OL. 32, NO. 10 OCTOBER 1977

ood·Drug·Cosmetic Law JOURNAL

Corporate Responsibility for Consumer Nutrition Education

. . . . . JERRY L. MOORE

Nutrition Regulation by the FDA in the Brave New World of Fabricated Foods

. . . . . STEPHEN H. McNAMARA

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $40; single copies, $4. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

October, 1977
Volume 32 • Number 10

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

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TO THE READER

Food Update '77. The papers in this issue were delivered at the Food and Drug Law Institute sponsored Food Update '77, held in Palm Beach, Florida on April 24—28, 1977.

The clash between the food industry and consumers is the focal point of an article by *Jerry L. Moore, Ph.D.*, "Corporate Responsibility for Consumer Nutrition Education." He claims that the food industry is content to manipulate people to do what it believes is right when it should be striving to educate them to the point where they may make their own choices. He addresses himself to the problem of nutrition labeling and the need for educated consumers, and challenges the food industry to find pathways to achievement of the educational goal. Dr. Moore is Associate Director of Scientific Services for the Pillsbury Company. The article begins on page 433.

The "Rule of Reason" in relation to restraint of trade is one of the main topics of *Joel E. Hoffman's* article, "Joint Industry Research and Other Cooperative Programs: Antitrust Hazards and Lawful Opportunities." In the article, which begins on page 444, the author discusses his belief that industry products should be of the highest standards, but antitrust laws create a competitive gap in information-sharing which leaves the goal unattained. Mr. Hoffman is a partner in the law firm of Wald, Harkrader & Ross.

Good Manufacturing Practices and Good Laboratory Practices are the subject of *Richard S. Morey's* paper, "GMPs and GLPs—Where Are We Going?" The authority of the Food and Drug Administration in the area of GMPs has been continually questioned he says, with the only link being the manufacturing of food under insanitary conditions. Mr. Morey, who is a member of the law firm of Kleinfeld, Kaplan and Becker, speculates on the problems that could arise concerning FDA authority and GLPs. He discusses the far-reaching effects of an FDA claim of bad laboratory practice on past, current and future research and developments of that laboratory. The article begins on page 459.

Increased technology and economic necessity have combined to produce an explosion of substitute food products says *Stephen H. McNamara* in his article "Nutrition Regulation by the FDA in the Brave New World of Fabricated Foods." Mr. McNamara, who is Associate Chief Counsel for Food at the Food and Drug Administration, expresses the concern of the FDA's Bureau of Foods, that the nutritional value of American foods does not deteriorate. He discusses FDA regulations to insure nutritional quality, but concludes that they are not adequate to protect the food supply in the future. The article begins on page 469.

IN MEMORIAM. We record with sadness the death of Michael F. Markel on September 11 at age 80, following a heart attack while vacationing in Germany. Mr. Markel, one of the first food and drug law specialists, earned an international reputation as a legal adviser in this field. A member of the Editorial Advisory Board of this Journal, he contributed an important article on Federal Food Standards to the first issue, March 1946, and additional articles over the years. After serving as Senior Attorney in the U. S. Department of Agriculture's Food and Drug Division, predecessor of the present Food and Drug Administration, he established a Washington, D. C. law firm, now Markel, Hill & Byerley. Mr. Markel was Industry Adviser to the Food and Agricultural Organization of the United Nations World Health Organization, in which capacity he helped in the development of uniform world food standards. He was long active in the Lutheran Church and worked for the cause of war refugee immigration. Mr. Markel received his bachelor's degree from Capital University in Ohio, and his law degree from Ohio State University School of Law. He received the honorary degree of Doctor of Laws in 1963 from Wagner College, New York. Expressions of sympathy may take the form of contributions to the Lutheran World Relief, 360 Park Avenue So., N. Y. 10010.

Vol. 32, No. 10 October, 1977

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Journal

Corporate Responsibility for Consumer Nutrition Education

By JERRY L. MOORE, Ph.D.

Dr. Moore Is Associate Director of Scientific Services for The Pillsbury Company.

A RECENT ARTICLE in *Nutrition Reviews* referred to 1976 as the year of "The Renaissance of Nutrition, a rebirth of vigorous intellectual activity in the science of nutrition and its application in medicine and the health sciences." Paralleling the growth of "intellectual activity" in nutrition is an intensifying public concern with health and physical well-being, and as a consequence, a growing public interest in the role nutrition plays in health promotion and disease prevention.

It seems very likely that among a significant segment of our population, a major new plateau in public interest in nutrition has been reached. Intense interest in cosmetics and products that might enhance physical appearance is gradually giving way to interest in dietary factors and practices that enhance health, fitness and prevention of disease. Physical self-enhancement, as Yankelovich calls it, is assuming more importance than simple personal appearance. It is not clear whether the increased public concern with health and nutrition is the result of more self-centeredness or the result of shaken confidence in the ability of industry, government and established institutions to assure safe and healthful diets.

You are aware of these trends, as the pervasiveness of nutrition in discussions at this conference have clearly revealed. Besides that, most food companies are responding to this increased public awareness of health and nutrition in a variety of ways: with products for special health concerns, nutrition labeling, a wide array of informa-

tional materials for consumers as well as health and education professionals. Indeed, the amount of industry activity in these areas has taken on major proportions, a fact I rather quickly discovered in preparing this presentation. I wrote to about 25 companies and associations, requesting examples of informational and educational materials and descriptions of speeches, current policies and programs relating to nutrition. Response to my request netted a huge stack of printed materials, frequently accompanied by notes about other materials that, "can't be talked about yet—will be out soon." These printed materials are, of course, but a tip of the iceberg of total industry activity in response to nutrition concerns. Witness the widespread adoption of nutrition labeling; the inclusion of nutrition claims or information in advertising of some food categories and the range of experimental approaches to public nutrition programs. Some examples are: Kellogg's "Stick Up For Breakfast" school education program; McDonald's Nutrition Labeling and Diabetic Exchange Listing activities, as well as classroom education units; General Food's print-ad campaign on nutrition and food additive usage; Best Food's print-ad education materials; General Mills' "Contemporary Nutrition" Newsletter with special editions for legislators and media professionals, and planned nutrition seminars for legislators, media professionals and health professionals; Foremost McKesson's "The Professional Nutritionist" magazine; Swift's "Food For Life" exhibit at the Chicago Museum of Science and Industry; National Dairy Council's Nutrition Education Materials, still considered the standard of excellence for comprehensive nutrition instruction; a symposium on nutrition education at the upcoming Institute of Food Technologists convention; Florida Citrus Commission's sponsorship of regional nutrition education conferences; nutrition ad campaigns by The Potato Board and other commodity marketing associations; Kraft's longstanding support to Home Economics Education Programs . . . the list could go on and on. All of the foregoing illustrate the variety, but not the full magnitude and quality of industry's *response* to increased interest in nutrition among consumers, educators and health professionals. *Reaction* to pressure from industry critics may also be somewhat responsible—but for now, let us ignore the speech title, "Corporate Responsibility for Consumer Nutrition Education," and assume that motives make no difference. Whether the motive is one of social obligation, one of a sense of panic over consumer alienation or one of conviction that consumer information is good business, pragmatically, the important thing is that there are industry materials and programs that speak effectively to consumer needs and concerns.

What Industry Is Doing

"What is industry doing now?" Conclusion No. 1 succinctly stated is that collectively—but not cooperatively—we are providing a wide variety of materials, programs and services that contribute to consumer education. The next question is, "How can we improve the impact and effectiveness of the materials we produce and improve our efficiency in producing them?" I want to formulate three or four answers to that question.

Even cursory examination of industry-provided consumer materials, including those sent in response to my request, leads to conclusion No. 2—we generally fail to establish a single, clear objective for each printed piece, campaign or program. Ideally, every consumer program or material should fit one of three categories: It should promote, inform or educate. Promotional materials openly advocate purchase or use of a particular product or brand. Obviously, these will have least credibility and least utility in any educational program, but that is not, or should not, be their purpose. The second category—materials that inform—should consist of objective, descriptive information about specific products, including product brands. These materials should be compatible with current scientific knowledge and educational content, both in language and format, and be devoid of overt health claims or promotional rhetoric. Finally, "educational" materials—should contain instructive information supportable by current scientific knowledge and should avoid presentation of only one side of controversial subjects. It should avoid promotional reference to particular companies, brands or products and preferably be presented in a context and format that have been tested for effectiveness with the target audience.

Economic realities, that is, the need to economize on service materials and functions, and the need to receive credit for materials produced, inevitably increase the temptation to develop materials and programs that are multipurpose—that try to meet all the objectives listed. The result of mixed-purpose materials, however, frequently is reduced acceptability in public instruction programs and increased vulnerability to charges that the materials are biased, subjective and self-serving. Thus, the ultimate objectives for such materials, to strengthen consumer relations and enhance corporate image, are also less likely to be achieved. Indeed, the effect can be a negative turn-off, a further alienation of consumers.

Just as there is a strong tendency to produce programs and materials with multiple objectives, there is also the tendency to develop

materials that are *not* directed to definable audiences. This brings one to my third conclusion—current materials and programs tend not to be directed to defined consumer segments. In other words, we try to be all things to all people. Ignore, for the moment, the differing informational needs of such special groups as home economics teachers versus low-income consumers versus consumers on special diets versus health professionals. Make it easier for yourself, imagine instead trying to create a pamphlet or brochure for: (a) the 30-40 year old homemaker with family at home and restricted income whose basic attitude is, "Don't burden me with a lot of detail, just tell me what I should and shouldn't eat or give to my family"; (b) the under-30, affluent, well-educated and employed person whose fundamental attitude is, "Don't try to run my life! Just give me the facts, and I'll make my own decisions"; and (c) the over-40, middle-income person saying, "Don't bother me at all, I know what I like and I have no intention of changing now." It is impossible to effectively meet the information needs of all these segments of main stream consumer audiences with a single approach. Yet, that is exactly what most of our consumer materials attempt to do.

What segment of consumers, students, teachers or health professionals most need and want the material we've planned or developed, and who would be best served by it? If we cannot answer the question readily, the materials or program could and probably should be examined for revision and improvement.

Conclusion No. 4 is a deductive impression that plans for consumer materials seldom include enough money to permit proper distribution to target audiences. This is another budget-saving mistake—it is easier to justify the funds for producing numerous materials than to justify funds to develop, then properly promote and distribute a few high quality materials to appropriate audiences. The result too often is materials stored unused in a warehouse, while potentially-interested consumers do not know to ask for them or, on the other hand, wholesale distribution of materials to inappropriate audiences, assuring only "throw-away" usage.

Lack of Strategy

Conclusion No. 5, and this encompasses the first four, is that most of our companies are developing their consumer service materials with little or no intentional, explicit strategy. Most of the respondents to my little survey acknowledged that their companies did not have formal policies or strategies regarding the development and distribu-

tion of consumer materials. It is, perhaps, this relative absence of internal guidelines and explicit objectives that keeps us collectively *reacting* to issues and crises, rather than *responding* effectively to emerging consumer interests and concerns before they become full blown conflicts. Material that has to be presented in a defensive tone is inevitably perceived by any antagonist to be action to protect the company's interest, not a genuine response to a concern of the company's customers. The corollary to this statement is that a defensive stand may win approval of current allies, but defensive reactions seldom win *new* allies.

So far, I have spent my time talking about possible ways of improving company-produced consumer materials. The first and most notable conclusion, the one listed at the outset, is that many individual companies and associations are spending substantial amounts of time and resources on consumer information and education services as a way to build better consumer relationships. In spite of some bright spots in consumer response to industry produced materials, consumer confidence in the food industry apparently is still declining, or at best has plateaued at a frighteningly low level, principally because, and this is conclusion No. 6, there are no substantive, industry-wide, cooperative efforts to define and respond effectively to consumer interests and concerns. In the current absence of overall leadership and strategic direction within the industry regarding consumer information and education materials, individual corporate responses are duplicative, yet still leave major gaps. Without effective early detection of consumer dissatisfactions, individual corporate responses tend to be untimely, tend to be reactive to criticism rather than responsive to genuine issues and concerns before they become allegations and indictments. Consequently, they tend to be defensive rather than positive. A recent Grocery Manufacturers of America, Inc. (GMA) publication epitomizes how far we have allowed the situation to slip; instead of being in a standard "question-and-answer" format, this one is an "allegation-and-fact summary" format. We can hardly become more defensive than we now are.

Now, I want to depart briefly from my prepared manuscript to address at least two subject areas raised by previous speakers.

First, I want to respond to the plea Mr. Clausi, (Vice President and Director, Technical Research, General Foods Corporation) made on the first day of this conference for a definition of the "core" problem facing the food industry. It seems to me that the symptom of our core

problem is the disaffection of consumers for industry, (as well as other established institutions) and the resultant intervention in industry-consumer interactions by government regulators and by advocators of various interests and points of view. I believe our core problem is the adversary and polarized relationships that now seem to characterize most of our dealings with consumers and with persons and organizations that claim to represent the consumer's interest. I postulate that the basis or origin of our core problem lies, at least in part, in the blind acceptance of the old, absolute and unqualified marketing dictum, "the exclusive objective of business is to make a profit." Lest I be accused of sedition or treason, I hasten to add that the dictum is not false—clearly no business exists to *not* make a profit—but I believe it is incomplete. A more complete dictum or premise would be, "the objective of business is to make a profit by providing legitimate products and services." This qualification is compatible with marketing practice, as evidenced by Mr. Rothchild's (Director, New Marketing, New Products, Hunt-Wesson) contention that successful marketing requires products that (a) meet a genuine need, (b) exhibit uniqueness, and (c) are timely commercialized. The unqualified version of the marketing dictum, with its exclusive focus on the corporate objective (profit) without mention of the consumer objective (products/service) is at least partially responsible, I believe, for the "us and them" syndrome which is at the base of consumer-industry alienation. It fosters the idea that "our" objective is paramount; "theirs" is unworthy of mention. It may suggest that anything that gets in the way of achievement of "our" objective is the enemy. In such an environment, the consumer may be accorded little respect or dignity and becomes someone to be outwitted. Government regulators as they attempt to intervene become agencies to be evaded or thwarted; advocates as they attempt to intervene become persons to be discredited; scientists and academicians when they attempt to influence become persons to be ignored as being out of touch.

Us and Them Syndrome

The chaotic mess in which we find ourselves as a result of the "us and them" syndrome is explained vividly by two phrases that Jack Allen (Professor of Economics, Michigan State University) recently used in personal discussion of this subject with me. He described the "ghetto mentality" of the giver/provider, in which a company seeks to protect what it has, and give no more than it absolutely has

to, matched by a "mentality of entitlement" in which the consumer/recipient demands the maximum, and the maximum continues to escalate.

If we have any hope of stemming current trends toward excessive regulation, toward disruptive intervention in the affairs of the food industry and its consumer, I believe it will be via voluntary actions that make the regulations and interventions totally unnecessary. It seems to me that industry-wide internalization of the more comprehensive marketing dictum, "the purpose of business is to make a profit by providing legitimate products and services," could go a long way toward creating the needed new conciliatory environment that dignifies all of our objectives rather than exalting "ours" over "theirs."

The second topic, divergent from the prepared manuscript, that I want to address relates to that perennial question, "Is there any evidence that nutritionally informed and educated persons actually eat better or are more healthy?" The question, whether asked by educators, dietitians, nutritionists or food scientists, seems always to presume that we have a responsibility for modifying the behavior of people toward eating patterns that we judge to be right. With all other sciences, we are content to expose students/consumers to knowledge that they may choose to apply to their own behavior and life style as they judge appropriate. With the science of nutrition, we presume, apparently, to tell people how to apply the science (via "food education") before or even without ever teaching them nutrition fundamentals. If we really concentrated on nutrition education, persons would be enabled to make continuing, intentional, informed decisions for themselves, even in the face of changing food supplies, cultural, social, economic environments, etc. As it is, we seem obsessed with changing (if not manipulating) behavior of people, and we exhibit inadequate concern for enabling people to modify their practices as they choose.

Dr. Call (Director, Cooperative Extension Service, Cornell University) said in the opening address that what we need are "informed consumers making decisions in the market place." Building on his concept, it seems to me that what is really needed are *"educated* consumers (capable of) making intentional, informed decisions in the market place." Consumers as well as suppliers of consumer products and services would benefit greatly.

Another perennial question is, "Is nutrition labeling really being used by consumers?" The implication seeming to be that if it is not being widely used, it ought to be removed from product labels. I

believe that nutrition information is descriptive product information that is potentially relevant to purchase decisions. As such, the consumer is entitled to that information, if he or she chooses to use it, regardless of whether the information is used 5 percent or 95 percent of the time by 5 percent or 95 percent of the consumers. Low frequency of use is as invalid a criterion for removing nutrition labeling as for removing ingredient listings, net weight statements or preparation instructions.

The point of the remarks made in this digression is that consumer alienation (and resultant intervention by groups seeking to represent consumer interests) is the fundamental issue we face as an industry. My assessment sounds awfully pessimistic, I know, but others far more astute in consumer affairs than I share these views. Let me especially note an article entitled, "Protect Your Public Image With Performance" by Joseph Nolan, formerly Senior Vice President for Chase Manhattan Bank, New York, now Professor in Journalism and Public Affairs at the University of South Carolina.[1]

Let me cite two quotations: "But when the public advocacy groups and political reformers start clamoring for business to change some of its practices, it appears, sadly, many companies have yet to learn that something might need changing, and that the changes required need to be substantive, not merely cosmetic or the old way, better communicated . . . ." "Three reasons businesses continue to fail (in public relations): One, they fail to learn from others' mistakes; two, they ignore signs of impending change in public opinion; and three, they neglect to match their performance with public expectations." Mr. Nolan notes that companies do not display these vulnerabilities in the areas of the products they sell, but rather in the service and support areas of their businesses. His remarks point the way to some optimism for solution of the issues we face. The major thesis of the balance of this presentation is that industry-wide responsiveness could assure that nutrition information and education services take their place along side recipe and product information services as key components in positive industry relationships with its customers, thus helping restore consumer trust and confidence. Or, by continued neglect, superficial treatment and defensiveness, industry can assure that nutrition grows as an industry-wide liability. It is no longer a matter of corporate (company) responsibility, it is becoming a matter of corporate (industry) necessity. I believe there is a need for radical and substantive,

[1] *Harvard Business Review* (March-April 1975), pp. 135-142.

industry-wide efforts to build nutrition education into the foundation of our consumer affairs programs.

Interaction with Consumers

Conclusion No. 8 is that any industry-wide effort focused on nutrition and nutrition education must involve interaction with consumers; not just one-way communication of nutrition science information that we think they should know.

The Association of Home Appliance Manufacturers (AHAM), as described by its President, Guenther Baumgart,[2] presents one model for the kind of industry-wide approach that I am advocating. In addition to having a Consumer Advisory Panel, AHAM has a bureau to accept consumer complaints and to recommend corporate action on complaints, regarding product performance, product repair or product advertising. AHAM also generates and reports consumer research data to all member companies. This organization provides a consumer with one place to articulate a series of concerns or complaints about the industry, something he or she is unlikely to do if it means writing several companies. Through such an organization, member companies can get maximum consumer information about areas of consumer service, areas that normally do not get significant market research attention in an individual company. Moreover, such an organization could help individual companies become and remain more aware of consumer concerns on nutrition than would be possible via smaller scale consumer research efforts conducted by any but the few giant companies in the industry.

Joel Ranum, Vice President, Corporate and Public Affairs, Whirlpool Corporation, has said, "The first tenet of our social responsibility is insuring that our products and services give fair value and live up to their expectations."[3] In the current environment of little consumer knowledge in nutrition, consumer expectations are volatile and readily influenced by everything from the evening news to magazines and unqualified authors. The industry needs better and more efficient ways to monitor changes in consumer attitudes on nutrition, better means of staying up-to-date with consumer expectations.

Additionally, effective nutrition education programs could enable consumers to become more sophisticated via "nutrition education," more capable of selecting and using *all* foods in a nutritionally sound way.

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[2] *California Management Review* (Spring 1974), Vol. XVI, pp. 52-57.

[3] Ibid.

This could make them less dependent on "food education" and less obsessed with categorizing all foods as either good or bad. Such a situation could help "stabilize" consumer attitudes and expectations on nutrition and make it easier for industry to respond meaningfully.

I reiterate that what is called for is not a consumer propogandizing campaign to "get them to see things our way." Guenther Baumgart says, "We use the tools of the publicity trades copiously, but do not depend on them to substitute for sound principles at the foundation."[4] Nutrition education could become an important part of the foundation for the food industry's consumer affairs programs, and I believe that would be to the advantage of both the consumer and the food industry.

What Kind of Approach?

Assuming that there is agreement on the need for a more coordinated, cooperative industry approach to consumer education, what will be the vehicle, GMA, with its existing consumer affairs committee? If so, new resource commitments and willingness of member companies to relinquish some of the parochial interests in designing and distributing consumer materials, and visionary new leadership must be developed. Or, could the Nutrition Foundation serve as the focus for the needed programs? Clearly, an expansion of charter, new priorities and new resourcing would be necessary. One advantage held by the Nutrition Foundation is its name—and the fact that nutrition is the thread, perhaps the only thread, that is common to all the diverse components of the food industry. Another advantage is that the Nutrition Foundation's current image with consumers and consumer representatives is more conducive to achieving consumer credibility objectives than are existing trade associations. Or, perhaps the best vehicle is a new organization altogether, such as was proposed by Paul Hopper, Louise Light and others at the San Francisco Nutrition Marketing Conference a year ago. This is still an active proposal, incidentally, that currently involves the staff of Redbook Magazine and The Society For Nutrition Education.

Whatever the vehicle, it will be a very difficult challenge to convince individual companies—and cumulatively, the entire industry—that scientifically sound consumer education materials and socially responsible improvements in consumer affairs programs should receive higher priority in the normal conduct of business.

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[4] California Management Review (Spring 1974), Vol. XVI, pp. 52-57.

How about it? You are an influential sample of the United States food industry management. Can you find any validity in the hypothesis that I have offered, that is "That consumer nutrition education could become a keystone to improved food industry consumer affairs, a route to more rational consideration of both consumer and industry objectives and that it should receive industry-wide cooperative attention and development?" If you agree at all, I challenge you to discuss pros and cons of the hypothesis, discuss means of confirming or rejecting the feasibility of the proposal and discuss possible ways of implementing the goal if it proves to be feasible. I hope you will be willing to accept the challenge; your response could make a big difference in the future of the food industry and its ability to establish a new alliance with consumers to work toward mutually beneficial goals.

I acknowledge the capable assistance of Catherine Hanley (Consumer Relations Specialist, The Pillsbury Company) in planning and preparing this manuscript. I express my thanks to her, to the consumer affairs directors who reponded to my request for information and to numerous other professional colleagues whose ideas probably were expressed herein without proper credit. **[The End]**

USE OF UNTREATED CONTROL ANIMALS IN TESTING PROPOSED

In order to maintain conformance between animal drug testing and human drug testing, the use of untreated control animals would be permitted in safety and efficacy tests for animal drugs under a recent Food and Drug Administration proposal. Use of untreated control animals would be limited to instances when placebo effects are negligible and results are objectively measurable, as is the case under the human drug requirements. Until May of 1970 the two sets of procedures—for veterinary and human drugs—had been kept parallel, but an amendment to the human drug testing requirements was not made concurrently for animal drugs. The proposed amendment would do so, and would also make editorial revisions to further conformance. Untreated controls would be added to the three controls now permitted: placebo control, active treatment control and historical control.

(CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 45,503

Joint Industry Research and Other Cooperative Programs: Antitrust Hazards and Lawful Opportunities

By JOEL E. HOFFMAN

Mr. Hoffman Is a Partner in the Law Firm of Wald, Harkrader & Ross.

THE FOOD INDUSTRY carries enormous public responsibilities. By definition, it is concerned with the health and safety of the consuming public. No one would quarrel with the proposition that the industry should constantly be encouraged to manufacture the most nutritious, palatable and economical products possible, according to the highest standards. Yet food manufacturers are private firms, competing in an economic marketplace and subject to antitrust laws designed to protect individual entrepreneurial freedom and the integrity of the competitive process. The tension between these two principles is manifested in a variety of practical settings, two of which I should like to discuss today.

First, it is common in complex, high-technology industries such as food that firms frequently make technological advances on their own or develop commercial information that might be useful when shared with others for the general good. Indeed, information sharing may sometimes be compelled, either by express statutory command or under the rubric of antitrust. Second, other important research and development programs are too burdensome for single firms to undertake alone, and their benefits can be realized only through joint effort. These activities involve joint action among competitors. They raise serious antitrust issues. Yet they also can be permissible under the antitrust laws. None are, or need be, *per se* violations of those laws.

The Rule of Reason

The key to this is found in a single basic analytic principle that even the most sophisticated antitrust counselor does well to keep before him. Section 1 of the Sherman Act (15 U. S. C. Sec. 1) states with deceptive simplicity that "every contract, combination * * * or conspiracy in restraint of trade" is unlawful. Yet as Justice Brandeis early held, "[e]very agreement concerning trade, every regulation of trade, restrains. To bind, to restrain, is of their very essence."[1] So the Sherman Act has been interpreted by the courts to proscribe only joint activity in *unreasonable* restraint of trade—the "Rule of Reason."

It is true that some activities are deemed by the courts to be so unreasonable and so utterly devoid of compensating social or economic benefit that they are condemned *per se,* without the necessity of elaborate legal or factual analysis. The three principal activities so characterized are price fixing agreements (in whatever form) between competitors, group boycotts of third parties by competitors, and agreements between competitors at the same level—horizontal competitors—to divide markets.

But as the Supreme Court has observed, "the area of *per se* illegality is carefully limited."[2] What of the much broader, some say amorphous, area where no *per se* rules apply? And how to decide whether a given practice deserves the fatal label of price fixing, boycott, or market division? As the Department of Justice cogently and successfully argued as a "friend of the court" on the side of the defendant in a recent private treble damage case, "caution must be executed in applying *per se* concepts, lest they become brakes on business ingenuity instead of safeguards for competition."[3] There has never been a better formulation of the Rule of Reason than Justice Brandeis' in *Chicago Board of Trade:*

"The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts."

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[1] *Chicago Board of Trade v. United States,* 246 U. S. 231, 238 (1918).

[2] *Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp.,* 382 U. S. 172, 178 (1965).

[3] Brief for the United States as *Amicus Curiae* at 16, *Worthen Bank & Trust Co. v. National BankAmericard Inc.,* 485 F. 2d 119 (CA-8 1973), *cert. denied,* 415 U. S. 918 (1974). The Court accepted the Department's analysis and declined to apply the *per se* rule.

Reduced to its essentials, one of the great antitrust practitioners has observed, the Rule of Reason can be stated with almost blinding simplicity. *First,* "[r]ealities must dominate the judgment."[4] *Second,* the Sherman Act "is aimed at substance rather than form."[5] Let us examine how this principle is currently being applied to situations in which competing food manufacturers may consider the possibility of acting jointly.

Exchange of Information and Agreement on Supplier or Customer Qualifications

Most of the litigated decisions on exchanges of information deal with information concerning price.[6] Even in this sensitive area, however, the present head of the Antitrust Division concedes that "the facts are crucial" and that to support a Sherman Act charge the facts "must reveal some intent to restrain competition or some necessary effect in this direction."[7]

The same criteria govern information exchanges not directly concerned with price. Anticompetitive motives and tacit agreements not to deal with individual firms or types of firms may bring an information exchange program within the condemnation of the statute.[8] At least in the absence of an agreement not to deal, however, exchanges of information on particular customers and suppliers or on their business practices is not *per se* unlawful.

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[4] *Appalachian Coals, Inc. v. United States*, 288 U. S. 344, 360 (1933).

[5] *United States v. Yellow Cab Co.*, 332 U. S. 218, 227 (1947).

[6] *E. g., United States v. Container Corp. of America*, 393 U. S. 333 (1969). Exchanges of technological information have only occasionally been challenged other than in the context of restrictive patent licensing, most notably in the *Smog* and *Aircraft Pool* cases. *United States v. Automobile Mfrs. Ass'n* 1969 CCH TRADE CASES ¶72,907 (DC Cal. 1969) (consent decree); *United States v. Manufacturers Aircraft Ass'n*, 1976-1 CCH TRADE CASES ¶60,810 (DC SD NY 1976) (consent decree). Industry-wide interchanges of this type are best analyzed as joint ventures subject to the same rules as (although factually distinct from) joint research projects, discussed below.

[7] Baker, "Exchange of Information for Presentation to Government Agencies," 44 *Antitrust L. J.* 354, 363 (1975).

[8] The leading case is *Eastern States Retail Lumber Dealers' Ass'n v. United States*, 234 U. S. 600 (1914), where the Supreme Court found the circulation to retailers of lists of wholesale dealers who also dealt directly with retail customers to be no more than an unlawful invitation to a boycott for the purpose of discouraging dual distribution. See also, *e. g., United States v. Champion Int'l Corp.*, 1975-2 CCH TRADE CASES ¶60,453, at 67,040 (DC Ore 1975):

> "Meetings between competitors are not illegal even when coupled with the exchange of information about each participant's interest in upcoming sales. A line must be drawn, however, between the mere exchange of interest and an implied agreement to act on this information."

(The Court went on to hold that "[t]he defendants crossed that line," finding them guilty on a criminal Section 1 charge.)

For example, the Sherman Act does not prohibit exchanges of customer information by competitors to protect themselves against attempted perpetrators of fraud. More than 50 years ago, the Supreme Court exonerated the "[d]istribution of information as to credit and responsibility of buyers," even though the effect was plainly to "cu[t] down to some degree commercial transactions which would otherwise be induced by fraud."[9] The Seventh Circuit more recently reached a similar result, holding that fire insurance companies' exchange of loss experience on particular insureds was permissible even though a party with a history of fire claims might consequently be unable to obtain coverage.[10] And in appropriate circumstances even price information may lawfully be exchanged to prevent unscrupulous customers from misrepresenting competitive bids and thus inducing unjustifiable price concessions that expose the seller to liability under the Robinson-Patman Act.[11]

Where health and safety are involved, the permissible scope of joint action among competitors is even greater. Rather than speculate as to what sorts of agreements you may find yourselves considering, let me give you some examples that have actually arisen.

Anticompetitive Agreements

Professor Donald Turner, when he was head of the Antitrust Division, once discussed a hypothetical agreement among manufacturers not to use a particular raw material inexpensive to purchase (and thus a competitive temptation) but unquestionably hazardous to the health of their employees.[12] "Would such an agreement be attacked under the antitrust laws?" he asked. And his conclusion was, "I hardly think so."[13]

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[9] *Cement Mfrs. Protective Ass'n v. United States*, 268 U. S. 588, 604 (1925).

[10] *Ruddy Brook Clothes, Inc. v. British & Foreign Marine Ins. Co.*, 195 F. 2d 86 (CA-7), *cert. denied*, 344 U. S. 816 (1952).

[11] *United States v. United States Gypsum Co.*, 550 F. 2d 115, 120-27 (CA-3 1977) and cases cited. This is not to say that creditworthiness or any other customer or supplier qualification is a talisman for warding off antitrust challenge to a boycott, whether the boycott is inferred from information exchange or otherwise. See, *e. g., United States v. First Nat'l Pictures, Inc.*, 282 U. S. 44 (1930), invalidating the use of a so-called "credit rule" by motion picture distributors to coerce new owners of theatres to assume their predecessors' contracts.

[12] Turner, "Cooperation Among Competitors," 61 *Northwestern L. Rev.* 865, 869-70 (1967).

[13] Professor Kauper, who succeeded Professor Turner at the Antitrust Division, similarly advised the FDA that nothing in the antitrust laws "would raise any legal obstacles to a joint advertising plan limited solely to warning the public of the safety hazards connected with matches." Letter from Assistant Attorney General Kauper to Paul W. Hallman, Deputy Director, Division of Compliance, Bureau of Product

(Continued on next page.)

The three criteria Professor Turner suggested for evaluating such an agreement were: (1) whether a less restrictive alternative is available for achieving the goal; (2) whether "the agreement makes a material contribution to health and safety"; and (3) whether the contribution is indisputable, or at least highly likely and the parties to the agreement gain no economic advantage therefrom. Where, as in his example, the agreement confers no benefit on consumers of the product, Professor Turner further suggested that in the long run legislation should be the only permissible vehicle for adjusting the conflicting interests of consumers and employees.

Whether or not Professor Turner's particular criteria are being applied, it seems clear that anticompetitive agreements designed to protect health and safety are in fact surviving antitrust scrutiny. The most famous example involves a distribution agreement prohibiting the resale of so-called "professional" hair treatment products to consumers.[14] The lawfulness of such agreements has been recognized by the Department of Justice in recent consent decrees, one of which permits the defendant—a manufacturer of automatic fire extinguishing systems—to confine its distributors to resale to trained installers with a good safety record and paid-up liability insurance.[15]

Similarly, horizontal agreements on safety measures (that is, agreements among direct competitors) are permitted in another recent consent decree.[16] Although the decree contains the usual extensive prohibitions against numerous specified types of boycott agreements, and even against mere discussions of any manufacturer's distribution policies at trade association meetings, it also expressly preserves the defendant manufacturers' right of "discussing with any person and implementing bona fide safety measures * * * relating to refrigerant gas." In addition, while the decree generally requires defendants to sell to any would-be reseller,[17] defendants are permitted to refuse to sell gas in bulk containers to persons not technically qualified as refillers—despite the objections of some customers, dur-

(Footnote 13 continued.)
Safety, March 28, 1973 (BNA Antitrust & Trade Reg. Rep. No. 608, at D-1, April 10, 1973).

[14] *Tripoli Co. v. Wella Corp.*, 425 F. 2d 932 (CA-3), *cert. denied*, 400 U. S. 831 (1970). The same result was more recently reached in *Clairol, Inc. v. Boston Discount Center of Berkeley, Inc.*, 1976-2 CCH TRADE CASES ¶61,108 (DC ED Mich. 1976).

[15] *United States v. Safety First Prods. Corp.*, 1972 CCH TRADE CASES ¶74,223 (DC SD NY 1972).

[16] *United States v. Air Conditioning and Refrigeration Wholesalers*, 1976-2 CCH TRADE CASES ¶61,160 (DC ND Ohio 1976).

[17] 41 F. R. 19134, 19136 (May 10, 1976) (Competitive Impact Statement) (so as "to remedy possible lingering effects of the conspiracy").

ing the pendency of the proposed decree for public comment, that they do not always refill but merely sometimes resell to large-capacity users.[18]

NAB Guidelines

There are signs that not merely the Justice Department but also the courts are prepared under the Rule of Reason to tolerate horizontal agreements that protect the public health and safety. During the maneuvering that led to enactment of the present statutory prohibition against cigarette advertising on radio and television, the National Association of Broadcasters (NAB) adopted guidelines for commercials dealing with tar and nicotine content that conformed to the relief then being sought in complaints by the Federal Trade Commission (FTC) against the cigarette manufacturers. The three networks refused to accept commercials not in compliance with the guidelines, and one of the manufacturers filed an antitrust suit. The Court denied relief on a motion for preliminary injunction, ruling that in light of the "persuasive" evidence linking cigarette smoking to cancer and the "growing concern" of government "over the danger cigarettes pose to health * * * [t]here is a substantial, if not compelling, public interest" in full disclosure of the "facts in cigarette advertising" and that the relief sought against the networks "would be contrary to the public interest."[19]

A much less direct health and safety concern was the basis for upholding another portion of the NAB Code in the *Children's Television* case. The broadcasters had responded to public concern (and to some not-too-subtle Federal Communications Commission encouragement) by agreeing not to air commercial messages delivered by the host or primary cartoon character from the surrounding program. The Court found that "[t]his concern can hardly be said to be frivolous, regardless of whether there was 'scientific' evidence demonstrating actual detriment to children," and dismissed a Sherman Act complaint by the performers' union.[20]

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[18] 41 F. R. 35866, 35867-68 (response), 35869 (objection) (August 25, 1976).

[19] *American Brands, Inc. v. National Ass'n of Broadcasters*, 308 F. Supp. 1166, 1169 (DC DofC 1969). Professor Turner's concern that private agreement not be allowed to replace legislation, while not necessarily applicable to these facts even on his own terms, was in any event met by the subsequent enactment of the Public Health Cigarette Smoking Act of 1969, 15 U. S. C. Sec. 1335. See *Capital Broadcasting Co. v. Mitchell*, 333 F. Supp. 582 (DC DofC 1971) (3-judge court), *aff'd per curiam*, 405 U. S. 1000 (1972) (upholding broadcast advertising ban as constitutional).

[20] *American Federation of Television and Radio Artists v. National Ass'n of Broadcasters*, 407 F. Supp. 900, 902 (DC SD NY 1976).

Justification for Agreements

Nevertheless, the health and safety factor must be a real one if an otherwise unlawful agreement is to be justified on that ground. In a recent pharmaceutical patent licensing case, agreements restricting the resale of bulk drugs were sought to be justified in part by the need to ensure the quality of the finished dosage form. The Court found that "[i]n view of the intensive Food and Drug Administration (FDA) regulation of the drug field, it is difficult to understand how such a defense legitimately could be offered."[21] One need not agree with this factual estimate to recognize the importance of a substantial showing that health and safety are benefited.

A related justification for agreements to limit the form of competition may be that the conduct abandoned is injurious to the consumer's economic interest, as with false or misleading advertising. The previously mentioned *Children's Television* case falls somewhere between this and the pure health and safety categories.

Professor Turner, the former chief of the Antitrust Division, recognized in the speech previously discussed that "the logic of [*Chicago*] *Board of Trade* would lead us to be quite unconcerned with an agreement among competitors not to utilize advertising which everyone agreed was false and misleading."[22] A number of FTC advisory opinions endorse agreements to comply with the law,[23] although enforcement of the pledge is a "no-no" and the Commission has expressed concern that such agreements not have an adverse impact on third parties.[24]

Litigation in this area has been sparse. The principal authority is still the Supreme Court's *Fashion Originators' Guild* decision of 35 years ago, which declared unlawful an agreement among dress manufacturers and their textile suppliers, enforced through heavy fines, to boycott manufacturers and retailers dealing in "knock-off" versions of designer fabrics and dresses. Sometimes overlooked is the Court's final ruling that "even if copying were an acknowledged tort under the law of every state" the antitrust laws would not tolerate the challenged combination.[25]

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[21] *United States v. CIBA GEIGY Corp.*, 1976-1 CCH TRADE CASES ¶60,-908, at 68,959 n. 14 (DC NJ 1976). Compare *United States v. Glaxo Group Ltd.*, 302 F. Supp. 1, 9 (DC DofC 1969), *subsequent denial of relief rev'd*, 410 U. S. 52 (1973), where the quality-control justification was apparently rejected as legally insufficient.

[22] Turner, "Cooperation Among Competitors," 61 *Northwestern L. Rev.* 865, 867 (1967).

[23] 16 CFR Secs. 15.64, 15.133, 15.287.

[24] 16 CFR Sec. 15.128(f) and (g).

[25] *Fashion Originators' Guild of America, Inc. v. FTC*, 312 U. S. 457, 468 (1941).

Finally, mention should be made of the FTC's current investigation into self-regulatory mechanisms that restrain the use of comparative advertising. Among the industry code provisions apparently targeted are those to the effect that "[u]nfair, derogatory, reflections upon other products should not be practiced."[26]

The premise of this investigation, however, is that comparative advertising is perfectly lawful except in some instances where prohibited by regulation such as liquor, securities, and professional services. Indeed, truthful disparagement is protected by the First Amendment and cannot constitutionally be enjoined.[27] False and misleading advertising, in contrast, like obscenity, enjoys no such immunity from regulation.[28] Perhaps it too can therefore be suppressed by private agreement.[29]

Product Standards

Like codes of conduct, voluntary product and process standards are a highly formal species of agreement among otherwise independently operating firms. Their importance in many technologically complex industries is enormous. To the extent they are developed by industry, included in this category are standards of identity[30] and Good Manufacturing Practices (GMPs).[31]

The private standard-setting process is the object of increasing governmental scrutiny. The FTC has for some time now been studying the necessity for imposing procedural requirements on private standard-setting bodies to ensure that all interests affected by a proposed standard have an opportunity to be heard, that an effective appeal mechanism is available, and that prompt relief can be obtained when a standard proves excessively anticompetitive or harmful to consumers. Proposed legislation to the same effect was the

[26] See Memorandum to Acting Director, Office of Planning and Evaluation (OPPE), FTC, from Neil E. Beckwith, Marketing Consultant to OPPE, Jan. 19, 1976, p. 11.

[27] *L. G. Balfour Co. v. FTC*, 442 F. 2d 1, 24 (CA-7 1971); *cf. Testing Systems, Inc. v. Magnaflux Corp.*, 251 F. Supp. 286, 288 (DC ED Pa. 1966).

[28] *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U. S. 748, 771-72 (1976); *Young v. American Mini Theatres, Inc.*, 427 U. S. 50, 69 n. 31 (1976) (opinion of Stevens, J.).

[29] *Cf. America's Best Cinema Corp. v. Fort Wayne Newspapers, Inc.*, 347 F. Supp. 328 (DC ND Ind. 1972) (upholding newspapers' joint refusal to print X-rated movie advertisements).

[30] Sec. 401 of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. Sec. 341.

[31] See *United States v. Nova Scotia Food Prods. Corp.*, 417 F. Supp. 1364 (DC ED NY 1976) (upholding issuance of binding GMPs under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. Sec. 342(a)(4)).

subject of extensive hearings in the last Congress and has been reintroduced.[32]

The critical question in antitrust analysis of a private standard-setting process is not procedure, however, but the presence or absence of anticompetitive purpose or effect.[33] The Department of Justice recently stressed this point in House Commerce Committee hearings on the impact of industry standardization on the use of energy-saving devices:

"[W]here no anticompetitive purpose exists, lack of participation by smaller competitors or other interested parties in a standards-setting activity does not itself necessarily render the resulting standards illegal. If a standard has no unreasonable anticompetitive purposes or effects, it will not give rise to a strong antitrust complaint. In particular, a safety standard which is technically well grounded, is not unreasonably restrictive, and which has not been established for anticompetitive purposes does not provide a sound antitrust cause of action on behalf of those who would market dangerous products to the public."[34]

Governmental adoption of a privately formulated standard, such as by the FDA under the standard of identity or the GMP provisions of the law, would almost certainly preclude the imposition of antitrust liability on those who comply with the official mandate, even where this means refusing to deal with those who do not qualify. Despite recent cutbacks in some of the more expansive applications of this principle,[35] the Antitrust Division continues to recognize that "the *command* of the *state as sovereign* provides an antitrust exemption for those private activities which have been commanded."[36]

The process by which a privately formulated standard is developed and by which the government is persuaded to adopt it,

[32] *Hearings on S. 3555 Before the Antitrust and Monopoly Subcommittee of the Senate Judiciary Committee*, 94th Cong., 2d Sess. 65-83 (1976) (testimony of FTC Chairman); S. 825, 95th Congress, 1st Sess.

[33] Letter from Thomas E. Kauper, Assistant Attorney General to Paul W. Hallman, Deputy Director, Division of Compliance, FDA Bureau of Product Safety, March 28, 1973 (BNA Antitrust & Trade Reg. Rep. No. 608, at D-1, April 10, 1973).

[34] Statement of Deputy Assistant Attorney General Sims Before the Energy and Power Subcommittee of the House Interstate and Foreign Commerce Committee, March 3, 1977, at 9-10. The spokesman did caution that exclusion of competitors from the standard-setting process may evidence an anticompetitive intent that a court finds easier to understand (and thus more persuasive) than "a difficult technical analysis of the effects of a particular industrial standard * * *."

[35] *Cantor v. Detroit Edison Co.*, 428 U. S. 579 (1976).

[36] Remarks of Assistant Attorney General Baker Before the Council of the Section of Public Utility Law, American Bar Association, October 28, 1976, at 14 (emphasis by Mr. Baker). The principle is fully applicable to commands of federal agencies acting within their statutory authority. See Baker, "Exchange of Information for Presentation to Government Agencies," 44 *Antitrust L. J.* 354, 366-67 (1975); *cf. Alabama Power Co. v. Alabama Elec. Coop.*, 394 F. 2d 672 (CA-5 1968), *cert. denied*, 393 U. S. 1000 (1969).

however, may be subject to extensive antitrust scrutiny. The *Noerr-Pennington* doctrine that joint efforts to induce even anticompetitive governmental action are constitutionally protected[37] is subject to an exception where misrepresentation to the government is involved, at least in some types of administrative proceedings.[38] In the famous *Smog Equipment* case, for example, the Department of Justice obtained a consent decree prohibiting joint presentations by the automobile companies on proposed antipollution standards, on the basis of allegations that the firms had falsely asserted the technical impossibility of incorporating certain emission control devices in mass production before a particular date.[39]

Any aspect of a private standard-setting process that might be characterized as suppression of relevant information, especially exclusion or even failure to invite unwanted participants, should therefore be pursued only with great caution whether or not the FDA is expected ultimately to adopt the standard. This is so despite the opportunity of all affected persons to participate in the FDA's public processes for adoption of a standard, as there is no basis for supposing that a suppression need be 100 percent effective to fall outside the pale.

Joint Research and Testing

Exclusion of unwanted participants is also a factor in antitrust evaluation of joint research and testing programs. Such programs are likely to become increasingly important in the food industry, as the demand grows for more and better testing and as our finite scientific resources (not to speak of corporate budgets) are drawn thinner.

The Department of Justice often makes known its view that "competition is as beneficial in research as in any other economic activity."[40] Such statements as these have led many in, and out, of industry to conclude—as did the Ford Administration's Assistant

[37] *Eastern R. R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U. S. 127 (1961); *United Mine Workers v. Pennington*, 381 U. S. 657 (1965). The Department of Justice recognizes that this applies to proposals for government-mandated standards. Remarks of Bruce B. Wilson (formerly Acting Assistant Attorney General) Before the Federal Bar Association, September 17, 1976, at 19.

[38] *California Motor Transport Co. v. Trucking Unlimited*, 404 U. S. 508, 513 (1972). See *Israel v. Baxter Labs., Inc.*, 466 F. 2d 272 (CA of DC 1972).

[39] *United States v. Automobile Mfrs. Ass'n*, 1969 CCH TRADE CASES ¶ 72,907 (DC CD Cal. 1969).

[40] *E. g.*, Turner, "The Scope of Antitrust and Other Economic Regulatory Policies," 82 *Harv. L. Rev.* 1207, 1210-11 (1969); see also, *e. g.*, Turner, "Patents, Antitrust and Innovation," 28 *U. Pitt. L. Rev.* 151, 158 (1966).

Secretary of Commerce for Science and Technology in her recent paper entitled *U. S. Technology Policy: A Draft Study:*

"Present antitrust opinion frowns on cooperative R & D among competing firms because it is construed as a form of collusive behavior tending to restrain competition. * * * Research leading to specific products is avoided both because of fear of antitrust action and because of a desire to complete [sic] with differentiated products."[41]

Properly planned, however, joint research and testing need not run afoul of the antitrust laws. Only a few basic guidelines need be borne in mind.

The most recent expression by the Department of Justice on joint research ventures is in the Antitrust Guide for International Operations released in January. No subject receives more extensive treatment in the Guide, which has already been stated by the head of the Antitrust Division to be fully applicable in this respect to domestic joint ventures.[42] The Guide confirms that "there is no *per se* rule applied to joint research agreements," and sets forth a three-part test: Whether

"(1) development costs and risks were high enough to make joint activity appropriate; (2) the venture was not unduly broad in time and scope; and (3) the venturers had continuing competitive incentives from others in the industry * * *."[43]

The Department of Justice has frequently suggested, as the above-quoted Commerce Department study reflects, that basic research is a much more appropriate subject for a joint effort than applied research.[44] This might imply that joint testing of food additives[45] or even of particular new synthesized foods should be avoided.

As the Justice Department concedes, however, it "has not challenged in court agreements purely for joint research, although it has investigated some."[46] And the rationale behind the asserted

[41] NTIS No. PB-263-806, at 49 (March 1977).

[42] Remarks of Donald I. Baker, Assistant Attorney General, Before the Southwestern Legal Foundation, Feb. 24, 1977, at 28.

[43] Antitrust Guide for International Operations, Jan. 26, 1977, at 23, 25.

[44] Statement of Thomas E. Kauper, Assistant Attorney General, Before the Aviation and Transportation Research and Development Subcommittee of the House Science and Technology Committee, May 20, 1976, at 11; Letter from Thomas E. Kauper, Assistant Attorney General, re Metal Treating Institute, April 21, 1976; Letter from Thomas E. Kauper, Assistant Attorney General, to Paul W. Hallman, Deputy Director, Division of Compliance, FDA Bureau of Product Safety, March 28, 1973 (BNA Antitrust & Trade Reg. Rep. No. 608, at D-1, April 10, 1973).

[45] Sec. 409(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. Sec. 348(b)(2).

[46] Statement of Assistant Attorney General Kauper, May 20, 1976, *supra* n. 44, at 6.

preference for basic research—that such work is more costly, less directly remunerative, and therefore less likely to be performed independently than applied research—seems unpersuasive as a reason for prohibiting joint effort in many if not most instances where the FDA is now requiring further testing of additives previously approved or thought to be generally recognized as safe. A further consideration where human safety testing is involved is the undesirability of unnecessary exposure of human subjects to risk of illness or injury.[47] At least in the food and drug industries, then, the supposed antitrust dichotomy between basic and applied research may well prove nonexistent.

The principal remaining concern identified by the Department of Justice in evaluating joint research programs is to ensure that competing third parties have access to important results. Almost all the law in this area is in advisory opinions from the Antitrust Division, called Business Review Letters. Provisions for access to competitively important innovations on a reasonable basis have been stressed in recent Business Review Letters approving joint research agreements in the metal heat treating industry,[48] the chemical industry,[49] and the heavy electrical equipment industry.[50] It is worth noting that the latter two joint research ventures were spurred by health concerns—the general need for toxicology data and a need to develop a substitute for polychlorinated biphenyls as a capacitor impregnant, respectively.

Allowing access to competitively significant innovations on a "reasonable basis" does not mean that industry leaders must subsidize their competitors. As stated by Professor Kauper shortly before concluding his service as head of the Antitrust Division:

"Clearly 'on a reasonable basis' does not require such a low royalty as to destroy competitive incentives by creating a 'free ride' problem. The courts, I believe, will balance these two concepts to preserve reasonable incentives for innovation and prevent unreasonable denial of access to the market place."[51]

[47] See 42 F. R. 19137 (April 12, 1977) (FDA regulation urging joint testing of Category III OTC drugs).

[48] Letter from Thomas E. Kauper, Assistant Attorney General, re Metal Treating Institute, April 21, 1976.

[49] Letter from Thomas E. Kauper, Assistant Attorney General, re Chemical Industry Institute of Toxicology, June 7, 1976.

[50] Letter from Donald I. Baker, Assistant Attorney General, re oil capacitor manufacturers, Oct. 15, 1976.

[51] Statement of Assistant Attorney General Kauper Before the Aviation and Transportation Research and Development Subcommittee of the House Science and Technology Committee, May 20, 1976, at 7.

Litigation—Its Joint Conduct and Its Settlement

Research, either by individual firms or jointly on an industry-wide basis, sometimes leads to litigation—over patent rights, for breach of contract, or for unfair competition through misappropriation of trade secrets or the like. Earlier in this presentation I referred to joint participation in administrative agency proceedings as protected by the First Amendment no matter how anticompetitive the common purpose. The same protection applies to the initiation of litigation—except for "sham" litigation intended to block new competitors not on the merits but by oppressiveness or misrepresentation.[52]

The joint prosecution or defense of a lawsuit may also entail a degree of cooperation not otherwise permissible. When there is a constitutional right to litigate effectively, and particularly when litigation is being defended, that right cannot be infringed by hobbling the parties' freedom to communicate. Thus, a recent price fixing consent decree under the State of Washington's antitrust law expressly provides that price surveys otherwise prohibited may be prepared for use in litigation, and may be distributed among competitors "as may be necessary or required in connection with" their use before the court or agency.[53]

Nevertheless, the relation of the information exchange to present or prospective litigation must be real. Where one of the parties to the exchange is not directly concerned with an alleged litigation posture, the protection afforded actual or potential co-litigants will be denied.[54]

Settlement Agreements

More serious antitrust risks arise when litigation between competitors is settled. Patent cases seem to be the most fertile vehicle for allegedly improper settlement arrangements.[55] Although the rule is well established that "the settlement of patent litigation, in and of itself, does not violate the antitrust laws," it has sometimes been found that "settlement agreements are entered into in bad faith

[52] *California Motor Transport Co. v. Trucking Unlimited*, 404 U. S. 508 (1972).

[53] *Washington v. Multiple Listing Serv. of Spokane, Inc.*, 1974-2 CCH TRADE CASES ¶ 75,439, at 98,488 (Wash. S. Ct. Spokane 1974).

[54] *Cf. SCM Corp. v. Xerox Corp.*, 70 F. R. D. 508 (D. Conn. 1976) (rejecting alleged co-litigant's claim of attorney-client privilege).

[55] See, *e. g., United States v. Singer Mfg. Co.*, 374 U. S. 174 (1963); *American Cyanamid Co. v. FTC*, 363 F. 2d 757 (CA-6 1966).

and are utilized as part of a scheme to restrain or monopolize" so as to create an antitrust violation.[56]

A striking example is the settlement between IBM and Sperry Rand that brought on an antitrust attack against Sperry Rand by another competitor, Honeywell.[57] Sperry Rand (SR) and IBM together possessed about 95 percent of the electronic data processing (EDP) market. IBM, by far the larger of the two, was subject to a prior government antitrust consent decree prohibiting it from entering into any agreement or understanding relating to EDP machines or systems that provided for disclosure to IBM on an "exclusive" basis of any "invention, formula, process or technical information."

SR and IBM, then in patent and antitrust litigation, proceeded to settle their disputes by, among other things, a nominally "non-exclusive" cross-license and exchange of technical information. The Court found that this actually was intended to be *de facto* exclusive, notwithstanding the 1956 IBM consent decree—in effect, a "technological merger." Practical exclusivity was achieved by a misleading joint press release "calculated to allay [the] suspicion" in the rest of the industry that SR and IBM "knew would follow the inevitable leak of information about the deal." This was done, said the Court, in the face of opinions by IBM's antitrust counsel that the SR/IBM "technological merger" would violate the antitrust laws "unless IBM made arrangements for the other companies in the industry to get the same benefits royalty-free."[58]

Interestingly, both IBM and SR had filed copies of the actual agreement (providing for "non-exclusive" exchanges) with the Justice Department. But they "knew and intended that the Justice Department would treat the matter as confidential under the express provisions of the 1956 [IBM] Consent Decree; it was so treated." Thus the government itself was an unwitting participant in the deception.

The Court acknowledged that "[s]ettlements are, of course, to be encouraged unless in the process the antitrust laws are violated and the public interest harmed."[59] But it found a Section 1 violation in the SR/IBM "technological merger" agreement. Although the findings of fact and conclusions of law do not expressly so state, the court appears to have been strongly influenced by the deceptive

[56] *Duplan Corp. v. Deering Milliken, Inc.*, 540 F. 2d 1215, 1220 (CA-4 1976).

[57] *Honeywell, Inc. v. Sperry Rand Corp.*, 1974-1 CCH TRADE CASES ¶ 74,874 (DC Minn. 1973).

[58] *Id.* at 95,920-22.

[59] *Id.* at 95,935.

nature of the SR/IBM joint press release and the heavy emphasis on secrecy to prevent the facts from emerging. In addition, the court clearly was impressed by the efforts of SR/IBM to use the "confidentiality" undertakings of the Justice Department under the 1956 decree, and to seek confidentiality protection from the court itself under protective orders, for the purpose of keeping secret "[t]he true scope of the 1956 Agreement and the breadth of information exchanged."[60]

Other types of potentially anticompetitive relief that might find their way into a judgment can easily be imagined.[61] Caution must therefore be exercised, particularly in patent, antitrust and unfair competition litigation, to ensure that the settlement cure does not contain within it the germ of an even worse disease.

Conclusion

The Rule of Reason provides no easy answers. What it does provide is the opportunity to pursue useful and legitimate goals through practical means when coordination, cooperation and concerted effort among competitors are required. While the hallmark of antitrust is that each case must ultimately be decided on the totality of its own facts, one principle is clear: A sensible and constructive business practice with a well documented justification, when measured by the Rule of Reason, may come off better than you think.

[The End]

[60] See note 57, *supra*, at 95,922.

[61] See, *e. g.*, 41 F. R. 35866, 35867 (Aug. 25, 1976) (response to comments on *Refrigerant Gas* consent decree, *United States v. Air Conditioning and Refrigeration Wholesalers*, 1976-2 CCH TRADE CASES ¶61,160 (DC ND Ohio 1976)).

GMPs and GLPs— Where Are We Going?

By RICHARD S. MOREY

Mr. Morey Is a Member of the Law Firm of Kleinfeld, Kaplan and Becker.

THE TITLE TO THIS presentation has been a source of considerable difficulty for me. I engaged in rather protracted negotiations with your program committee before arriving at the title listed in the program. Now I would like to change it again.

So that you can follow the progression of my thinking, the first title was "GMPs and GLPs—the Latest Developments." My problem with that title is that it really does not seem to me that there are at the present time that many really new developments which I could discuss here in either Good Manufacturing Practices (GMPs) or Good Laboratory Practices (GLPs).

The basic good manufacturing practice regulations for human foods, commonly called the "umbrella" GMPs, were first promulgated by the Food and Drug Administration (FDA) in April 1969. There was considerable controversy over these regulations in a number of respects at the time of their promulgation including, among other things, controversy over the FDA's basic legal authority to issue such regulations in the first place, controversy over the general scope and thrust of the regulations, and of course controversy over a number of specific requirements contained in the regulations. As I will discuss further, some of that controversy still remains eight years later although it has narrowed somewhat in scope.

The "umbrella" GMPs were followed, as you know, by the promulgation of a number of more detailed GMP regulations applicable to specific categories of foods. Prominent among these are, of course, the regulations for smoked fish products and for low acid canned foods which are based primarily on potential hazards in-

volved in inadequately or incorrectly processing these classes of foods. There have been further specific GMP regulations either finally promulgated or proposed for confectionary products, bottled drinking water and bakery products and I understand that such regulations are also being considered for further classes of foods including frozen foods, fresh and frozen fish, frozen raw breaded shrimp, macaroni and noodle products, and prepared dry mixes.

Still, in terms of significant new developments the GMP area in my view is a rather static one. The specific GMPs which are in the works follow a pattern similar to those already promulgated and there appear to be very few new developments in that area. The trend to more specific GMPs seems to be slowing down. This, I think, is good because in most cases the GMP requirements deal with problems common to the food industry and not unique to the particular class of food. As to the umbrella GMPs, there are periodic, almost continual, indications from the FDA that they will be expanded, revised, and tightened. I would anticipate that this eventually will come to pass, probably after work on the specific GMPs has subsided, but it will be a year or two before a new umbrella regulation becomes effective.

Good Laboratory Practices

Turning to the GLPs, I was also troubled with the requirement of my initial title that I speak to you about new developments. The proposed good laboratory practice regulations were published in the *Federal Register* in November 1976. They were, and are, very controversial. But since then there have been relatively few developments. From where I sit, there has been basically a lot of confusion, uncertainty, and even disbelief, as to how and when these regulations will be applied. At the public hearing held on the GLPs in February 1977, many members of the industry protested many aspects of the proposal, again ranging from the basic concept to many of the specific provisions.

In terms of FDA activity, I understand that the Agency has been inspecting various laboratory facilities under the standards of the proposed regulations both to gain experience in applying the standards in the regulations and to assess the current status of the industry in meeting those standards. I am sure it will be no surprise to this group that the results of these inspections, so far as they have been reported, show that the industry is not meeting completely the standards set forth in the proposal. Basically, I under-

stand that the operations reviewed have been evaluated by the FDA investigators as being subject to various sloppy and inappropriate practices. But no fraudulent or other seriously defective conditions were encountered.

Despite the protests by the industry at the February hearing, the FDA inspections, and the numerous comments filed by members of industry and other interested persons, the situation as to GLPs is basically in flux at this point and there is little in terms of new developments to be reported. I think we can safely anticipate that the FDA will eventually promulgate GLP requirements in some form, probably as regulations which the Agency will claim to have binding legal authority. But for the present there is little solid news to report.

Continuing my difficulties with the title for this presentation we next arrived at the title "Current Regulatory Developments, Including GMPs and GLPs." This title was designed to allow me to talk on any subjects I wanted as long as they included GMPs and GLPs. However, as I thought about it further, I realized while there are not many new developments there are a number of useful points that may be discussed as to GMPs and GLPs, and I am going to limit my presentation to those subjects.

The final title which I have arrived at is "GMPs and GLPs—Where Are We Going?" Basically, I believe that the industry's experience with the GMP regulations which it has now operated under for eight years provides important clues and lessons as to what can be anticipated when the FDA institutes its GLP requirements. So the simple answer to the question in my title—if you want to know where we are going to go with GLPs the best way to figure this out is to examine the analogous GMP situation. In the balance of the presentation I will do this on several legal issues. However, I suggest that even when considering non-legal issues that this is a worthwhile method of analysis.

Statutory Authority

As a lawyer, I like to approach the analysis of any regulation by looking first to the Agency's authority to promulgate that regulation. This is important not only because of the possibility—and I admit that it is usually a remote possibility—that the entire regulation may be upset for lack of statutory authority but also in defining the scope of the regulation and the potential penalties which are available to the Agency in case the regulation is found to be violated.

Looking first at the GMPs, the FDA's statutory authority has been a matter of continuing controversy since the regulations were first proposed. There is of course no reference in the food provisions of the Federal Food, Drug, and Cosmetic Act to "current good manufacturing practice" as there is for drugs. The FDA's only claimed authority is the prohibition against manufacturing food under "insanitary conditions" which does not appear to cover all the requirements which are part of the GMP concept. Eight years later, these questions have not yet been completely settled by the courts. In fact, there are presently two cases in two United States Courts of Appeals dealing with the FDA's legal authority as to specific provisions contained in the confectionery GMP regulations and the smoked fish GMP regulations. In both cases it is claimed that the provisions in question do not relate to "insanitary conditions." In terms of decided cases, I am only aware of three such cases, all district court decisions. Of the three, the FDA has won two, the lower court decisions in the two Court of Appeals cases which I just mentioned. The third case was a criminal case in Wisconsin also involving the smoked fish GMPs which the FDA lost and, because of the nature of the case, was not able to appeal.

There are, of course, other important recent precedents which are relevant to the FDA's statutory authority. The decision of the United States Court of Appeals for the Second Circuit in the *National Nutritional Foods* case, which involved the vitamin regulations, suggests that the Agency ultimately will be found to have the least general authority to issue GMP regulations for foods. This still leaves open, however, the type of question involved in the two cases under appeal, which deal with the scope of such regulations and whether specific regulatory requirements are within the claimed statutory authority. I think it is fair to sum up this issue by saying that although the regulation has been widely enforced, there are still substantial unresolved questions on the FDA's statutory authority to promulgate GMP regulations.

Turning to the GLPs, I can see even greater possibilities for challenging the Agency's statutory authority. I would anticipate that if these regulations are promulgated as legally binding regulations, and possibly even if they are promulgated merely as advisory guidelines there will be extended litigation and a long period of doubt as to the Agency's legal authority. Of course, the Agency will enforce the regulations anyway in the meantime.

FDA's Statutory Authority

One of the fundamental legal questions as to the FDA's statutory authority to issue the GLPs can be readily analogized to the situation in criminal law where damning evidence is thrown out by a court on the basis that it was illegally obtained by the police. This does not mean that the evidence is not extremely probative of the guilt of the defendant. It is simply a case in which the courts have recognized as important a competing policy that such evidence must be excluded in order to prevent the police from using the illegal tactics involved.

I think we can readily envision a similar situation with the proposed GLP regulations. Actually this is a reverse analogy. By this I mean I can easily foresee the situation in which there are available data which any reputable scientist would accept as valid but which the FDA, pursuant to these regulations, would seek to exclude from consideration in evaluating a regulatory application such as a food additive petition. This particular situation in which there are valid data obtained from a facility which is allegedly in violation of one or more GLP requirements and the data are excluded from consideration by the FDA, raises a very fundamental legal question.

The various provisions of the Federal Food, Drug, and Cosmetic Act which the FDA administers require that the Agency evaluate valid data submitted to it and on the basis of such evaluation make its regulatory determinations. There is nothing in the statute that says that data which are in fact valid and reliable may be excluded from regulatory evaluation simply because the FDA wishes to pursue another policy and avoid general sloppiness in laboratory practice. This may be a very worthwhile policy but it is not one which is at present recognized in the Act. In my view, the FDA is required to consider all relevant and valid data submitted to it in support of an application, and I would certainly anticipate a legal challenge if the Agency should seek to exclude such data simply because some minor niceties of GLPs were not observed.

Disqualification Procedures

The proposed regulations, moreover, offer greater problems in terms of legal authority and perhaps even raise issues of constitutional fairness in the proposed disqualification procedure for laboratories found not to have complied with good laboratory practices. An extension of the situation I have just been discussing but an even more appealing one from a factual standpoint would be a case in which the FDA refused to consider in support of a regulatory application a study performed by a research laboratory, even though it found no GLP defi-

ciency relating to that study, because such deficiencies had been found in the course of other work performed by the laboratory. This particular situation, by the way, does not even have an analogy in the GMP regulations since to my knowledge the FDA has never sought to take action against one food based on alleged GMP deficiencies relating to other foods. From my reading of the proposed regulations it is entirely possible that such a situation could arise with respect to GLPs. Even worse, GLP problems with a laboratory could tend to cast doubt on studies already accomplished and applications and licenses already granted in addition to affecting pending applications.

Depending upon how the proposed disqualification procedure will be applied, I can even conceive of situations which raise constitutional questions about the rights of persons to engage in lawful businesses. For example, by their nature these regulations are likely to be widely adopted for purposes other than those for which they are being promulgated by the FDA. The range of interest in these regulations is apparent from the wide variety of organizations including other government agencies which have been participating in the rulemaking proceeding. The great potential scope of application of these regulations, taken together with the many requirements of different specificity and different relevance to a particular situation plus the questions I have discussed above relating to the Agency's statutory authority to promulgate these regulations at all, all combine to suggest that here is administrative rulemaking carried to an unreasonable extreme.

Still further questions arise in connection with the status of a laboratory which the FDA seeks to disqualify. These include the effect of such adverse information upon the laboratory from the moment that its proposed disqualification is announced until such time as it might, weeks or months later, be vindicated in a public hearing. This is particularly true when the hearing is before an FDA employee and not before an impartial tribunal. Further, assuming the situation that a laboratory is accused but later found innocent either by the Agency or ultimately by the courts, there are many questions relating to the status of studies then ongoing, to the status of pending regulatory applications by clients of the laboratory based on studies performed by the laboratory other than those directly in question, and so forth. While the basic concepts or principles which the Agency believes constitute good laboratory practices may usefully be set forth by the FDA for the guidance of interested persons, the promulgation of these standards as binding regulations and particularly the elaborate disqualification procedure is an unnecessary administrative house of cards.

Scope and Format

Turning from the matter of statutory authority I would next like to look briefly at the scope and format of the GMPs and the proposed GLPs.

Both superficially in their organizational structure, and as a more detailed examination is made, the similarity between the GMPs and the proposed GLPs is readily apparent. In each case requirements are set forth for personnel, facilities, equipment, operating procedures, recordkeeping, etc. In each case, these requirements are rather vague and general in their terms, making considerable use of words such as "adequate", "sufficient," "minimize," "appropriate," "proper" and "necessary." All of these words are of course subject to interpretation and your interpretation as an industry expert may differ considerably from that of the FDA investigator who inspects your plant. Moreover, it all too frequently appears that such opinions may also differ from investigator to investigator. The trouble is of course that words such as "adequate" are so vague as to be meaningless. It is quite clear that if there are no facilities for a certain operation there are not "adequate" facilities. But as soon as there are some relevant facilities, it becomes a matter of opinion and interpretation between your experts and those of the FDA.

Words like "adequate", moreover, are even more troublesome because they permit ever changing standards. I am sure most of you have experienced in dealing with the GMPs, the situation in which something that used to be adequate is no longer considered to be so by an FDA inspector who found one of your competitors has a procedure which the inspector happens to think is better. The original concept of GMP or current good manufacturing practice meant what was the good, prevalent practice by the majority of the industry in question. However, "adequate" has come to mean instead only the very best which the particular FDA investigator has encountered to date. Every other facility is considered inadequate compared to the one outstanding operation and more or less subtle pressure is put on other manufacturers to upgrade their operations.

While there may be something to be said from a policy point of view in requiring all manufacturers constantly to improve their operating facilities, personnel, etc., it is in my view a perversion of the basic concept of current good manufacturing practice to require this under the GMP regulations. Once again, if the FDA believes such a policy is in the national interest, it should seek authority from the Congress to carry it out. I find nothing in the present Act which authorizes

this approach. Nonetheless, I can predict with some confidence that if the GLP regulations are promulgated as binding regulations we can look forward to the same process in this respect as has been encountered under the GMP regulations.

Future GLPs

Another possibility suggested by the development of the GMP regulations is that, after initial GLP regulations are promulgated, the FDA may in the future issue more specific GLPs covering certain types of research. This is in addition to the type of regulations or guidelines long promised by the FDA as to what the requirements are for conducting certain types of studies in a manner which will meet the Agency's approval and the also promised guidelines as to what types of testing may be needed for the clearance of substances by the FDA depending upon their composition and intended use. Since I do not have scientific expertise, I cannot predict in what areas more specific GLPs might be promulgated, but the history of GMPs suggests that some such regulations are a likely prospect for the future.

Comparing the GMPs and the proposed GLPs there are also a number of important differences which must be considered. One such difference which seems to me to raise considerable legal questions is the incorporation in the GLP regulations of requirements promulgated in other regulations enacted for different purposes and also in certain government publications. For example, Section 3e.43, dealing with animal care facilities says that in certain situations the recommendations contained in HEW publication No. 74-23 entitled "Guide for the Care and Use of Laboratory Animals" shall be used. Thus, these proposed regulations have incorporated by reference and made mandatory something which was merely a recommendation as initially promulgated. A similar situation occurs in Section 3e.115 relating to the handling of carcinogenic substances. This incorporation by reference of other materials is also troublesome because such materials may well be changed without notice to the FDA or to persons subject to these regulations.

Operating Under the GLPs

The final aspect that I would like to compare between our eight years of experience under the GMP regulations and the proposed GLP regulations is how operations are likely to be on a routine basis should binding GLP regulations be promulgated. Here I con-

fess that I have not had the operational experience many of you have. But I think from my view in participating in several litigated cases involving GMP regulations that certain points are clear.

First, as has obviously been true in the case of GMP regulations, the proposed GLP regulations cover such a broad area involving such complex operations that it is almost literally impossible to imagine that any facility could ever be in complete compliance or, if it were, could remain so for any extended period of time. This is true because there usually are many, detailed, repetitious operations in which any slight deviation may constitute an alleged violation. The situation is further complicated by the problem of vagueness which I have referred to above so that, even if an investigator cannot find any specific deficiencies, he can always charge that something is not quite "adequate." Thus, it would be theoretically possible with the GLPs as with the GMPs for the FDA to shut down or disqualify almost any given operation on any given day.

Fortunately, of course, this has never been a problem with the GMPs and I do not seriously anticipate that it will be a problem with the GLPs. The general standard, and I think it is the proper one, is that the inspector looks for a reasonable effort to comply with the requirements and to correct and improve as to the deficiencies which are observed. Serious difficulties with the GMPs have been largely restricted to cases in which there was either a potentially dangerous situation or the Agency apparently felt that the manufacturer was recalcitrant or at least unresponsive to constructive suggestions. It is reasonable to assume that this same standard generally will be applied even if there are binding GLP regulations.

The Agency can and obviously should deal with situations in which unreliable data is produced and certainly any situations, which fortunately are rare, in which fraudulent conduct is detected. But it seems to me that dealing with both of these situations the Agency already has sufficient authority under existing law and regulations and there is no need for the promulgation of an elaborate new superstructure of regulations, disqualifying procedures, etc.

As to unreliable data it is quite clear that the Agency can and does reject or disregard such data when it is offered in support of a regulatory application. There is no question that the statute supports the Agency's position in this regard. Why it is necessary to superimpose a set of regulations which add nothing to this authority

but which create the possibility that valid data will not be considered is hard to see.

The situation as to any fraudulent data encountered is similar. Again, there is no question that the Agency can, and under its statutory authority must, reject such data when offered in support of a regulatory application. Further, depending on how the fraudulent conduct occurred, there is ample statutory authority to deal with it either under the Federal Food, Drug, and Cosmetic Act or under Federal criminal provisions. Once again I do not see how the promulgation of the proposed GLP regulations really adds anything to the situation.

Thus, it seems to me that the proposed GLP regulations particularly when considered in the light of our experience under the GMP regulations raise a great many problems from a legal standpoint and otherwise have very little to offer. I think that many of the principles set forth in these regulations are good ones which should be brought to the attention of the industry but not in the form proposed by the Agency. A set of guidelines, principles, and recommendations would accomplish just as much without creating GLP problems to go along with each of our existing GMP problems.

[The End]

LIQUID PROTEIN DIETS OFFER NO UNIQUE BENEFITS, FDA SAYS

The use of liquid "predigested" protein diets does not appear to offer any unique benefits to a dieter beyond those of a diet utilizing any other protein source, according to the Food and Drug Administration (FDA). The Agency has expressed concern about persons who use such modified fast diets without medical supervision and is pursuing a number of investigations regarding the diets and their marketing. The FDA is responsible for the labeling of these products, but the labeling does not usually give directions for weight-loss programs. Claims concerning weight loss are generally made in the media, which are beyond the scope of the Agency's control.

CCH Food Drug Cosmetic Law Reporter, ¶ 42,058

Nutrition Regulation by the FDA in the Brave New World of Fabricated Foods

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IT IS OFTEN SAID in casual remarks that the Food and Drug Administration (FDA) has responsibility for assuring a safe, wholesome and nutritious food supply in the United States. However, insofar as such remarks assume that the FDA has ample authority to assure the nutritional quality of the United States' food supply, they are not necessarily justified. The Federal Food, Drug, and Cosmetic Act (FDC Act)[1] provides the FDA explicit and extensive authority to undertake regulatory action with respect to toxic substances or filth in food; in contrast, the Agency's ability to regulate the nutritional quality of the food supply is much more dependent upon arguments of implicit authority, and the extent of that authority may be much less extensive.

Perhaps in former decades this was a matter of small import.[2] In the 1970's, however, there have been significant new developments in food technology, developments that make possible new fabricated food products which substitute for and resemble traditional foods but which may not provide the same nutritional value as the traditional foods.

[1] Title 21, United States Code ("U. S. C."), sections 301 *et seq.*

[2] I am not suggesting that the citizens of this Nation have been uniformly well fed in prior decades. Poverty and poor eating habits have no doubt taken their toll even in years of abundant harvest. However, in prior decades there was no real and present prospect that new developments in food technology might result in extensive use of synthetic substitutes for traditional staple foods, substitutes which might have nutritional characteristics significantly different from the foods they replace.

Fabricated substitutes for meat, cheese and eggs are already on the market. Such products may be purchased directly by consumers for use in place of traditional articles of food, for example, "cholesterol-free egg substitutes" or hamburger meat "extenders," or they may be used by manufacturers to replace traditional ingredients in food products, for example, a frozen pizza product may be made with a cheese substitute instead of cheese. All commentators seem to agree that the substitute foods now on the market are only the beginning of an anticipated "explosion" of new developments with respect to synthesized substitute food products, made possible by rapid advances in food technology and encouraged by the economic conditions of the era immediately facing us.

As a lawyer serving the FDA, it is clear to me that the FDA's Bureau of Foods is now concerned about finding ways to assure that the appearance of new fabricated foods does not lead to significant degradation of the nutritional quality of the American food supply. Accordingly, it is my purpose in this paper to discuss some of the FDA's possible regulatory options in taking action to assure the nutritional quality of the food supply in these circumstances. First, I shall review various approaches the FDA has taken in the past with respect to nutrition regulation and consider their possible application to new substitute food products. Thereafter, I shall suggest some *new* approaches the FDA might pursue for the purpose of assuring nutritional quality of new substitute food products.

Existing "Nutrition Regulation" Programs

Speaking generally, the FDA has five existing "nutrition regulation" programs which might have significance with respect to new substitute food products, and the Agency has proposed a sixth.

Standards of Identity

The FDC Act authorizes the FDA to establish a "definition and standard of identity" for a food "whenever in the judgment of the Secretary [FDA] such action will promote honesty and fair dealing in the interest of consumers."[3] The FDA has used this authority to establish definitions and standards for several "enriched" foods, including enriched flour,[4] enriched rice,[5] and enriched bread.[6] Speaking

[3] 21 U. S. C. 341. The authority of the Secretary of Health, Education, and Welfare under the FDC Act has been delegated to the Commissioner of Food and Drugs, who directs the FDA. 21 CFR 5.1.

[4] 21 CFR 137.165 (formerly 21 CFR 15.10).

[5] 21 CFR 137.350 (formerly 21 CFR 15.525).

(Footnote 6 on next page.)

generally, the effect of a standard for an "enriched" food is to require that if any vitamin or mineral is added to the food, the food must provide *all* of the nutrients required by the standard, in the amounts required by the standard.[7] Historically, such enrichment practices have had a profoundly beneficial effect on the Nation's nutritional health.

Note that while the FDC Act thus provides the FDA authority to standardize an "enriched" food, the Agency generally has *not* attempted to use this authority to prohibit the existence of an *un*enriched article. For example, the FDA has established standards of identity for "bread" and "enriched bread," "farina" and "enriched farina," etc., and has then depended upon the marketplace for consumer selection of the enriched article rather than the unenriched article.[8]

Standards of identity for various "enriched" foods were promulgated in the 1940's, soon after enactment of the Federal Food, Drug,

[6] 21 CFR 136.115 (formerly 21 CFR 17.20). The standard for enriched bread has been so widely embraced within this country that it appears to be difficult to find an *un*enriched white bread for sale on the shelves of our supermarkets.

[7] In an early case under the FDC Act, the Supreme Court of the United States recognized that the FDA had the authority to standardize "farina" and "enriched farina" and that all farina products containing added vitamins must comply with the requirements of the standard for "enriched farina". *Federal Security Administrator v. Quaker Oats Co.*, 318 U. S. 218 (1943).

In 1976 Congress enacted new amendments to the FDC Act which, speaking generally, have the effect of limiting the FDA's authority to establish formulation requirements for dietary supplements of vitamins and/or minerals which are offered for use by adults other than pregnant or lactating women (except that the FDA retains full authority to impose restrictions on such preparations for reasons of safety). 21 U. S. C. 350. This legislation, however, applies to vitamin/mineral preparations in "tablet, capsule, or liquid" [droplet] form, 21 U. S. C. 350(c)(1)(B)(i); it does *not* limit the FDA's authority to establish nutrient formulation requirements for new fabricated food products which substitute for and resemble traditional foods. I. e., the new legislation provides that its restrictions upon the FDA's authority do not apply to preparations which simulate or are represented as "conventional food". 21 U. S. C. 350(c)(1)(B)(ii). The legislative history with respect to this provision explicitly states that: "The Secretary retains his current authority to regulate the nutritional formulation and composition of, and potency of vitamins, minerals and other ingredients in conventional foods such as milk, enriched bread and enriched rice, *as well as in products which simulate conventional foods such as soybased protein substitutes for meats and poultry.*" [Emphasis added.] S. Rep. No. 94-743, 94th Cong., 2d Sess. 26 (1976); H. R. Rep. No. 94-1005, 94th Cong., 2d Sess. 26 (1976).

[8] However, cf. the standards of identity for: "evaporated milk", 21 CFR 131.30 (formerly 21 CFR 18.520); "lowfat milk", 21 CFR 131.135 (formerly 21 CFR 18.10); "skim milk", 21 CFR 131.145 (formerly 21 CFR 18.20); and "margarine", 21 CFR 166.110 (formerly 21 CFR 45.1)—all of which require vitamin addition without providing for the existence of an *un*enriched analog.

and Cosmetic Act in 1938, and through the intervening years the FDA has continued to promulgate (and revise) such standards. However, thirty years passed before the FDA seriously undertook additional types of regulatory programs bearing upon the nutritional quality of the American food supply.[9] In the 1970's, partly in response to increased interest by consumers in the nutritional quality of the foods they eat, and partly out of a concern to protect the nutritional quality of the American food supply, the FDA has instituted several additional regulatory programs with respect to nutrition.

Nutrition Labeling

In 1973 the FDA ushered in a new era of nutrition regulation by publishing final regulations with respect to nutrition labeling of foods.[10] Speaking generally, these regulations provide that if any vitamin, mineral or protein is added to a food, or if "any nutrition claim or information" is included in labeling or in advertising for a food (for example, "nutritious," "high in vitamin C," etc.), full nutrition information with respect to the calorie, protein, carbohydrate, fat, vitamin and mineral content of the food, must be included on the label of the food in a standardized format.

While nutrition labeling does not impose any requirements with respect to the nutritional quality of the food supply, the FDA believes that as a result of such labeling consumers will become more aware of the nutritional value of the foods they purchase, and more likely to consider nutritional value in making purchasing selections.[11]

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[9] Of course, through the years the FDA has undertaken regulatory action to prevent misleading labeling, and these efforts have sometimes involved vitamins or other nutrients. See, e. g., *United States v. Nuclomin*, 482 F. 2d 581 (CA-8 1973), and *United States v. Vitasafe*, 226 F. Supp. 266 (D. N. J. 1964), modified 345 F. 2d 864 (CA-3 1965), cert. den. 382 U. S. 918 (1965). However, in the context of this paper, I have not included these important enforcement activities as a "nutrition regulation program" because they reflect a more general FDA program to prevent misleading labeling and are not particularly the result of concerns by FDA nutritionists to foster sufficient nutritional content in the food supply. (For an *un*successful action with respect to sugar believed by the FDA to have been fortified irrationally, see *United States v. New Dextra Brand Fortified Cane Sugar*, 231 F. Supp. 551 (DC SD Fla. 1963), affd. 334 F. 2d 238 (CA-5 1964)).

[10] 21 CFR 101.9 (formerly 21 CFR 1.17), 38 F. R. 6951 (March 14, 1973). See also 21 CFR 101.25 (formerly 21 CFR 1.18), "Labeling of foods in relation to fat and fatty acid and cholesterol content", 38 F. R. 6961 (March 14, 1973) and 38 F. R. 20071 (July 27, 1973).

[11] The FDC Act does not explicitly require nutrition labeling. However, 21 U. S. C. 343(a) prohibits labeling which is "misleading in any particular", and 21 U. S. C. 321(n) provides that in determining whether labeling is misleading, "there shall be taken into account (among other things) not only representations made or sug-

(Continued on next page.)

Common or Usual Names

The FDC Act provides that the label of a food must bear "the common or usual name of the food, if any there be."[12] In the interest of "efficient enforcement" of the Act,[13] the FDA has provided that, in appropriate circumstances, it will establish by regulation the "common or usual name" for a particular food.[14]

While most common or usual name regulations that have been published up until now have not focused upon nutritional factors, the FDA has established a final common or usual name regulation for "frozen 'heat and serve' dinners" which requires *inter alia* that frozen dinner products include at least one component which is "a significant source of protein."[15] The Agency has also proposed to establish a common or usual name for "plant protein products" (extenders and replacements for meat, seafood, poultry, eggs or cheese which are produced from edible plant protein sources such as soybeans) which would establish minimum nutritional criteria to be met by certain types of such products.[16]

The general regulations providing for establishment of common or usual names and the frozen dinner regulation have recently been upheld by the United States District Court for the District of

(Footnote 11 continued.)
gested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations . . ." Furthermore, pursuant to 21 U. S. C. 371(a) the FDA has "authority to promulgate regulations for the efficient enforcement of this chapter" [the FDC Act]. The FDA's nutrition labeling regulations are based on the premise that failure to provide "full" nutrition information, in the manner established by the regulations, would cause labeling to be misleading within the meaning of 21 U. S. C. 343(a) and 321(n) for failure to reveal facts material in light of "triggering" nutritional representations. (The addition of a nutrient to a food product results in a "triggering" nutrition claim or information because the presence of the nutrient ingredient must be declared in the labeling in the list of ingredients, as required by 21 U. S. C. 343(i)(2)). See discussion of this premise in 38 F. R. 2125 (Jan. 19, 1973). While consumers have occasionally asked that the FDA require nutrition labeling on *all* foods, it is doubtful that this premise, at least, could be used to justify such a requirement, e. g., if no vitamin, mineral or protein is added to canned applesauce and no nutrition claim or information is included in labeling or advertising, it becomes difficult to argue that the failure to provide nutrition information causes the food's labeling to be misleading.

[12] 21 U. S. C. 343(i)(1).

[13] 21 U. S. C. 371(a), quoted in relevant part in footnote 11.

[14] 21 CFR 102.5, 102.19 (formerly 21 CFR 102.1, 102.2), 38 F. R. 6964 (March 14, 1973).

[15] 21 CFR 102.26(a)(1) (formerly 21 CFR 102.11(a)(1)), 38 F. R. 20742 (Aug. 2, 1973).

[16] Proposed 21 CFR 102.22, 39 F. R. 20892 (June 14, 1974).

Columbia.[17] The plaintiff in this case, a trade association representing manufacturers of frozen foods, has appealed the decision upholding the regulations, and the matter is now pending before the United States Court of Appeals for the District of Columbia Circuit. Assuming the regulations are sustained on appeal, the FDA can be expected to promulgate common or usual names for additional foods in the future.

Nutritional Quality Guidelines

FDA regulations provide for the establishment of "nutritional quality guidelines" for particular foods.[18] A nutritional quality guideline prescribes the minimum level or range of nutrient composition (nutritional quality) appropriate for a given class of food. The regulations provide that a food which complies with all of the requirements of an applicable nutritional quality guideline may bear a label statement that the product "PROVIDES NUTRIENTS IN AMOUNTS APPROPRIATE FOR THIS CLASS OF FOOD AS DETERMINED BY THE U. S. GOVERNMENT."[19]

Imitation Policy

The FDC Act provides that a food which is an "imitation" of another shall clearly be labeled as such.[20] The FDA has concluded that the "imitation" section of the Act should not be interpreted so as to become a trade barrier which might present a serious obstacle to the development and marketing of new substitute food products with sound nutritional content. (Indeed in light of the connotations of inferiority applicable to the term "imitation," it might be misleading to consumers to require that a new substitute food be labeled as an "imitation" if it is nutritionally equivalent—or superior—to its traditional counterpart.)

Pursuant to this policy (and a policy favoring informative labeling) the FDA has promulgated a regulation providing, *inter alia*, that a food which substitutes for and resembles another food must be labeled as an "imitation" if it is nutritionally inferior to the other food, but that

[17] *American Frozen Food Institute v. Mathews*, 413 F. Supp. 548 (DC DofC 1976), appeal pending. (The Court also upheld a common or usual name regulation requiring that seafood cocktails declare, as a part of the name, the percentage by weight of seafood ingredient contained in the product.)

[18] 21 CFR 104.5, 104.19 (formerly 21 CFR 100.1, 100.2), 38 F. R. 6969 (March 14, 1973).

[19] At the present time, the only food for which a nutritional quality guideline has been established is "frozen 'heat and serve' dinners." 21 CFR 104.47 (formerly 21 CFR 100.5), 38 F. R. 6969 (March 14, 1973).

[20] 21 U. S. C. 343(c).

a food which substitutes for and resembles another food need not be labeled as an "imitation" if (1) it is not nutritionally inferior to the food for which it substitutes and which it resembles and (2) it bears an appropriate name which accurately identifies or describes its basic nature.[21] Obviously, the FDA intended this "imitation" regulation to have a "carrot" effect to encourage that a new substitute food be formulated so as to be nutritionally equivalent to its traditional counterpart in order to avoid pejorative "imitation" labeling.[22]

The FDA's "imitation" regulation has been upheld by the United States District Court for the District of Columbia and, on appeal, by the United States Court of Appeals for the District of Columbia Circuit.[23]

General Principles Governing the Addition of Nutrients to Foods

The FDA has also proposed "general principles" to govern the addition of nutrients to foods.[24] The goal is establishment of rules to determine when fortification of foods with vitamins, minerals and/or protein is nutritionally appropriate and to encourage that only nutritionally rational fortification practices are undertaken.[25]

Problems for the FDA: The Limitations of Present Programs

The FDA's present "nutrition regulation" programs, discussed above, do *not* necessarily assure the nutritional quality of the American food supply.

Consider a hypothetical situation which is not at all fanciful, and which illustrates the problems the FDA may face in the near future. Let us, first, accept the premise that cheese is a basic and important component of the American food supply. Accepting the importance of

[21] 21 CFR 101.3(e) (formerly 21 CFR 1.8(e), 38 F. R. 20702 (Aug. 2, 1973).

[22] On the other hand, at least one manufacturer appears to have chosen to employ "imitation" labeling for a product —"imitation mayonnaise"—which appears to be nutritionally equivalent to its traditional counterpart and might thus have been labeled with another name.

[23] *Federation of Homemakers v. Schmidt*, 385 F. Supp. 362 (DC DofC 1974), affd. 539 F. 2d 740 (CA DofC 1976).

[24] Proposed amendments to 21 CFR 104.5 (formerly 21 CFR 100.1), 39 F. R. 20900 (June 14, 1974).

[25] In addition to the six "nutrition regulation" programs discussed above, the FDA has established regulations governing the labeling and composition of dietary supplements of vitamins and minerals and other foods which purport to be or are represented for special dietary uses (e. g., infant formulas), 21 CFR 105 (formerly 21 CFR 80.1 and 125). However, while these regulations involve vitamins and minerals, they have little immediate relevance to new fabricated food products which substitute for and resemble traditional foods, but which are not offered for some special dietary use.

cheese, let us suppose that a manufacturer develops a new cheese substitute which has the appearance and taste of high quality cheese with twice the shelf life and half the cost. Suppose, however, that the new food, unlike cheese, contains no significant calcium content, and that it provides ten times as much sodium as would be provided by an equal serving of cheese. Suppose that the FDA becomes concerned that a significant segment of the American population may be adversely affected by use of this product in substitution for cheese, that is, suppose the FDA discovers that older citizens who (1) want soft foods, (2) have limited incomes, (3) have previously consumed cheese as a significant source of calcium, and (4) should avoid high intakes of sodium, are purchasing the new product instead of cheese, and that the Agency concludes that these older citizens are thereby depriving themselves of needed calcium and exposing themselves inadvisedly to high intakes of sodium. Now let us consider the FDA's existing programs for nutrition regulation, and see whether it would be able to take effective action under any of these programs to prevent the adverse nutritional impact threatened by the hypothetical cheese substitute.

Standard of identity? The FDA could promulgate a standard of identity for "cheese substitute products" establishing appropriate nutritional requirements for this class of food products. However, if a manufacturer should decide, perhaps for reasons of cost or because of technological limitations, not to reformulate his product to comply with the nutritional criteria established by the standard, he would remain free to sell the product as "imitation cheese" without improving its nutritional characteristics.[26]

Nutrition labeling? If a manufacturer of a cheese substitute product adds any vitamins or minerals to the product, or makes any nutrition claims on behalf of the product, nutrition labeling will be required on the label, pursuant to the FDA's nutrition labeling regulation. However, under existing regulations if a manufacturer adds no nutrients and makes no nutrition claims, he may sell his product without providing nutrition labeling. Furthermore, even if nutrition labeling does appear on the product, our hypothetical older citizen may continue to purchase the less nutritious cheese substitute perhaps because the substitute product is cheaper and/or because the purchaser pays little attention to nutrition labeling.

[26] The courts have recognized that a food product which resembles a standardized food but fails to comply with the standard may be sold as an "imitation." *62 Cases . . . Jam v. United States*, 340 U. S. 593 (1951) ("imitation jam"); *United States v. 856 Cases . . . Demi*, 254 F. Supp. 57 (DC ND NY 1966) ("imitation margarine").

Common or usual name regulation? The FDA could promulgate a common or usual name for "cheese substitute products," which might require appropriate nutritional characteristics for foods bearing that name; but again, as in the case of a standard of identity, this would not appear to prevent a manufacturer from selling his product as an "imitation cheese" without improving its nutritional characteristics.

Nutritional quality guideline? The FDA could promulgate a nutritional quality guideline for cheese substitute products, thereby encouraging manufacturers to formulate such products in compliance with the guideline in order to be permitted to use the label statement that the product "PROVIDES NUTRIENTS IN AMOUNTS APPROPRIATE FOR THIS CLASS OF FOOD AS DETERMINED BY THE U. S. GOVERNMENT." But a manufacturer would remain free to forego use of this "stamp of approval" and instead sell a less nutritious product.

Imitation policy? The FDA's imitation regulation, in effect, tells a manufacturer of a cheese substitute product that he may avoid imitation labeling if he (1) fortifies his product so that it is nutritionally equivalent to cheese and (2) employs an appropriately informative name. But a manufacturer is not required to take such action, and he may instead choose to continue marketing a nutritionally inferior substitute product as an "imitation."

General principles? Finally, the FDA's proposed general principles to govern the addition of nutrients to foods would, if finalized as proposed, establish approved rationales for the addition of nutrients to foods, but they would not require a manufacturer to fortify his product.

In summary, the FDA's existing nutrition regulation programs might be used to encourage manufacturers to produce, and consumers to select, a substitute cheese product with a sound nutritional profile; but none of these programs would compel a manufacturer to add calcium, or limit sodium content, or even to reveal his product's nutritional composition in labeling, if he chooses instead to sell his product as "imitation cheese" without making any nutrition claims.[27]

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[27] Of course, cheese substitute products have already appeared upon the market. E. g., a full page color advertisement announcing that "Kraft introduces Alamo, the imitation cheese that doesn't taste like an imitation" appears on page 73 of the February 1977 issue of *Food Product Development.*

In a petition filed with the FDA, Anderson Clayton Foods states as follows:

"Anderson Clayton Foods has for a number of years marketed under the brand name 'Unique' a series of products designed to serve as substitutes for cheese. To satisfy its own market-

(Continued on next page.)

New Regulatory Approaches

If the FDA should conclude that one or more new substitute foods may have a significant adverse impact upon the nutritional quality of the American food supply, that is, if the existing regulatory programs discussed above should not be sufficient to avoid such a situation, the question naturally arises: Is there any way the FDA can take effective action under existing statutory authority to correct such a situation? Four possibilities, at least, come to mind.

Expansion of Nutrition Labeling Requirements

(a) Nutrition labeling for "imitation" foods.

The nutrition labeling regulations might be amended to require that "imitation" foods bear such labeling. This would, of course, be an expansion of the existing regulations, which presently require nutrition labeling only if a nutrient is added to a food or if nutrition claims are made on its behalf. Nevertheless, the FDA might conclude that the labeling of an "imitation" food product is misleading to consumers unless it advises them of the nutritional value of the food.[28] The Agency could then amend its nutrition labeling regulations to require that all imitation foods bear nutrition labeling.[29]

(Footnote 27 continued.)

ing objectives and, more recently, to avoid nutritional inferiority as defined in FDA's 'imitation' labeling rule, 21 CFR § 1.8(e) [note: now recodified as 21 CFR 101.3(e)], the Company has added to these products the nutrients necessary to make them nutritionally equivalent to cheese. Thus fortified, Unique cheese analogues have been widely used by other manufacturers to replace all or part of the cheese component of such foods as macaroni and cheese, pizza, and Mexican-style dishes.

"When marketed solely for use as ingredients in other foods, Unique products are, of course, exempt from nutrition labeling under 21 CFR § 1.17 (h)(8) [note: now recodified as 21 CFR 101.9(h)(8)]. Because Unique products are not standardized, however, their use by food processors does trigger the nutrition labeling requirement for the final food in which they are used. Either lacking the necessary economic or technical capability to analyze their finished products for the full range of nutrients present or for valid marketing reasons, many of the Company's customers have been unable or unwilling to comply with FDA's nutrition labeling rule. Although it has been reluctant to do so, Anderson Clayton Foods has thus found it a commercial necessity to offer an unfortified, or 'stripped,' version of its Unique products." Petition to Amend 21 C. F. R. Section 1.17 to Exempt Certain Foods from Nutrition Labeling Requirements, Appendix B, dated June 10, 1974.

[28] I. e., the FDA might conclude that the labeling of a food denominated as an "imitation" is misleading for failure to reveal material facts, within the meaning of 21 U. S. C. 321(n), unless it apprises the consumer of its nutritional value.

[29] Alternatively, the FDA might conclude that "imitation" labeling is properly considered a "nutrition claim" (albeit a negative one) within the meaning of the FDA's existing nutrition labeling regulations, and thus that nutrition labeling is properly required of imitation foods by the existing regulations.

It is of course possible that the FDA's authority to require nutrition labeling for imitation foods would be contested.[30] Furthermore, even if nutrition labeling were required, its presence would not guarantee that a consumer of the food would read it or act upon it. Even if nutrition labeling were required for "imitation cheese" products, there would be no guarantee that the existence of such labeling would solve the problem posed above.

(b) Inclusion of sodium content information.

Information with respect to sodium content is not presently required by the FDA's nutrition labeling regulations.[31] Because of the importance of control of sodium intake for many persons, the FDA might amend its nutrition labeling regulations to provide that, when nutrition labeling is required, information with respect to sodium content must be provided.[32]

Affirmative Warnings

The FDA might promulgate new regulations to require that an imitation food bear a prominent warning with respect to the nature of its inferiority. For example, with respect to an "imitation cheese," consider the possible effect of requiring a warning such as "This product fails to provide calcium, an essential nutrient provided by cheese"[33] or "This product provides excessive amounts of sodium as

[30] E. g., in light of the fact that the FDA's premise for requiring nutrition information is that labeling is misleading in the absence of the information, food industry lawyers might argue that the absence of such information is not misleading in the case of a food labeled as an "imitation" because the "imitation" terminology sufficiently apprises the consumer of the fact of inferiority.

[31] The regulations presently provide that "sodium content may also be declared . . ." [emphasis added]. 21 CFR 101.9(c)(6) (formerly 21 CFR 1.17(c)(6)). When sodium is declared, the information on sodium required by 21 CFR 105.69 "Foods used to regulate sodium intake" (i. e., "a statement of the number of milligrams of sodium in 100 grams of such food and a statement of the number of milligrams of sodium in a specified serving of such food") is necessary. 21 CFR 101.9(c)(6)(iv).

[32] The FDA's proposal to establish a common or usual name regulation for plant protein products notes that "the sodium content of a finished food containing a plant protein product may be significantly greater than that of the food made with the traditional protein source which has been extended or replaced." 39 F. R. 20894 (June 14, 1974). The proposal includes a provision to require declaration of sodium content when the substitution of a light protein product for meat, seafood, poultry, eggs, or cheese results in a significant increase in sodium content. See proposed 21 CFR 102.22(g). 39 F. R. 20895 (June 14, 1974).

[33] Cf. 21 CFR 100.155 (formerly 21 CFR 3.87) "Salt and iodized salt." Inter alia, this regulation provides that salt for human food use to which iodide has not been added shall bear the statement "This salt does not provide iodide, a necessary nutrient." 21 CFR 100.155(b).

compared with cheese."[34] The FDA might justify regulations requiring such warnings on the premise that the labeling of a substitute food product is misleading unless it affirmatively advises consumers of significant differences between it and the food for which it substitutes and which it resembles.

Promulgation of a Standard of Identity or Common or Usual Name Regulation for an "Imitation" Food

The FDA might promulgate a standard of identity or a common or usual name regulation for an "imitation" food product such as "imitation cheese," establishing certain nutritional requirements, and then argue that it would be illegal to sell an "imitation" that failed to comply with the regulation.[35]

However, it is not clear whether the FDA has the authority to impose such requirements with respect to a product labeled as an "imitation". The Supreme Court has recognized that inferiority is a basic characteristic of a food labeled as an "imitation,"[36] and a United States district court has held that the FDA may not standardize an imitation product and then ban from the market all other similar substitute foods by means of an argument that the other foods fail to comply with the standard of identity for the imitation product.[37]

[34] Arguably, a substitute food which contains significantly more sodium than the food for which it substitutes and which it resembles should be deemed to be nutritionally inferior and thus an imitation. *Cf.* 21 CFR 101.3 (e)(4) (formerly 21 CFR 1.8(e)(4)). With respect to labeling concerning sodium content, see also footnote 32 *supra*.

[35] 21 U. S. C. 343(g)(1) provides that a food shall be deemed to be misbranded "If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations . . . unless . . . it conforms to such definition and standard . . ." 21 U. S. C. 343(b) provides that a food shall be deemed to be misbranded "If it is offered for sale under the name of another food."

[36] *62 Cases . . . Jam v. United States*, *supra*, 340 U. S. at 600.

[37] *United States v. 856 Cases . . . Demi*, *supra*. The product involved in *Demi* was a reduced fat margarine substitute labeled as "imitation margarine". The Government argued that it had established a standard of identity for products which imitated butter, i. e. the standard of identity for "margarine", and that all products which substituted for or resembled butter but were not butter must comply with the standard of identity for margarine. The Court ruled that it was legal to sell as "imitation margarine" a product which failed to comply with the standard of identity for margarine in that it had less fat than was required by the standard. The product was found not to be misleading, and no issues of human safety were involved.

Demi may not be a particularly strong precedent for prohibiting standardization of an imitation food if such standardization can be shown to be needed to prevent misleading labeling or for reasons of safety. The United States Court of Appeals for the Third Circuit has observed, with respect to the FDA's authority to establish a standard of iden-

(Continued on next page.)

Furthermore, the effect of such a regulation would be, to some degree at least, to require that the imitation product not be nutritionally inferior, which would appear to be inconsistent with the FDA's definition of an "imitation" as a nutritionally inferior product.[38]

Increased Restrictions on Use of Food Additives to Prevent Nutritional Degradation of the Food Supply

The FDC Act provides that it is illegal to use a food additive except in a manner consistent with an approving food additive regulation.[39] The Act further provides that a food additive regulation shall limit use of the additive to "the conditions under which such additive may be safely used."[40] Traditionally, in enforcing this provision of the Act, the FDA has thought of safety in terms of toxicity, that is, speaking generally, if a food additive has been shown to accomplish its intended technical or functional effect, or if it "works" as a preservative, stabilizer, emulsifier, etc., and if it has been shown not to pose problems of acute or chronic toxicity at the level of intended use, the FDA has approved use of the additive.

It is likely that most new fabricated food products that substitute for and resemble traditional foods are dependent upon the use of one or more food additives. The FDA could expand its concept of "safety" when imposing restrictions on the use of food additives in such food products. For example, the FDA could revise pertinent food additive regulations to require that the additives not be used in the production of a cheese substitute unless the substitute is fortified to provide as much calcium as cheese (or, no more sodium than cheese) on the premise that otherwise the use of the additives would not be safe for the American public. In other words, the FDA could revise its concept of safety under the food additive provisions of the FDC Act to

(Footnote 37 continued.)
tity, that "One making a rule for the future which in practical effect will determine whether millions of people shall eat something every day may reasonably refuse to subject the general public to even slight risks and small deceptions." *Atlas Powder Co. v. Ewing,* 201 F. 2d 347, 355 (CA-3, 1952), cert. den. 345 U. S. 923 (1953). Cf. *National Nutritional Foods Assn. v. FDA,* 504 F. 2d 761, 777-781 (CA-2 1974), cert. den. 420 U. S. 946 (1975).

[38] Alternatively, the FDA might rely on 21 U. S. C. 341 to establish a standard of quality for "imitation cheese products" and require, pursuant to 21 U. S. C. 343(h)(1), that imitation cheese products falling below the standard bear a label statement of substandard quality. The FDA proposed regulations of this type for imitation milk products in 33 F. R. 7456 (May 18, 1968) and 34 F. R. 15657 (Oct. 9, 1969), but the proposal was withdrawn by a notice in 35 F. R. 8584 (June 3, 1970) because "the production of the foods to which the proposed standards would apply has steadily declined and is now negligible."

[39] 21 U. S. C. 321(s), 342(a)(2)(C), 348.

[40] 21 U. S. C. 348(c)(1)(A).

prohibit use of a food additive which may have considerable adverse impact upon the nutritional quality of the American diet.

New Legislation

Each of the suggestions outlined above would be a response under the FDA's existing statutory authority. The time may have come, however, for the FDA to consider going to Congress to seek more authority in order to enable the Agency to cope more efficiently and effectively with any prospect of significant nutritional degradation of the American food supply. For example, the FDA might seek explicit authority from Congress to establish mandatory nutritional criteria, which could not be avoided by "imitation" labeling, for substitute foods which are used in place of important traditional components of the diet and which might, in the absence of mandatory controls, have a significant adverse impact on the nutritional quality of the American food supply.

Some Final Comments

The sum of my foregoing remarks is that first, the FDA's existing regulatory programs with respect to nutrition may not be sufficient to assure that significant nutritional degradation of the American food supply will not result from the appearance of new fabricated food products which substitute for and resemble traditional articles of food, but second, there are some new regulatory approaches the FDA could pursue to respond to a serious prospect of nutritional degradation.

In closing, let me emphasize that whether the FDA undertakes new regulatory programs will be determined by whether it perceives a need to undertake such action. The only reason that the Agency's lawyers have occasion to be giving serious thought to such regulation is that the FDA's Bureau of Foods is presently concerned about the appearance of new substitute food products. The Bureau anticipates considerable proliferation of new substitute foods in the American diet in the years ahead, and Bureau administrators are asking their lawyers to consider possible regulatory options to assure against degradation of the nutritional quality of the American food supply.

It seems to me that in circumstances such as these, communication between the industry and the FDA becomes very important. The food industry would be well advised to apprise itself of the FDA's concerns and to keep the FDA's Bureau of Foods[41] informed of the directions

[41] And in particular, the Office of the Associate Bureau Director for Nutrition and Consumer Sciences.

the industry is pursuing with respect to new substitute food products. If the food industry has reason to believe that new substitute food products will not have significant adverse impact upon American nutrition, the FDA should be advised of any relevant data. In any event, the food industry should be aware that the FDA's nutritionists and their colleagues are presently looking ahead with concern in respect to these new substitute food products, and the industry would be well advised to attempt to understand and address this concern because, if not allayed, it may well lead to increased regulation. **[The End]**

EIGHT SKIN TESTS FLUNK REVIEW PANEL APPRAISAL: OTHERS FOUND EFFECTIVE

Based on the recommendations and findings of an advisory review panel on the safety, effectiveness, and labeling of skin test antigens, the Food and Drug Administration (FDA) will propose, on or before October 31, 1977, to revoke the licenses of eight skin tests used to detect a variety of medical conditions. An opportunity for a hearing will be offered. The products in question are used to test for past and present infections of tuberculosis, lymphogranuloma venereum, mumps, and susceptibility to diphtheria. According to the panel report, current data is not sufficient to classify the tests as safe and effective and they should he removed from the market.

In addition to recommending revocation of the eight skin tests, the panel also declared that five tests used to detect tuberculosis are safe and effective, and that additional effectiveness studies are required for six other tests. Licenses for four tests included in the review of the 23 tests submitted have already been revoked by the FDA, based on their apparent lack of effectiveness. The Agency noted that, while there are no other tests on the market to replace the lymphogranuloma venereum, trichinosis, and mumps skin tests, physicians can use other diagnostic methods, which are more reliable in the detection of these infections.

Comments on the panel's report and its proposed implementation by the FDA may be submitted on or before November 29, 1977.

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FOOD AND DRUG ADMINISTRATION ANNUAL REPORTS 1950-1974

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