and the medical profession to begin searching for an answer as promptly as possible.

A. The five substantive principles embodied in the FDA's regulations governing drug investigations are simple enough to state. They are:

(1) that the objectives of the study be clearly stated;[13]

(2) that the subjects of the study be selected by methods designed to ensure patient suitability and comparability in assignment to test groups;[14]

(3) that the methods of observation and recording of results be explained;[15]

(4) that some form of control group be provided so that results achieved can be compared so as to permit quantitative evaluation;[16] and

(5) that all practicable steps be taken to minimize possible bias in investigators wherever necessary.[17]

Many experts in the field of medical devices have testified that these principles simply do not apply to devices.[18] Their greatest concern appears to be about the blinding requirement.[19]

Blinding

Blinding is the principal tool for minimizing bias in reporting by investigators. What these concerned experts are really saying, however, is that the same basic scientific principles which define adequate and well-controlled studies also provide for waiver of the various components in particular cases—as the FDA drug regulations recognize.[20] This is the sixth principle of adequate and well-controlled clinical investigations; namely, that which is practically or ethically impossible of attainment is not required.

An example of what should be acceptable as the "well-controlled investigation" of a medical device was described to Congress in the

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[13] 21 CFR Sec. 314.111(a)(5)(ii)(a)-(1).

[14] 21 CFR Sec. 314.111(a)(5)(ii)(a)-(2).

[15] 21 CFR Sec. 314.111(a)(5)(ii)(a)-(3).

[16] 21 CFR Sec. 314.111(a)(5)(ii)(a)-(4).

[17] 21 CFR Sec. 314.111(a)(5)(ii)(a).

[18] Hearings on H. R. 5545 et al. before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, 94th Congress, 1st Session, Ser. 94-39, at 298-299 (testimony of V. L. Willman, M.D., Chairman, Medical Devices Committee, American College of Surgeons), 311 (statement of William Donaldson, M.D., President, American Academy of Orthopedic Surgeons), 419 (statement of R. T. Rylee II, President, Orthopedic Surgical Manufacturers Association) (1975) (hereafter 1975 House Hearings).

[19] 1975 House Hearings, at 324 (testimony of V. L. Willman, M.D., note 18, *supra*).

[20] 21 CFR Sec. 314.111(a)(5)(ii)(a)(5).

1973 testimony of Dr. Dwight E. Harken, who discussed his own experience in the development of the ball-valve heart valve.[21] First, Dr. Harken described his observation, over a period of ten years, of 87 patients with aortic valve disease for whom he believed an artificial valve was indicated. Seventy-seven were dead within seven months of diagnosis. Such observation of 87 patients with damaged heart valves provided an historical control group, one of the several forms of controls recognized by the drug regulations as acceptable in clinical trials.[22]

Second, Dr. Harken described laboratory work to "develop a valve that would last many years, would not produce strokes, would not damage blood and among other requirements would function much like nature's normal valves."[23] Moreover, he reported "hundreds of animal and engineering experiments over a period of years" prior to development of what he described as necessary for his patients—a "good but not necessarily perfect valve."[24] Dr. Harken and his colleagues thus clearly had their objectives in mind, and had studied their invention on the bench and in laboratory animals prior to testing in humans.

Third, Dr. Harken testified in 1973 that the first two patients to receive his valve in 1960 were still alive. He further reported that the procedure now experiences only a ten percent surgical mortality, that patients have an 80 percent chance of full recovery, and that over 200,000 patients have so benefited.[25] This experience suggests two important questions for which there are no easy answers. First, at what point is the effectiveness of the device established? Must we wait for the survival rate in the treatment group to exceed the mortality rate of the control group or can we rely upon the developers of the device (and FDA's scientists and advisory committees) to make an informed judgment that the device and the procedure are more effective than no therapy at all? Second, does proof that a device is effective in the hands of its development and investigative teams establish effectiveness in general? In other words, will it be effective in the hands of the average health care team?

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[21] Hearings on H. R. 6073 et al. before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, 93rd Congress, 1st Session, Ser. 93-61, at 232 (1973) (hereafter 1973 House Hearings). Dr. Harken is a clinical professor of surgery, emeritus, Harvard Medical School. A past president of the American College of Cardiology, he was speaking on its behalf. *Id.* at 228.

[22] 21 CFR Sec. 314.111(a)(5)(ii)(a)-(4)(iv).

[23] *Id.* at 232.

[24] *Id.* at 232-33.

[25] *Id.* at 233.

Cardiac Pacemakers

A second case was described in the House Hearings by Dr. Arthur C. Beall, Jr., in response to an inquiry by Representative Rogers as to how one goes about establishing the effectiveness of a device.[26] The Congressman asked specifically about the applicability of the double-blinding principle to the study of cardiac pacemakers. Dr. Beall responded that many years of experience have demonstrated that patients with third-degree or complete heart block have a one-year survival rate of 50 percent. Pacemakers have increased that survival rate to 90 percent. Dr. Beall seriously questioned whether double-blind studies with a dummy (placebo) control pacemaker would be possible in such a situation. Obviously, they would not be.

Here, too, the proper form of control in such a case would be the historical control. In light of the now-established effectiveness of pacemakers, placebo or no-treatment controls in such a situation are simply unacceptable from an ethical standpoint.

Moreover, a physician-investigator operating within the strictures of the investigational provisions of the new legislation[27] must obtain the informed consent of his patient before proceeding to perform such a study. Also, he must have the approval of his institutional review committee. It is doubtful that patients would consent to, or that committees would approve, placebo or no-treatment controlled investigations in the face of statistics such as those stated above.

It would not be unlikely, however, for the FDA and its scientific advisors to require that a new pacemaker or a new heart valve be tested against a control device of proven effectiveness. This is an established and recognized control[28] which the device industry and the medical profession can look forward to utilizing extensively in establishing the clinical effectiveness of new products.

Comparative Efficacy

To a degree, this means that such trials will be establishing "comparative efficacy" which is, in theory, a forbidden determination under the drug provisions of the Federal Food, Drug and Cosmetic Act.[29] It

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[26] 1975 House Hearings at 324. Dr. Beall is a professor of surgery at Baylor College of Medicine. He spoke as President of the American College of Chest Physicians and on behalf of three organizations of surgeons. *Id.* at 316.

[27] S. B. 510, proposed Sec. 514(k); H. R. 5545, proposed Sec. 515(f).

[28] 21 CFR Sec. 314.111(a)(5)(ii)(a)(4)(iii).

[29] Hearings before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary on Drug Industry Antitrust Act, 87th Congress, 1st Session, Part 5, at 2585 (1962) (testi-

(Continued on the following page.)

seems appropriate, therefore, that comparative studies as such, and a showing of comparative advantage, be required only when a device is claimed to be an improvement over its predecessors.

B. Difficult as these questions concerning the proper applicability of the drug regulatory principles to devices may be, the industry and the medical profession can look to the detailed provisions of the drug regulations as a starting point. A principal problem encountered by the drug industry in applying the effectiveness requirements of the 1962 Drug Amendments was that the term "adequate and well-controlled clinical investigation" was not authoritatively defined until almost eight years after the statutory provision was enacted. The device industry, physicians and other health professionals who use medical devices would be well advised to begin now to devise the proposed regulations defining the statutory term "well-controlled investigation," particularly as it applies to clinical investigations.

Without a clear and authoritative definition, it is possible that those seeking approval of devices under scientific review will be faced with a constantly shifting standard as they seek to make the necessary showing of effectiveness. Without clear guidance, individuals within the Bureau of Medical Devices and Diagnostic Products are free to apply personal, and perhaps *ad hoc*, interpretations of the statutory language. This is exactly the situation which the industry and the medical community it serves should seek to avoid.

Interview

A personal note may be instructive at this point. In preparing for this presentation, I found it impossible to discover a consistent viewpoint, much less a comprehensible policy, on this subject with the FDA. Almost any degree of rigidity and flexibility, hawkishness and dovishness, can be discovered if you ask enough people what they think are the criteria for a well-controlled investigation of a device. The closest approach to a policy is reflected in an interview in May of 1975 of the FDA Chief Counsel at the time and the FDA attorney principally responsible for device legislation.[30] The FDA spokesmen were asked directly whether "FDA intend[s] to allow any information to support the approval of new devices other than adequate and

(Footnote 29 continued.)
mony of Department of Health, Education and Welfare Secretary Ribicoff that the new efficacy authority "would not require a showing of relatively greater efficacy than that of other drugs").

[30] Published in *Devices and Diagnostics Letter*, Special Supplement, p. 4 (May 23, 1975).

well-controlled studies." In response, they noted that both the House and Senate bills would give the FDA the "administrative flexibility" to accept "other adequate scientific evidence as sufficient to justify the finding of safety and effectiveness." They stated, however, that "nonscientific evidence" would always be unacceptable, and that "anecdotal evidence or mere opinions by experts would under no circumstances meet this statutory test."

The FDA spokesmen did say that "there are other types of scientific evidence, such as well-documented case histories, which, if they are enough, and if it is a product for which additional studies will either be hazardous or for other reasons not warranted, would be sufficient to justify a finding of safety and effectiveness and hence approval." But this raises as many questions as it answers.

For example, when is a physician's observation of his patient mere "anecdotal evidence" and when is it a "well-documented case history"? What is "nonscientific evidence"? When are the "mere opinions of experts" acceptable? Are the opinions of the FDA's advisory committees merely the opinions of experts, or something more, and if so, what and why?

Definition of Statutory Term

Clearly, lawyers alone should not be filling in the definition of the statutory term we have been discussing. This should be done by experts "qualified by scientific training and experience to evaluate the effectiveness of devices." The work should begin now. These experts, under the sponsorship of the FDA, should proceed as expeditiously as possible to develop the basis for a regulatory standard.

The FDA is certainly entitled to some degree of flexibility in its administration of the law. What should not be tolerated, however, is a regulatory vacuum that permits the Agency—or, more likely, individual members of its staff—to utilize the broad contours of the term "well-controlled investigation" as a cover for advancing whatever prejudices, preferences or jurisdictional claims may constitute the official policy of the moment. That would not be responsible regulation, and it would serve the public interest only by coincidence, if at all.

Congress is surely ill-equipped to provide the necessary detailed definitions and principles. The task rightfully belongs to the FDA. The Agency should be encouraged in every way possible to perform promptly this basic regulatory function. **[The End]**

The Use of Regulations to Enforce Statutory Quality Assurance Requirements

By TERRY COLEMAN

Mr. Coleman Is Associate Chief Counsel for Food in the Food and Drug Administration.

THE FEDERAL FOOD, DRUG AND COSMETIC ACT contains identical provisions governing the conditions under which food, drugs and cosmetics must be manufactured and handled. One of these provisions, Section 601(c) of the Act, declares that a cosmetic is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." Decisions in the cases which the Food and Drug Administration (FDA) has brought to enforce these provisions have established two fundamental principles. The first is that the statute is directed at conditions creating a risk of contaminating the product, adulteration in its incipiency, as one court put it.[1] It is not necessary for the government to demonstrate that any product was actually contaminated. Second, in order to save the statute from being unconstitutional on the ground of vagueness, the courts have interpreted the term "insanitary conditions" in a way that requires the government to prove that the conditions under which the product was manufactured or held were those which would result, with reasonable possibility, in the product becoming contaminated.[2]

For many years, the FDA has enforced these provisions without the benefit of regulations defining insanitary conditions. Based on the testimony of FDA inspectors, the government has proved its cases in

[1] *Berger v. United States*, 200 F. 2d 818 (CA-8 1952).

[2] See, for example, *Berger v. United States*, *supra*.

court by establishing that, taking all the conditions of the plant into consideration, there was a reasonable possibility that the product would become contaminated. In reviewing the reported decisions on charges of insanitary conditions, one notes that very few charges have been brought unless they were accompanied by findings of products actually contaminated. Thus, it seems that judicial action usually has been taken only for extreme violations. This history presumably is a result, at least in part, of the difficulty of establishing that there is a reasonable possibility of contamination. Reliance on the statute has therefore established, as a practical matter, a standard for regulatory action considerably higher than preventing adulteration in its incipiency, which is what the courts have, at least in the abstract, held the standard to be.

Need to Establish Regulations

The first formal recognition of the need to establish regulations to define insanitary conditions may have been in 1956 by the Court of Appeals for the Seventh Circuit.[3] In a case involving insanitary conditions at a food cannery, the court stated that if the FDA wanted to improve the sanitary conditions of canneries, it would be more likely to receive the support of the courts if it promulgated regulations that provided detailed standards and then seized food packed in plants not meeting the specific standards set. However, the FDA did not respond to the offer at that time.

In 1969 the FDA published final regulations establishing good manufacturing practices (GMPs) to define the term "insanitary conditions" for food. This so-called umbrella GMP sets forth, in general terms, the requirements for food handling to assure that a food is processed under sanitary conditions. These regulations have been followed by a number of GMP regulations directed at specific industries within the food manufacturing industry. It is anticipated that eventually about 30 separate GMPs will be published to cover the food industry. Presumably, a similar approach would be used for the cosmetics industry, beginning with a broad GMP applicable to all aspects of the industry and eventually followed by more detailed GMPs applicable to specific portions of the cosmetics industry where there are particular problems.

The most controversial aspect of the GMP regulations may be their legal effect. The FDA has issued numerous regulations in recent

[3] *United States v. 1500 Cases*, 236 F. 2d 208 (CA-7 1956).

years to define certain statutory requirements with particularity. For example, in the cosmetics area, the Agency has defined the conditions under which the word "hypoallergenic" and similar terms may be used without being false or misleading. That regulation will be treated by the FDA as having the force and effect of law. Cosmetics GMP regulations would have the same legal effect and could be enforced in particular seizure, injunction or prosecution actions without having to show that, in an individual case, the product had been produced under conditions where there was a reasonable possibility that it might become contaminated. Instead, the question would be whether the product had been manufactured or held under conditions conforming to the requirements of the regulation.

Reasonable Possibility of Contamination

This approach has several advantages. First, it identifies to the cosmetics industry what specific conditions must be met in order to comply with the statutory requirement that cosmetics be produced under sanitary conditions. The statute itself gives very little specific guidance. Second, it eliminates the necessity for the FDA to establish in every enforcement action that there is a reasonable possibility that the conditions existing in the cosmetic plant would lead to contamination of the product. The requirement that a "reasonable possibility" of contamination be shown was introduced into the law by the courts only because the statute was sufficiently vague that, without the judicial definition of "insanitary conditions," the statute does not place manufacturers on notice as to what conduct is unlawful. However, once the FDA has promulgated regulations defining what constitutes insanitary conditions, manufacturers would be on notice as to their obligations. It then would not be necessary for the Agency to demonstrate that there was a reasonable possibility of contamination. Instead, the question would be whether the regulation had been violated. Third is a related point. Since the standard of "reasonable possibility" of contamination would no longer apply, the regulations could focus more closely on preventing adulteration in its incipiency. Regulatory action could be taken against less offensive conditions than now appears to be the practice.

The transition from enforcement by individual judicial actions to enforcement by general regulation has changed the time at which manufacturers must make known their views on the reasonableness of the Agency's view of satisfactory practices. Regulations of the FDA will be upheld by the courts if they have a reasonable basis, and the

reasonableness will be determined on the basis of the administrative record compiled by the Agency during the rule-making proceeding. A manufacturer could challenge a cosmetics GMP regulation prior to enforcement or at the time of enforcement. However, the validity of the regulation would depend on the support in the administrative record. The manufacturer would be required to demonstrate that the regulation was arbitrary or capricious based on the information in the administrative record in order to challenge its validity successfully.

Rule-Making Proceeding

If an issue is not presented to the FDA during the rule-making proceeding, the Agency will object to any consideration of it by a court during an enforcement action. The FDA would expect to prevail on that objection. Consequently, it is necessary that any data or information tending to show that a GMP regulation is unreasonable be brought before the Agency by the affected manufacturers during the rule-making period so that the objection will be part of the administrative record.

One area of concern to both the FDA and industry is that the regulations may be too confining by establishing standards in terms of the current technology and allowing insufficient flexibility for new procedures. It is the Agency's intention to write the regulations with sufficient flexibility to permit the use of different technology to accomplish the same functional effect. It is important, therefore, that manufacturers be alert to this consideration so that they can assist the FDA in drafting the regulations in a way that does not prohibit progress and change of methods.

The FDA is also taking steps to ensure that each issue involved in the validity of a regulation will be challenged only once. While the Agency is always prepared to defend the validity of its regulations, it is burdensome and conceptually unnecessary to defend the regulation against repeated challenge.

It ought to be sufficient to test once whether the regulation is legally valid. Thus, the FDA has taken the position that in pre-enforcement review of its regulations, it will attempt to have a lawsuit converted into a class action when the lawsuit is brought by a trade association. Thus, for example, if the Cosmetic, Toiletry and Fragrance Association (CTFA) were to challenge a cosmetic GMP after it was final, the FDA would seek to have that suit made into a class action, thus binding on all members of CTFA and, perhaps, on other

members of the cosmetics industry as well, so that the regulation could not be contested again in individual enforcement actions.

In summary, the use of GMP regulations for the cosmetics industry would set forth explicitly the requirements a manufacturer must comply with to satisfy Section 601(c) of the Federal Food, Drug and Cosmetic Act. At the same time, the use of regulations would restrict the occasions on which the reasonableness of the regulations may be tested. The result should be an industry more informed of its legal obligations and an FDA making better use of its limited resources.

[The End]

COURT UPHOLDS WARNING LABELING FOR AEROSOL FRAGRANCES

Regulations that require warnings to appear on aerosolized food, drug and cosmetic products have been upheld by a federal court against charges that the regulations are arbitrary and capricious as applied to aerosolized fragrances. Once the Food and Drug Administration determines that regulations apply to a category of products, the burden falls on complaining parties to demonstrate that a sub-category of products should not be subject to the regulations, the court said. The requirement that the warnings appear on the product's immediate labeling was also upheld, despite claims that the requirement would cause the fragrance industry a severe economic burden and destroy the aesthetic value of the industry's product packaging. *Cosmetic, Toiletry and Fragrance Association v. Schmidt.*

CCH Food Drug Cosmetic Law Reporter, ¶ 38,047

Quality Assurance Procedures for the Cosmetics Industry—The FDA's Viewpoint

By JOHN A. WENNINGER

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THE CONCEPT OF GOOD MANUFACTURING PRACTICES (GMPs) for quality assurance has been an important aspect of manufacturing safe foods, drugs and cosmetics from the beginning of the industrial era. Inherent in this concept is the fact that standards of GMPs are standards which are set, to a large degree, by industry itself. In most instances, the Food and Drug Administration (FDA) can rely on the management of cosmetics firms to apply the principles of GMPs to achieve an acceptable degree of self-regulation or voluntary compliance. However, there are instances where a back-up system is needed to protect the interests of the consumer when voluntary compliance measures either fail or are inadequate to do the job. I will discuss the FDA's viewpoint on GMPs for the cosmetics industry.

In recent times, the Agency has carried out a continuing dialogue with the regulated industries on the need and the content of GMP regulations for many commodities under its jurisdiction. Having reviewed these regulations, I am impressed by the fact that the principles of GMPs set forth in these documents were both reasonably attainable and contained requirements which reputable firms probably would have already implemented by the time the regulations were promulgated. When this is not the case, firms marketing consumer products are not carrying out their responsibility under the Federal Food, Drug and Cosmetic Act.

The FDA has made plans to develop and ultimately propose in the *Federal Register* a GMP regulation for the cosmetics industry. It is the FDA's duty to inform those who are regulated of the precise requirements that they are expected to follow under the law. It has been the Agency's experience that effective regulation induces widespread compliance and avoids misunderstandings and time-consuming litigation. This practice ultimately fosters a spirit of compliance which improves the quality of marketed cosmetics and, in turn, increases consumer confidence in both industry and government.

There are several reasons why the FDA is proceeding now to develop a GMP regulation for cosmetics. Such a regulation will:

(1) inform the industry of what is expected under the law;

(2) serve as a guideline for Agency officials who must make administrative decisions in the compliance area;

(3) conserve our scarce resources by improving the efficiency of our inspection and review processes; and

(4) improve the quality of marketed cosmetic products.

Factory Inspection Provisions

Under Section 601 of the Federal Food, Drug and Cosmetic Act, the conditions whereby a cosmetic is deemed to be adulterated are enumerated. The factory inspection provisions of the Act (Section 704(a)) authorize the FDA to inspect, at reasonable times and in a reasonable manner, cosmetics manufacturing establishments and all pertinent equipment, finished and unfinished materials, containers and labeling.

In enacting the law, Congress, for the most part, chose to express the mandate in broad and general terms. The fundamental objectives are provided. However, the FDA has a responsibility to specify these objectives in greater detail in the form of regulations and implement them to assure consumers of their full measure of protection under the law.

Traditionally, the FDA has carried out its responsibility under the law by conducting establishment inspections and sample analyses. The inspection monitors the operation and sample analysis monitors the product. The primary purpose of most inspections is to determine if products are manufactured under conditions assuring their safety.

GMP regulations will assist the Agency in making informed and consistent judgments during the inspectional process. At the same time these regulations will inform the cosmetics manufacturers of the criteria used to evaluate their operations. In addition, they will learn what is regarded as GMP under the law. One important aspect of GMPs is the nature and the extent of a firm's quality control procedures. By that is meant ascertaining what safeguards a firm has instituted to assure that products:

(1) do not contain unsafe ingredients;

(2) are free of filth;

(3) have been prepared under sanitary conditions; and

(4) are not packaged in unsafe containers.

Potential Impact on Consumer Safety

These are important issues which require careful evaluation because of potential impact on consumer safety. A comprehensive GMP for cosmetics would serve as an effective guide in resolving these questions. It will help to prevent violations of the law and to detect them before a defective product reaches the consumer.

During the fiscal years 1973 and 1974, the FDA conducted about 1,000 inspections of cosmetics establishments. These inspections were carried out utilizing guidelines that were very general in nature. To a large extent, individual investigators applied the principles of the more extensive guidelines in the food and drugs area to cosmetics firms. Although this appeared to be effective, the investigators lacked the objective guidelines necessary to make specific judgments regarding potential problems associated with the manufacture of cosmetic products. During inspections of cosmetics establishments, the most frequently identified problems were associated with deficiencies in GMPs. During the next 18 months, the Agency will attempt to document with greater specificity these problems as a basis for developing reasonable and effective guidelines for the industry.

What effect will an FDA GMP regulation have on the cosmetics industry? For firms that are already following GMPs, the effect will be minimal, if any at all. Of course, there may be some firms which either do not subscribe to the concept or, if they do, have made only a limited effort to follow GMPs effectively. For these firms compliance may well be painful and will require expenditure of additional resources depending on individual circumstances.

Quality Assurance Guidelines

The FDA recognizes the substantial effort made by the Cosmetic, Toiletry and Fragrance Association (CTFA) in the self-regulation area when it published its quality assurance guidelines. This document will have a substantial impact on the FDA's development of a GMP for the cosmetics industry. However, the Agency does not expect simply to publish CTFA's guidelines in the *Federal Register* as its proposed regulation. In developing a meaningful GMP for cosmetics, the FDA will draw extensively from its own experience in developing GMP regulations for food and drugs.

At the start of this discussion I alluded to the fact that GMPs are standards set by industry. The government's role must be one of assuring compliance. No doubt, there will be disagreements concerning the need, the content and the Agency's authority for promulgating a GMP regulation for the cosmetics industry. This is to be expected, as each party tends to interpret the law to its own best interest.

However well meaning our intentions may be, the fact still remains that the regulated industry has a right to know what the government believes, what its policies are, and how it intends to implement them. Even after we have done this, we still may disagree, but at least we will know what we are disagreeing about. **[The End]**

FOOD AND DRUG ADMINISTRATION LISTS LAWFUL SOURCES OF DRUGS WITH BIOEQUIVALENCE PROBLEMS

The Food and Drug Administration (FDA) has made publicly available a list of drug firms authorized to market drugs having known or potential bioequivalence problems. The FDA had provided a partially completed list of such drugs in the preamble to proposed procedures for establishing bioequivalence requirements, issued June 20, 1975. Drugs having known or potential bioequivalence problems may lawfully be obtained from firms that hold approved new drug applications or abbreviated new drug applications, or are listed in NDAs, ANDAs, or supplemental applications, for such products. Based on current evidence, the FDA estimates that only 20 to 25 drug entities have had documented bioequivalence problems.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,565

Quality Assurance Guidelines—The Industry's Viewpoint

By EDWARD MILARDO

Mr. Milardo Is Director of National Quality Control of Avon Products, Inc.

I AM PLEASED to have the opportunity to be a part of a discussion of quality assurance guidelines. Joint participation, by the Food and Drug Administration (FDA) and industry, provides a good opportunity for different viewpoints to be heard and, hopefully, understood. It is my hope that we can mutually define the *true needs* of the *consuming public*, and develop a course of action that will provide the best means of meeting these needs. It is my intention to furnish some background information on the quality assurance guidelines of the Cosmetic, Toiletry and Fragrance Association (CTFA).

As a start, I would like to review the basic elements involved in bringing safe cosmetics to the marketplace. It is important, I think, to distinguish between the design—or developmental—stage, and the manufacturing and distribution stage. In the first, we are concerned with substantiating the safety of a given formulation and with establishing the necessary specifications and controls required for maintenance. In the second stage, we are concerned with the implementation of the plan. Having designed a good safe product, we must implement the necessary procedures and controls required to faithfully duplicate, by the thousands, the original product. Unless these two tasks are done well, we cannot have adequate assurance that the products being sold are the good, safe products we intended.

I would like to discuss the second stage, the manufacturing and distribution cycle. Because of its potential effect on quality, and its complexity, it is important that proper attention be given to this element. In essence, we are talking about the areas which are embraced by the term "quality assurance guidelines."

Successful Quality Assurance Program

In order to have a successful quality assurance program, it is necessary to have two basic ingredients, *commitment* and *knowledge*.

The means for a successful quality assurance program occur when there is dedication to a particular goal (in this case, to the distribution of safe cosmetics) combined with the knowledge of what is specifically required to achieve it. The success or failure must be measured by the end result—what is happening in the marketplace. It would seem to follow, then, that any *need* to change must come from failure to achieve our goal, as measured by the results.

Despite the various statistics which have been published in recent years, it is a matter of fact that no one has yet made a solid case for the proposition that cosmetics present a serious risk to consumers. This is not surprising since solid evidence from the marketplace apparently does not exist. One of the contributing factors to this is the fact that the industry has been alert and responsive, and has taken many steps to provide adequate testing and controls. Another factor is the vigilance and the perseverance of the FDA in carrying out its responsibilities with regard to the integrity and safety of cosmetics. I once read that "fear is the beginning of wisdom." While I have not explored all of the philosophical implications of this profound statement, I can recognize the truth in it as applied to some situations. I believe that, in all honesty, we must admit that the presence of this Agency, looking over our shoulders, has provided a significant impetus to our efforts.

Voluntary Compliance

In 1968, in an address to members of the cosmetics industry, FDA Commissioner Goddard challenged the industry to pursue a more aggressive program of voluntary compliance with the law. He said that industry should do a better job of anticipating the needs of the public and of initiating action in the public interest, especially in those areas requiring scientific and engineering expertise.

I believe that was, and still is, a fair challenge. As an industry, we must recognize the increasing demands being placed on us, and respond to them in a responsible way. As technology improves, we must be ready to provide answers to new questions which arise.

The CTFA, through its various technical committees, has done a very creditable job of meeting this challenge. I would like to review

some of the work of two committees—the Microbiological Committee and the Quality Assurance Committee. Both of these committees were started in response to an industry-wide need for more information in two vital areas. Since its start in early 1970, the Quality Assurance Committee has devoted itself almost exclusively to the subject of proper manufacture, and quality control, of cosmetics. Similarly, the Microbiological Committee has devoted much of its time to this area, with particular emphasis on microbiology.

Results of Committees

The initial results of these committees were two documents—the quality assurance guidelines and guidelines concerning the microbial aspects of quality assurance. These guidelines were designed to outline the major areas of concern and to provide information to cosmetics manufacturers to assist them in the establishment of quality assurance programs. Since that time, the committees have concentrated on a number of supplemental guidelines, which focus on a particular area and provide specific information designed to help manufacturers in finding the best answer for their particular situations.

The Quality Assurance Committee has issued supplemental guidelines on factory inspection, plant housekeeping and cleanliness, packaging equipment, processing equipment, and production and control documentation. The Microbiological Committee has issued guidelines on process water, microbiological limits, and preservation. Additional subjects are being pursued by both Committees.

In addition to the various guidelines mentioned, several audio-visual slide presentations have been prepared for use in training programs. These include an introduction to the quality assurance guidelines and four specific presentations on microbiological subjects. These guidelines and audio-visuals are designed to provide specific information on a variety of subjects. They can be used for training programs as well as for developing company operating procedures.

Production and Control Documentation

As an example, the production and control documentation guidelines cover key operational steps which should be documented and properly maintained to assist in achieving product uniformity and integrity. In addition, such documentation provides a history of manufacture. Actual examples of formulas, batching procedures, product specifications, testing methods and inspection reports are shown.

Similarly, the slide presentations furnish pictorial examples of the ideas being expressed. The sanitary practices slides are actual photographs of bacteria cultures which demonstrate sources of contamination, such as dirty hands, sneezes, hair and clothing.

Each of the other subjects is handled in the same manner, with a statement of the objective followed by specific information.

I think it is interesting to note that the membership of these committees is broad in scope and interests. The Quality Assurance Committee has had members representing 21 different companies. At present, the number stands at 16. The Microbiological Committee and its subcommittees have had representatives from 32 different companies. The companies range in size from small to large and include contract packagers as well as manufacturers and distributors. The interests and work experience of individual members includes research and development, quality control and production.

Work to Be Done

While pointing out the accomplishments of these CTFA committees, I must also mention that we are aware of the amount of work yet to be done. There are specific areas which have not yet been covered in detail, and documents already issued must be reviewed for improvements. At the present time, the quality assurance guidelines are undergoing an exhaustive review to identify any deficiencies in specific wording and coverage.

I believe that the scientific community of the cosmetics industry is well aware of its obligations regarding the well-being of our customers, and stands ready to make any additional contributions required. We recognize the significant contribution made by the FDA in carrying out its statutory responsibilities. We recognize and welcome the trend, in recent years, for increased cooperation between the FDA and the industry. This cooperation has resulted in better utilization of existing knowledge and experience, to the benefit of the consuming public.

It is my hope that, through continued cooperation of this type, we can make further strides in the area of quality assurance. The cosmetics industry has shown that it can rise to a responsible challenge, and I have confidence it will continue to do so. **[The End]**

Cosmetic Ingredient Labeling— An FDA Chimera

By WALTER E. BYERLEY

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ASKING ME TO DISCUSS COSMETIC INGREDIENT LABELING is like asking George Allen to discuss the Dallas Cowboys. There may be something good to be said about the subject, but I am unwilling to search very hard to find it.

Before I begin, I should make one point. "Cosmetic ingredient labeling" is a misnomer. It might be described more accurately as cosmetic ingredient *packaging* because compliance with this regulation will require vast changes in size, shape, style and design of a great many cosmetic packages.

It might even be described more accurately as a "cosmetic ingredient changes" regulation since, as a result of this regulation, a great many formulations may be changed for one reason or another. At any rate, what is involved is much more than simply preparing new labels and labeling.

The only real challenge to this regulation has been brought by my clients, the Independent Cosmetic Manufacturers and Distributors (ICMAD). The burden of our complaints, both substantively and procedurally, has been spelled out repeatedly in the two court cases we have filed. I will not repeat them here. Suffice it to say that, although the District Court refused to grant us an injunction and the Circuit Court refused to grant us a stay, we still are confident that the Circuit Court, when it reaches the merits of this case, will hold this regulation invalid.

But by that time, the issue may well be moot. The fact is that the cosmetics industry is already well down the road to changing its packages and labeling to comply with this regulation. With the first effective date—May 31, 1976—close at hand, industry cannot wait any longer for a decision from the court. On May 31, the industry must have the multitude of necessary changes completed, so that any packages and labels ordered after that date will be in compliance.

There are others who can tell you, better than I, the "nuts and bolts" of what the cosmetics industry must do to comply with the regulation. So I will not discuss that area. Rather, I will take the liberty of indulging in a little philosophizing. Since both the Food and Drug Administration (FDA) and the courts have thus far denied me a chance to present my views to them, I will impose them on you.

Costly Compliance

Compliance with this regulation will be difficult, time-consuming and costly. None of these, of course, constitute reasons for prohibiting the issuance of a regulation that is useful and necessary. But it seems to me that they are good reasons not to issue a useless, unnecessary regulation, such as the one under discussion.

No finding has ever been made that this regulation meets the sole statutory basis for its existence. No authority exists for the issuance of this regulation under the Federal Food, Drug and Cosmetic Act. Under the Fair Packaging and Labeling Act (FPLA), the only possible source of such authority, a regulation such as this can be issued only if the FDA finds that the regulation is necessary to prevent the deception of consumers or facilitate value comparison. No one has proved yet that this regulation will do either. I submit to you that the regulation, as presently drawn, cannot prevent deception or facilitate value comparison.

The most common reason advanced for ingredient labeling is that this will enable consumers who have allergies to avoid those ingredients which trigger those allergies.

This seems a reasonable goal. If this regulation had any chance of achieving that goal, I would have to admit that it might serve a useful purpose.

Avoidance of Allergens

But, as dermatologists and other allergy experts have repeatedly pointed out, the ingredients in cosmetics which most frequently cause allergies are the components of flavors and fragrances. Guess which cosmetic ingredients are specifically exempt from being listed by name? The answer, of course, is flavors and fragrances. So, when you draw up your ingredient list, you will have to list all those ingredients that usually do not cause allergies, but you will place those that most frequently do cause allergies under the umbrella names "flavors" and "fragrances." Frankly, I am at a loss to understand how this helps the consumer avoid allergens.

Occasionally, a base, a binder or a filler will cause an allergy. And these will be listed. But they will not be listed in any coherent order, so that the consumer who may be allergic to that ingredient can find it quickly and easily. Rather, they will be listed in descending order of predominance. The allergen may be listed first, or fifteenth, or thirtieth on the list—or, of course, it may not be listed at all. Any consumer who wants to search for a specific allergen will have to read 20, or 30, or 100 strange chemical names, each printed in one-sixteenth inch type, to find out if it is there or not.

Wouldn't it be more logical to list only the allergens? Then the consumer need read a list of only one, or two, or maybe five names, rather than dozens.

If this is unacceptable because of the argument that *somebody* is allergic to everything, so all ingredients must be listed, then why not list them alphabetically? If the consumer is allergic to benzocaine, she need only search under the "Bs" to see if it is there.

Heinz Eiermann, Director of the Division of Cosmetics Technology in the FDA,[1] has told me that the regulation cannot permit partial listing or alphabetical listing because the FPLA says that the Commissioner can issue regulations requiring that each ingredient be listed in order of descending predominance.

Listing of Ingredients

That is what the law says, I agree. But the fact is that, despite this language, the regulation does *not* require the listing of each ingredient by name in order of descending predominance. Flavors and fragrances need not be listed by name at all. Ingredients present at a level of less than one percent can be listed in any order whatever.

So the Commissioner has, in fact, made exceptions to the strict language of the FPLA. If he has the power to make these exceptions, he has the power to make others, such as partial listing or alphabetical listing.

But he has not done so. The result is going to be that very few consumers are going to take the time and make the effort to search through a lengthy ingredient list for that ingredient to which they are allergic.

So the allergen argument as a good reason for these regulations falls flat.

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[1]For article by Heinz Eiermann, see page 115.

About the only other argument consistently advanced is the "value comparison" argument. Since the ingredients are listed, goes this argument, one can tell if cosmetic A contains a valuable ingredient not contained in cosmetic B.

But what is a valuable ingredient? Is lanolin, for instance, more valuable than glycerin? I sure don't know, and neither do most consumers. On the other hand, many of them might say that both are valuable, for different purposes and uses.

Again, even assuming that a few consumers wish to look for a specific ingredient, how are they going to find it? They must read all those chemical names, in no coherent sequence. Very few will do it.

Predominance Labeling

Suppose both cosmetic A and cosmetic B contain the valuable ingredient, but in a different place in the sequences? Lanolin might be listed seventh in cosmetic A and fifteenth in cosmetic B. Does this mean that A has more lanolin than B? Of course not. All predominance labeling tells you is that any given ingredient in a cosmetic is present in that product in an amount less than the ingredient which of dollars. One would think that before the FDA issued a regulation dominance labeling cannot tell the consumer anything about the relative amounts of an ingredient in two different products.

So how does one compare value? If cosmetic A and cosmetic B are the same price, which is the "best buy"? I defy any of you to answer that question simply by reading a list of ingredients which complies with this regulation. So that argument, also, falls flat.

I know of no other argument that can be used to support cosmetic ingredient labeling. Nor, as near as I can tell, does the Commissioner. In his preamble to the October 17, 1973 order, the Commissioner was reduced to saying that cosmetic ingredient labeling "can be meaningful."

I submit to you that the wistful hope that ingredient labeling "can be meaningful" is a weak straw upon which to base a regulation that will cost the industry—and, ultimately, the consumer—millions of dollars. One would think that before the FDA issued a regulation that has as great an impact as this one, it would have considered the matter seriously to determine if the benefits to be gained would justify the cost. As a matter of fact, the President, in late 1974, ordered all agencies to consider the economic consequences of their actions. But that did not happen in this case. No one has ever proved that there are any benefits from this regulation, let alone proved that these bene-

fits are commensurate with the cost. I submit that no one *has* shown these things because no one *can* show them.

Legality of the Regulation

When we decided to challenge in court the legality of this regulation, we asked the FDA to delay the effective date, so that, if the Court does declare it to be invalid, the industry will not have wasted the time and money necessary to bring its products and packages into compliance.

The FDA refused this request. Not only did the Agency refuse to grant a delay itself, it has fought very hard—and thus far successfully—to persuade the courts not to grant a delay in the effective date.

Why is this, I wonder? There is a possibility—I think a great possibility, the FDA thinks a remote possibility—but there is *some* possibility that this regualtion will be held invalid by the courts. In view of this possibility, why is the Agency so insistent that the effective dates of May 31 and November 30, 1976, be met? Why the urgency now, when there was none earlier? The FPLA was passed in 1966. At any time after that date, the Commissioner could have started proceedings to issue this regulation, if the need for it was urgent. But apparently there was no urgency, for the Commissioner took no action in this direction until 1973, seven years after the Act was passed. Action was taken only after Joseph Page and the Consumer Federation of America had filed a citizen's petition.

And even then there was no sense of urgency. The first "Final Order" was published October 17, 1973, with an effective date of March 31, 1974. After this order was objected to, negotiations with the objecting parties were held. The effective date was moved to March 3, 1976, a delay of nearly two years. The last order in this matter moved the date even further, to May 31, 1976.

Present Effective Date

So where is the urgency? The present effective date is ten years after the law was passed, four years after the petition was filed, over three years after the initial proposal, and over two years after the first established effective date.

What possible harm can result from delaying it another six months or a year, so as not to run the risk of subjecting the industry to an enormous waste of time and money? Certainly, there is no clear and present danger to the public health. So why the sudden steely determination to adhere to the effective dates? I do not know for sure, but I can give you my analysis.

The FDA does not like the regulated industries to challenge it in court. The Agency would much rather see industry acquiesce and accept regulations which may or may not be valid. After all, if every regulated industry filed suit, the FDA would have to devote its time and energy to opposing those suits, and would not have time to issue new regulations. And that, of course, is unthinkable.

So maybe the FDA's insistence that the effective date not be delayed is simply a method of punishing an industry that had the temerity to file a lawsuit. Maybe the reasoning of the FDA went like this: "ICMAD may eventually win this lawsuit or they may not, but either way, we'll make it so troublesome and expensive that they, and every other industry, will think long and hard before they ever file another one."

I do not know whether or not the FDA, or anyone in the FDA, ever articulated this thought so clearly, but I do know that my suspicion is based on more than speculation. The FDA has, in the promulgation of this regulation, very clearly demonstrated punitive intent. In the orders published March 3, 1975, the FDA purportedly made the basic requirement for predominance listing final and issued some new subsections which, in the Agency's view, mitigated the basic requirement. The FDA then said that, if anybody dared challenge the "mitigating" subsections, it would stay those and those only, while putting the basic requirement into effect. The net result of that statement is:

". . . All labels will have to be changed to meet the requirement of the present regulation, and after the hearing, they would be required to be changed again to meet the rules for declaration of color ingredients established following that hearing."[2]

In other words, accept unquestioningly, what we have done, and change your labels once. Dare to object and we will make you change them twice. In polite terms, such reasoning is called coercion.

But that is all behind us now. The FDA has spoken. And so all cosmetics manufacturers can revise their packages, containers, silkscreens and labels, to comply with this regulation, secure in the knowledge that not one consumer in a thousand will ever read the ingredient list. Of those who do, not one in ten thousand will thereby derive any benefit. But it must be done because Joseph Page and the Consumer Federation want it done. The FDA says do it, whether it helps anybody or not, and do it now. **[The End]**

[2] 40 *F. R.* 8922 (March 3, 1975).

Cosmetic Ingredient Labeling Requirements

By HEINZ J. EIERMANN

Mr. Eiermann Is Director of the Division of Cosmetics Technology in the Bureau of Foods in the Food and Drug Administration.

AFTER MORE THAN THREE YEARS of urging, petitioning, rule-making, objecting, amending and litigating, cosmetic ingredient labeling now appears to be on its way to becoming a reality. By May 31, 1976, all labels must be ordered with ingredient declarations. All products must be labeled with these new labels before November 30, 1976. Although manufacturers may ship cosmetics which do not list ingredients until inventories are depleted, the distribution of products without ingredient declarations will soon run its course for competitive reasons. Consumers will learn that cosmetics without ingredient declarations could be old merchandise.

During the coming months, cosmetics manufacturers will be busy preparing for ingredient labeling. Many last minute questions will arise for which answers may not readily be found in the regulations. It is hoped that this discussion will answer some of these questions.

(1) *Order of declaration and identification of ingredients.*—The ingredients must be declared in descending order of predominance and must be identified in the declaration by the names adopted for the purpose of ingredient labeling in the compendia listed in the October 1973 order.

I would like to make one comment concerning the Cosmetic, Toiletry and Fragrance Association *Cosmetic Ingredient Dictionary.* Almost every ingredient monograph offers other names for listed ingredients as a convenient reference, particularly to proprietary raw materials. In some instances, a proprietary raw material contains additional ingredients which are not mentioned in the ingredient

definition and which must be declared on the label. The cosmetic manufacturer is therefore well advised to confirm with the supplier the accuracy of a proprietary raw material composition. The cosmetic manufacturer is fully responsible for the truthfulness of the ingredient declarations of its products.

Concentration of One Percent or Less

Ingredients present at a concentration of one percent or less may be declared without respect to order of predominance after declaration of the other ingredients in the order of predominance.

Color additives present at any concentration may be declared without respect to order of predominance after declaration of the other ingredients.

(2) *Incidental ingredients.*—Incidental ingredients need not be declared. An incidental ingredient is a substance which is present in the cosmetic at an insignificant level and which has no technical or functional effect in the cosmetic. It may enter the cosmetic as an ingredient of another ingredient, or it may be added as a processing aid. Some examples are a filter aid, a small quantity of an ingredient to adjust a pH or to neutralize an acid or alkali, or a small amount of an ingredient to correct the viscosity of a batch. However, three percent of propylene glycol, for example, would not qualify as an incidental ingredient if it were added to a shampoo to adjust its viscosity.

Also not considered incidental ingredients are color additives that are sometimes added for shade matching of a batch. They must be declared on the label. A manufacturer may, however, list such color additives on all packages of a product, whether they are or are not present in a particular batch. They must be listed following the declaration of other color additives and following the phrase "may contain."

(3) *Alternative ingredients in the event of ingredient shortages.*—I will not discuss the provisions regarding the declaration of alternative ingredients because cosmetic raw material shortages are no longer an issue, and will not be in the foreseeable future. Shortages of raw materials resulting from logistical difficulties of individual suppliers or cosmetic manufacturers do not qualify for alternative ingredient labeling.

(4) *Letter size of ingredient declarations.*—The ingredients must be declared in letters not less than one-sixteenth of an inch in height using the lower case letter "o" as the minimum standard. On packages

with a total surface area to bear labeling of less than 12 square inches, the ingredients may be declared in letters not less than one thirty-second of an inch in height. If physical characteristics of the package surface make labeling impractical, that surface area is not considered available for labeling. Examples of unavailable surface area include surfaces with a decorative relief, fluted surfaces and sculptured surfaces.

(5) *Multiunit and multicomponent packages.*—Multiunit packages and multicomponent packages must bear ingredient declarations only on the outside package. An example of a multiunit package is a gift set containing two or more individual products. A hair coloring kit consisting of color solution, hydrogen peroxide and conditioner is an example of a multicomponent package. The Fair Packaging and Labeling Act (FPLA) defines "package" as the container or wrapping in which a consumer commodity is enclosed for delivery or display to retail purchasers. However, where the retailer customarily breaks up a multiunit or multicomponent package and sells the inside packages individually, the distributor is required to label also the inside items.

(6) *Off-package ingredient labeling.*—Under certain conditions, the ingredient labeling regulations provide for off-package labeling. The total surface area of the package must be less than 12 square inches, the cosmetic cannot be enclosed in a folding carton, and the products must be held and displayed for sale in tightly compartmented trays or racks of a display unit.

Compartmented Trays

Off-package labeling is also permitted in some instances where the products are not held in a display unit. This provision, however, applies only to shaded products, namely, eye and facial makeup products and nail enamels. With these products also, the total surface area of the package must be less than 12 square inches, the cosmetic cannot be in a folding carton, and the products must be held in tightly compartmented trays or racks. They may be stored below the counter, however.

The ingredient declarations must appear on padded sheets or leaflets which must be shipped with the display unit or, when the products are held in compartmented trays below the counter, with the display chart which shows the product shades and which is displayed on the counter. The holder of the padded sheets or leaflets must be attached to the front or the side of the display or chart in the prescribed manner and must be readily accessible to purchasers.

The padded sheets or leaflets must state the ingredient declarations of all products sold in conjunction with a display or chart and for which off-package ingredient labeling was chosen. Enough copies of the declaration must be provided with each shipment of merchandise so that a consumer may obtain a copy with each purchase.

Copies supplied with refills must be attached to, or inside, the nested disposable carton in which refills are usually stored and shipped. The carton may not contain another product. Furthermore, the distributor is obligated to mail a copy of the declaration to any person requesting it.

When a formulation change is made, the leaflet must state the old and new ingredient declaration of the product, and it must inform the consumer that either declaration may be applicable. Furthermore, the leaflet must be dated when not shipped with the display or chart.

(7) *Assortments of cosmetic products.*—When a cosmetic which is an assortment of products in one package is distributed, color additives may be declared in a single composite list, provided it is indicated on the label that the list pertains to all products.

Common Ingredients

Where the products of such an assortment are similar in composition and are intended for the same use, a manufacturer may declare the ingredients that are common to all the products in a single list in their cumulative order. The other ingredients must be listed separately and must be identified with the products in which they are present. The color additives may be declared in a single composite list without identifying the products in which they are present.

When an assortment of products of similar composition and intended for the same use is in a package which has a surface area suitable to bear labeling of less than 12 square inches, the ingredients of all products may be declared in a single list in their cumulative order. The products in which they are present need not be identified. As mentioned earlier, surface area is not available for labeling where physical characteristics of the package surface make labeling impractical.

(8) *Branded shade lines.*—Shade lines of eye or facial makeup products or nail enamels which are sold under a common trade name or brand designation may have a single ingredient declaration serving all line products. A manufacturer must declare first the ingredients

that are common to all products in a single list in their cumulative order; second, the other ingredients not common to all products with identification of the products in which they are present; third, the color additives that are common to all products; and fourth, preceded by the phrase "may contain," the color additives not common to all products. There is always the option of dividing a shade line into groups of products and using more than one ingredient declaration.

(9) *Branded shade line assortments.*—Sometimes shade lines of eye or facial makeup products consist of several assortments containing two or more shades in the same package, as for example, a line of compacts containing eye shadows of different colors. These branded shade line assortments are labeled like single items of a branded shade line, namely: (1) single list of common ingredients; (2) noncommon ingredients identifying the products in which they are present; (3) single list of common color additives; and (4) noncommon color additives preceded by the phrase "may contain."

(10) *Ingredients considered trade secrets.*—Ingredients considered to be trade secrets and accepted by the Food and Drug Administration (FDA) as exempt from public disclosure need not be declared on the label. The FPLA excludes trade secrets from label disclosure. In place of the trade secret ingredient, the phrase "and other ingredients" may be used at the end of the ingredient declaration.

In order for a cosmetic manufacturer to have an ingredient exempted from public disclosure, it must file with the FDA the cosmetic product formulation. In addition, the manufacturer must request confidentiality for the ingredient in question and must submit supportive data justifying the request.

Agency's Criteria

Many questions have been asked about the Agency's criteria for exempting cosmetic ingredients from public disclosure. Although a difficult task, it is by no means shrouded in mystery. The Freedom of Information regulation defines the term "trade secret" as follows:

"A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one's business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."

Furthermore, paragraphs 80 through 87 of the preamble to this regulation discuss the trade secret issue at great length.

In the case of cosmetic ingredients, requests for exemption from public disclosure are evaluated by reviewing the information sub-

mitted in support of such requests and determining: (1) to what extent the ingredients are unique and important to the product and, hence, make the information valuable to the manufacturer and its competitors; (2) what measures have been taken to guard the secrecy of the information; (3) that the information is not known to competitors; and (4) what difficulties others would encounter to acquire the information by means of chemical analysis or other legal means to duplicate the product.

It should be pointed out that the determination of an ingredient's trade secret status is greatly influenced by the quality of the data submitted in support of the requested confidentiality. A determination whether or not an ingredient is exempted from public disclosure constitutes final Agency action. Of course, any decision not to accept an ingredient as a trade secret may be contested in the courts, and the records may be withdrawn. If suit is brought within ten days after the denial of a request for confidentiality of an ingredient is communicated to the cosmetic manufacturer, the FDA will not disclose the records involved, should they not be withdrawn. Furthermore, the Agency will not require that the ingredient in question be disclosed in labeling until the matter has been decided in the courts.

Further Delays

A cosmetic manufacturer should allow about three months for a determination by the Agency of the confidentiality of an ingredient. Further delays can be expected if a submission is incomplete or if a major backlog of requests occur.

The FDA's current backlog consists of approximately 50 confidentiality requests. A last minute upsurge in requests is expected. The Agency will do its best and review as many requests as circumstances permit. However, cooperation of the cosmetics manufacturer is needed. Requests should be submitted without delay. Whether or not all requests can be processed in time to meet the ingredient labeling deadline will depend as much on industry's cooperation as it does on the Agency's resources to process the requests expeditiously. **[The End]**

Status Report on Cosmetic Ingredient Labeling

By MARGARET GILHOOLEY

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THIS PRESENTATION CONSISTS OF AN UPDATE on the status of the Food and Drug Administration's (FDA's) cosmetic ingredient labeling regulations. I will first summarize the status of the regulations as the Agency has established it. Then, I will explain the effect of the current litigation or, to be more precise, the noneffect of the litigation as of the moment. The Agency has promulgated final regulations with delayed effective dates and, absent a judicial reversal, cosmetic ingredient labeling will be required in stages, beginning as early as May of 1976.

To explain the status of the regulations, it is necessary to survey very briefly the regulations' history. The FDA issued its cosmetic ingredient regulations in two parts. The basic regulations[1] were issued as final regulations in the October 17, 1973 *Federal Register*.[2] Because the regulations were issued under the Fair Packaging and Labeling Act, formal rule-making procedures had to be observed.[3] Accordingly, when the Commissioner issued the basic regulations, he gave affected persons an opportunity to raise objections and to exercise their statutory right to request a hearing on disputed material issues of fact. The Commissioner ruled on the objections raised to the basic regulations in the March 3, 1975 *Federal Register*.[4] He identified two issues raised by the objections which would have required a formal hearing, if not withdrawn. These related to colors and small packages in racks. In

[1] See 21 CFR Sec. 701.3(a)—(e).
[2] 38 *F. R.* 28912 (Oct. 17, 1973).
[3] 15 U. S. C. Sec. 1455(a), incorporating by reference Sec. 701(e)(f) and (g) of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. Sec. 371(e)(f) and (g).
[4] 40 *F. R.* 8924 (March 3, 1975).

the same issue of the *Federal Register*,[5] the Commissioner promulgated the second part of the cosmetic ingredient labeling regulations in the form of amendments.[6] These provide alternative methods for making the declaration of ingredients. At that point, the Commissioner gave affected persons an opportunity to file objections and request a formal hearing with respect to these new provisions. He expressed his expectation that the new amendments would meet the objections raised to the basic regulations by those who had made a timely request for a hearing, and that they would withdraw their objections. This is indeed what happened.

Alternative Methods of Declaring Ingredients

In the intervening period between October of 1973 and March of 1975, FDA representatives had met with the objectors and others in an effort to arrive at alternative methods of declaring ingredients that would eliminate the need for a formal hearing on the objections. The papers relating to these discussions have been made part of the public record, including a tentative revised final order which was made available for public comment in July of 1974.

The May 30, 1975 issue of the *Federal Register* contains the order which governs the present status and effectiveness of the cosmetic ingredient labeling regulations.[7] In that order, the Commissioner announced that the objections to the basic regulations had been withdrawn and that virtually all the regulations would go into full effect at the same time, with new effective dates.

The effective dates established in that order are still governing. Under the order, no labeling can be ordered after May 31, 1976 without having a declaration of ingredients, and no labeling can be placed on cosmetic products after November 30, 1976 if the labeling does not contain a declaration. Labeled packages without declarations may be used up after November 30, 1976 but only if held in inventory on that date.

Minor Exception

There is one minor exception with respect to the effectiveness of Section 701.3. Objections requiring a hearing were raised to the amendments contained in paragraphs (f)(1) and (2). These provisions allow noncolor ingredients, present in a concentration of less than

[5] 40 *F. R.* 8918 (March 3, 1975).
[6] See 21 CFR Sec. 701.3 (f)—(q).
[7] 40 *F. R.* 23458 (May 30, 1975).

one percent, to be listed without respect to order of predominance. The hearing will be held on whether it is reasonable to establish a cutoff and whether the cutoff should be at the one percent level. Accordingly, paragraphs (f)(1) and (2) are stayed pending a hearing, but as stated in the *Federal Register* of May 30, 1975, the Agency will not take compliance action against manufacturers who label their products in accordance with these provisions.

I will briefly describe the lawsuits about these regulations so that you can understand the nature of the challenge and, thus, the status of the regulations. Since a court decision is pending, I want to avoid a debate on the merits of the contentions of the FDA and of its adversary in the suit.

The Independent Cosmetic Manufacturers and Distributors (ICMAD) brought two suits challenging the FDA's cosmetic ingredient labeling regulations. One of the lawsuits was brought in the District Court for the District of Columbia seeking to enjoin the regulations.[8] The FDA argued that the regulations could only be challenged in the Court of Appeals under the procedures governing this type of rule-making. At a hearing on October 16, 1975, Judge Waddy dismissed the District Court suit.

Substantive and Procedural Objections

In addition, ICMAD filed a lawsuit challenging the cosmetic ingredient regulations in the Court of Appeals for the District of Columbia, and this lawsuit is still pending.[9] In it, ICMAD petitioned for review of the May 25, 1975 order which put the regulations into effect. Among the various substantive and procedural objections raised by ICMAD are the FDA's failure to hold a public hearing on ICMAD's objections to the need for the basic regulation. (Brief for the petitioner.) A hearing was requested by ICMAD after the FDA published its orders on the basic regulations and amendments in the March 3, 1975 *Federal Register*. In the May 30 order, the Commissioner stated his reasons for rejecting ICMAD's objections as untimely:

"Full opportunity to object and request a hearing on the ground that ingredient declaration does not prevent consumer deception or facilitate value comparisons was offered at the time of publication of the order on October 17, 1973. Had

[8] *Independent Cosmetic Manufacturers and Distributors, Inc. v. Mathews*, Civil Action No. 75-1413 (DC DofC 1975).

[9] *Independent Cosmetic Manufacturers and Distributors, Inc. v. Department of Health, Education and Welfare*, Civil Action No. 75-1845 (CA DofC).

objections and a request for hearing been made at that time, the Commissioner would have placed any appropriate additional evidence in the record at such a hearing, demonstrating that ingredient declaration prevents consumer deception and facilitates value comparisons. The Commissioner concludes, therefore, that the objection presented is not timely and the request for hearing is denied."[10]

The brief by ICMAD was filed with the Court of Appeals on November 17, 1975. In addition, the organization also filed a motion with the Court of Appeals for a stay of the regulations pending the outcome of the litigation. This motion was denied by the court on October 24, 1975. The petitioner then filed a renewed motion for a stay pending review. This renewed motion has not yet been acted upon by the court. Thus, as of now, the regulations continue to have the effective date set in the May 25, 1975 order. **[The End]**

CERTAIN LABEL REQUIREMENTS FOR FLAVOR INGREDIENTS ARE RELAXED BY THE FOOD AND DRUG ADMINISTRATION

Labeling requirements applicable to flavors made up of more than one ingredient and which are shipped to a manufacturer or a processor for use in fabricated foods have been relaxed by the Food and Drug Administration (FDA). Any such flavorings that are not specifically approved in an FDA regulation but are included in the FDA's review of "generally recognized as safe" (GRAS) food ingredients do not have to bear a label declaring each ingredient by its common or usual name if (1) the ingredients are listed in a reliable industry association list of GRAS ingredients and (2) the label states that the ingredients are so listed. The regulation involved provides, as the only alternative to declaration, the use of a label statement that all ingredients are approved by regulation. The new alternative, issued as a *proviso* to an extension of the effective date of the regulation, will be available until July 1, 1979. Further extensions will be granted, as appropriate.

The FDA has also given notice of the conditions under which it will accept additional flavoring substances for incorporation into its safety review and has announced that the Flavoring Extract Manufacturers' Association (FEMA) GRAS listed flavors, published as FEMA GRAS, lists 3 through 9, have been approved for inclusion in its program.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,564

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[10] 40 *F. R.* 23459 (May 30, 1975).

Cosmetic Ingredient Labeling—The Nomenclature Problem

By MURRAY BERDICK, Ph.D.

Dr. Berdick Is Director of Regulatory Affairs of Chesebrough-Pond's Inc. and Chairman of the Inter-Industry Color Technical Committee.

THROUGHOUT THE CONTROVERSY surrounding cosmetic ingredient labeling, most of the attention has been directed to questions about legal authority, cost, confidentiality of formulas, need for naming individual colors and label space difficulties.

Strangely enough, a much more basic problem was ignored or overlooked by the advocates of ingredient labeling. That problem concerns how to convey to the consumer in a meaningful fashion what the ingredients are.

Fortunately, by the time the Food and Drug Administration (FDA) regulations were promulgated, the intensive efforts of the Cosmetic, Toiletry and Fragrance Association (CTFA) had brought us back to solid ground from the tottering Tower of Babel that would have resulted from our nomenclature dilemma.

Meaningful Nomenclature

The uninformed consumer expects to find a list of ingredients in terms that are meaningful to the layman. If cosmetics were still made today from chalk, lard, charcoal, wool grease, rose petals, logwood, goose grease, clay and similar items, the consumer would understand what these names mean. Fortunately for the user, the modern cosmetics industry uses a wide array of highly purified or wholly synthetic materials that are far safer for their purposes than the cosmetic components of antiquity. But, unfortunately, these materials have complex, lengthy and tongue-twisting names.

If consumers were to see precise chemical names on the label, they would still think the manufacturers were hiding something from them even though such a listing would name the ingredients very specifically.

The earliest proponents of cosmetic ingredient labeling, including Virginia Knauer, Professor Page, Esther Petersen, and Senator Thomas Eagleton, did not recognize the difference between the composition of foods and the composition of cosmetics. They assumed simple names, readily understood by the lay consumer were readily at hand. They accused industry of resisting ingredient labeling for reasons of secrecy and cost. These were factors, but an even more significant reason for delay was the problem of nomenclature.

A New System of Nomenclature

The nomenclature problem became very obvious after CTFA initiated its early efforts more than five years ago to compile a compendium of cosmetic raw materials. One of the difficulties is that complex chemicals can be named in many different ways. In attempting to assemble a single list, CTFA, with the help of computer experts, tried to cross-reference the list as it was assembled to eliminate duplication under different names. For a long time it was not clear how many different cosmetic raw materials were actually being used. At one point, CTFA thought that there might be some 5000, not including from those essential oils and aromatic chemicals used to make perfumes and fragrance compounds. Once CTFA was able to eliminate duplications, it began to appear that the total number of materials in use is somewhere around 2500, plus those used in perfumery.

Then the question remains: Which of numerous alternative names should be adopted and standardized for use in presenting information to the general public?

In industry, many of these materials are specified and purchased by trade name, and these names would not be suitable for labeling purposes. If one were to try to find these chemicals in *Chemical Abstracts,* one would find that the names would be most complex, in order to make them precise.

It became clear that a completely new compendium was required for labeling purposes, and a CTFA committee was created to implement a crash program to design a suitable system of nomenclature and to adopt consistent names for all of the ingredients on the list that had been compiled. The task force was headed by James

Akerson, who later became chairman of the Editorial Advisory Board of the resultant *CTFA Cosmetic Ingredient Dictionary.*

He has described the approach to the nomenclature in a brief history of the *Dictionary* in the following way:

"Several preliminary nomenclature systems were investigated and tentatively proposed to the Food and Drug Administration. These systems included abbreviated designations with names consisting of no more than two words with a maximum of four syllables each and generic systems where ingredients were identified with names similar to food listings such as fatty acids, ethoxylated esters and so forth. After a series of conferences between CTFA and FDA, the general guidelines for preparing an acceptable standardized nomenclature for cosmetic ingredients were laid out.

"These guidelines required that all names be technically representative or suggestive of the chemical composition of the ingredient and that whenever systematically consistent, names already familiar to chemists should be retained. However, it was also recognized that cosmetics are distinct from both foods and drugs and that we need not be locked into terminology used in those fields."

Cosmetic Ingredient Dictionary

The *Dictionary* is much more than a list of names. It specifies adopted names suitable for labeling purposes for thousands of materials used in cosmetics and toiletries. Each name has a monograph, including a definition, with structural formulas or chemical descriptions, CAS numbers (where applicable), information sources and raw materials to which the name may be applied. It is cross-indexed, and contains suppliers' names and addresses.

A preliminary edition of this *CTFA Cosmetic Ingredient Dictionary* was published in October of 1972, and the formal first edition was published in 1973. Publication of a new, completely revised and much expanded second edition is expected early in 1976. It will include over 2500 monographs, with many new features and indexes.

In the absence of any explicit action by the FDA to the contrary, the correct name (for labeling purposes) of each ingredient in a cosmetic product is the CTFA-adopted name. Thus, the *CTFA Cosmetic Ingredient Dictionary* is the controlling compendium in the regulation.

Unfortunately, despite all the effort expended on this project, there still remain some misunderstandings, and new problems continue to appear.

For one thing, it is important to understand that listing of several trade-named materials in the same monograph does not imply that they are interchangeable. Nor does the *Dictionary* specify grades of

purity. For information on specifications, you must go to *CTFA Standards,* or *CTFA Cosmetic Ingredient Descriptions,* or other such reference sources.

Although CTFA has repeatedly updated the first edition with a series of supplementary bulletins, there are some substantive changes in the second edition. For example, 59 names have been discontinued or changed. Thus, manufacturers who have designed new labels with ingredient legends will have to check the second edition for correctness.

Another problem is that, since the first edition, it has been learned that some trade-named materials previously listed as single ingredients are now known to contain secondary ingredients, which will be shown as components. It becomes the responsibility of the cosmetic manufacturer to determine whether these secondary ingredients must be listed on the label of its product. In some cases, these secondary ingredients perform a function in the raw material, but become nonfunctional incidental ingredients present in insignificant amounts in the cosmetic product. If so, the regulations permit you to ignore them for labeling purposes.

One place where confusion about secondary ingredients is still not resolved completely is in the emulsion polymers sometimes used for opacifying cosmetic products. Users of such raw materials should consult their suppliers regarding the completeness of the information in the *Dictionary.*

Summary

To summarize, meaningful, informative cosmetic ingredient labeling is possible only with consistent nomenclature. In order to achieve this, CTFA has, in the short space of three years, compiled a massive list of ingredients, devised a new system of nomenclature based on rational principles, adopted names for thousands of materials, prepared monographs for them, cross-indexed them, and published a *Dictionary* that is recognized by the FDA as the controlling compendium in the final regulation. **[The End]**

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