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Food Drug Cosmetic Law JOURNAL

The Food Industry Briefing on Nutritional Labeling Education

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

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REPORTS

TO THE READER

The Food Industry Briefing on Nutritional Labeling Education took place in Washington on May 30, 1974. The following articles are derived from presentations at the Briefing. They represent a cross-section of the views and opinions of enlightened observers on the present state of nutrition labeling.

Dr. D. Mark Hegsted opened the Industry Briefing, and he cautions in his "Nutrition Labeling: Not All Good—Not All Bad" that there are disadvantages as well as advantages to nutrition labeling. Dr. Hegsted is a professor of nutrition at the Harvard School of Public Health. His article begins on page 412.

Dr. Alexander Schmidt, Commissioner of the Food and Drug Administration, traces the history and growth of nutritional concern in the United States and relates his views of the purposes and goals of nutrition labeling and the need for greater public nutritional education. Dr. Schmidt also notices the increase in nutritional misinformation in his article "Nutrition Labeling and the Consumer: Feast or Famine?", which begins on page 414.

Dr. Virgil O. Wodicka looks with keen insight from his position as Director of the Bureau of Foods, FDA, at "Progress in Nutrition Labeling." Dr. Wodicka also describes a "nationwide survey of base line consumer nutrition knowledge" and a survey to investigate how interested the public is in nutrition labeling. His article begins on page 420.

Dr. Harry C. Mussman examines what impact USDA nutrition labeling regulations are having on meat labeling. His article "U. S. D. A. Nutritional Labeling Regulations and the Growth of Voluntary Nutrition Labeling on Meat" also looks into the results of U. S. D. A. attempts to encourage voluntary nutrition labeling. Dr. Mussman is the Deputy Administrator for Scientific and Technical Services of the U. S. D. A. His article begins on page 425.

J. Thomas Rosch, Director of the Bureau of Consumer Protection of the Federal Trade Commission, looks into problems and issues involved in bringing nutritional information to the consumer through the broadcast media. His article "Nutrition Information and Nutrition Advertising," which begins on page 429, examines the Federal Trade Commission's role.

Pharmaceutical Update IV.—The following papers were presented at the Food Drug Law Institute's Pharmaceutical Update IV, which was held in New York City on May 22 and 23, 1974.

Henry E. Millson, Jr., counsel for the Professional Products Group, Warner-Lambert Pharmaceutical Company, looks ahead to see what the future holds for the pharmaceutical industry. The author makes special mention of the future and direction of governmental drug reimbursement programs, Poison Prevention Packaging Acts and the Controlled Substances Laws. The article entitled "What Lies Ahead?" begins on page 443.

In his article, "The Interplay of Federal and State Regulatory Programs on the Distribution of Pharmaceuticals—The Legislative Aspects," *Clifford C. David* discusses uniform state and federal pharmaceutical laws and the degree and manner in which such "uniform laws" vary. Mr. David is legislative counsel for the SmithKline Corporation. The article begins on page 449.

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Nutrition Labeling: Not All Good—Not All Bad

By D. MARK HEGSTED

Dr. Hegsted Is a Professor of Nutrition at the Harvard School of Public Health.

THE TOPIC OF NUTRITIONAL LABELING quite obviously sparks no universal response. It is a complex subject with far-ranging manifestations and it therefore engenders varied reactions and envelops many different opinions.

However, I feel there is much more agreement on the proposition that the consumer has a right to know what is in his food. The debate may rage about how that right can best be served, how the information should be provided to the consumer, whether the label is the proper place to do it, whether the consumer has enough information to utilize the information provided, or whether the correct information is being provided, but at least there is agreement that the consumer has the right to know.

Moreover, there would most likely also be general agreement that nutrition information on product labels affords an opportunity for some form of nutrition education and a spectrum of generally beneficial possibilities for the future. Yet, amid the clanging approval

of nutrition labeling in its benefit to the consumer there must be the tempering ring of certain clear disadvantages and these ought to be sounded at least as loudly as the advantages if the consumer is to be truly protected.

Two of these drawbacks can be stated briefly. First, there is bound to be a tendency to increase fortification with the concomitant implication that 100 percent of the Recommended Daily Allowances (RDA) removes the consumer from any further worry about his nutritional well-being. In light of the present state of nutritional science such a conclusion is unwarranted and misleading.

Second, the consumer may bring little understanding and sophistication to his or her reading of nutrition labels. A feeling that the longer the label, the better the food, may become a common syndrome in consumer buying.

In any event, if the nutrition label is to be of maximum utility and of greatest aid to the consumer, the disadvantages as well as the advantages must be kept in mind in formulating policies for the future.

[The End]

LABELING REGULATION FOR ANIMAL TREATMENTS ISSUED

The use of the terms "tonic", "tone", and "toner", and similar terms in the labeling of a product intended for use in or on animals implies that such a product is a drug, according to a new Food and Drug Administration regulation. The use of the term "conditioner" implies that the product is either a food or a drug depending on the manner in which the term is qualified in the labeling to reflect the product's intended use. The unqualified use of these terms, said the FDA, fails to provide adequate directions and indications for use and causes it to be misbranded under the Federal Food, Drug, and Cosmetic Act. An article represented as a drug must be the subject of an approved new animal drug application unless the use of the article under the conditions set forth in its labeling is generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs. The regulation controlling the use of such terms becomes effective September 9, 1974.

Reg. § 135.114, CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 72,214M

Nutrition Labeling and the Consumer: Feast or Famine?

By ALEXANDER SCHMIDT

Dr. Schmidt Is Commissioner of the Food and Drug Administration.

WHEN I CAME TO THE FDA a year ago, one of the first things that I did was to encourage a greater educational role as an effective adjunct to our role as a policeman.

No one told me before taking the job that I would be spending so much time as a policeman. I suppose I should have known that. However, I do know that preventive education is much better than preventive detention.

Historical Review of Food Labeling

I think it would be useful to begin this conference by reviewing how we got here. Not since World War II has there been such widespread public interest in nutrition as there is in this country today. World War II is the last time our nation had to confront critical problems of food supply and quality.

We were concerned not only whether there would be enough food to go around but whether the available food would contain the nutrients necessary to keep the soldiers, factory workers, "Rosy the riveter" and the entire civilian population healthy.

In 1941 a standard for an enriched flour was promulgated by the Food and Drug Administration. This was the first action taken to meet the need to supplement the basic food with essential vitamins and minerals.

Coincident with those developments, nutrition science was making discoveries of great public interest. As expected, there were those who sought to cash in on progress and on popular interest. It was about then that the vitamin boom began.

Many early vitamin products were lacking in potency. The public had no way of knowing this. To protect the consumer the Food and Drug Administration stepped up its surveillance, its programs and its research.

Exaggerated and misleading health claims for so-called health foods were already confusing the public and were then, as they are today, a potential danger to those people needing medical diagnosis.

In 1941 the FDA issued the original special dietary food regulations. I think these regulations served their purpose well. For one thing, they kept food labeling largely free from unsubstantiated patent medicine type claims for the treatment of disease. However, such claims have continued to be transmitted to the public mainly by advertising or by the medium of self-proclaimed health books and periodicals but by and large not through food labeling.

Need for New Regulations

By the 1960's, however, it was clear that the 1941 dietary food regulations were out of date. Nutrition science had gone on to new discoveries. Industry had developed new products and the public acquired new buying and eating habits.

In 1962, the FDA proposed a massive revision of the 1941 regulations. This was the beginning of a decade of struggle.

I won't attempt to review that ten-year struggle. I think most everyone is familiar with it.

Further changes were taking place. Many court decisions against food supplement misbranding sustained the FDA in its efforts to protect the public.

Changes in the U. S. food supply accelerated products like prepared mixes, dehydrated potatoes and frozen dinners. These took over a progressively larger share of the consumer market, partially replacing conventional foods in the diets of many people.

FDA's responsibility in the consumer nutrition area was correspondingly increased. The White House Conference on Food, Nutrition and Health late in 1969 wrapped up the situation as it then existed and made important recommendations.

Since the White House Conference there has been a constant broadening of FDA's nutritional concerns and objectives. This is reflected in the extensive nutritional labeling regulations we have now established.

The regulation seem to come at a most appropriate time, for we are confronted today with food problems similar to those that we faced in World War II.

The world's food supply is now marginal at best. News cameras increasingly bring evidence from Africa and other parts of the world of the prospects of spreading famine and starvation.

Here in the United States there is concern about the nutritional adequacy of some foods designed to stretch the available food supply.

Public interest in nutrition is at a new peak at the same time. There seems to be an all-time high in the incidence of nutritional misinformation. This includes an organized attack by some special interests on public confidence in the general wholesomeness and excellence of the United States food supply.

Food Industry Briefing Committee

This is the background as we gather here today in the fourth session of the Food Industry Briefing Committee. As you may recall, the first was held in 1971. Its purpose was to assess the food industry in preparing its response to FDA's review of substances generally regarded or generally recognized as safe.

The second, in 1972, was held to announce the first proposal for nutrition labeling. More than 3,000 comments from industry, academia and consumers were received in response to this proposal.

A third briefing session was held last year. Its purpose was to describe the final FDA nutrition labeling regulations.

As of today, nutrition labeling and revision of special dietary food regulations have provided the foundation for three major regulatory packages from the FDA.

The first was announced in January of 1972, the second in March and the third in August of the same year.

In the January, 1973 conference then Commissioner of the Food and Drug Administration, Charles Edwards, predicted that the program would, and I quote, "result in the most significant change in food labeling practices since food labeling began."

Modern Regulatory Initiatives

I agree with that prediction. I also believe that this FDA food labeling program will be a landmark along the path of modern regulatory initiatives. To the regulated industry the program offers positive incentives rather than negative restrictions. To the consumers it offers more accurate information with which to make better food purchasing decisions.

All of these FDA actions and all of the briefing sessions that we have held have significant common points. The most important is that they represent an unprecedented cooperative effort involving the industry, the Food and Drug Administration and the American consumer.

Nutrition labeling as well as closely related regulations for label identification of facts, cholesterol and sodium, represent the best thinking of the food manufacturers, packagers, retailers and consumers.

Educating the Public

At this point in the briefing session, it is my distinct pleasure to announce that nutrition labeling is a reality. This major positive effort has borne abundant fruit, some of it nutritionally labeled. Now we are facing the even more difficult task of carrying nutrition labeling and nutrition education to the consuming public.

I am pleased to be able to announce that we are ready to take the first step in a public media campaign. All of our good intentions and hard work would be wasted if the public fails to understand and to use nutrition labels.

We need and we welcome all the help we can get to achieve this necessary understanding and acceptance. Much has been said and written about the necessity to combat false information, modish fads and peculiar views on food.

I submit that one excellent way to accomplish our common goal to guarantee a safe and nutritious food supply and public knowledge of its nutritional needs is to unite, as we have in the past, and as we have come here today, to speak with a single voice on the purposes and the application of the new labeling regulations.

We realize that, first of all, we in government must be united. To this end, we in FDA have worked closely with the U. S. Department of Agriculture (USDA). That Agency has now developed nutrition labeling regulations for red meat and poultry which are parallel to ours for other groups. We also are working with USDA to establish a common approach to our educational efforts.

We have also worked closely with the Federal Trade Commission, which is developing guidelines to cover the advertising of nutritional claims.

I am pleased to welcome Mr. Rosch of the Federal Trade Commission and Dr. Mussman of the U. S. Department of Agriculture, who will discuss their progress and their pledge to you later.

As Dr. Hopper will explain to you tomorrow, this group already has joined in our campaign of public education and its spokesmen have rendered help in specific and constructive ways. I am personally proud of the effective meetings that we hold monthly with concerned consumers.

These meetings are always interesting, rarely acrimonious and sometimes frustrating but uniformly useful, at least to the Food and Drug Administration.

Only last Wednesday, we sponsored with the Ad Hoc Consumer Council a full-day session on the changing food supply. We expect this valuable liaison to continue.

Constant Vigil

I don't want you to think that the FDA, after having labored and delivered its quadruplicate food regulation package, is now ready to settle back to a period of sterility.

Zero population growth notwithstanding, we are entering a period of gestation and will soon deliver nutritional quality guidelines for various classes of food as recommended by the National Academy of Sciences.

One guideline is for frozen heat-and-serve dinners and that has been issued. Another, for main dishes, is ready. Also ready are guidelines for breakfast cereals, breakfast juices, meal replacements and texturized plant proteins.

We have developed concepts to regulate special dietary foods for weight reduction. This provides a basic regulation on which many related actions will depend. One of these was a direct outgrowth of the White House Conference.

I refer to the regulation which provides that a new product need not bear the stigma of the word "imitation," provided that it has a suitably descriptive common or usual name and that it is nutritionally equivalent to the food which it resembles, and for which it may substitute.

I don't believe I need go into the essence of specific food regulations or food standards that are being changed to bring them into line with our general umbrella-type initiative.

Perhaps all our actions can best be summarized by stating that we are codifying all food labeling regulations into a more understandable and more enforceable regulatory program.

Finally, we are putting the finishing touches on a massive food fortification policy. We believe that "this baby" can be formally delivered during the next few weeks. You will be hearing more about our efforts in the days and weeks to follow.

What it all adds up to is beneficial change in the labeling of foods by industry and in the buying habits of the American public. Our educational effort is an important part of these landmark changes.

[The End]

Progress in Nutrition Labeling

By VIRGIL O. WODICKA

Dr. Wodicka Is Director of the Bureau of Foods of the Food and Drug Administration.

IT IS MY PLEASANT DUTY to describe to you the progress that has been accomplished since our last Industry Briefing session, which was held about fifteen months ago. You may recall, at that time we were deeply engrossed in explaining and clarifying several regulations dealing mainly with nutrition, special dietary foods, and a new labeling standard for nutrients, the U. S. Recommended Daily Allowances. These regulations, and all those related in some way, are now nearing unification into a comprehensive labeling policy.

Just these past few weeks FDA staff members have been assembling a report of our progress in meeting recommendations of the 1969 White House Conference on Food, Nutrition, and Health. We were pleased with the large number of recommendations that have been fulfilled by the four labeling packages issued last year on January 19 (nutrition labeling proposal), March 14 (final on nutrition labeling), July 26 (GRAS (Generally Recognized as Safe) criteria), and August 2 (special dietary foods). More of the White House recommendations will be implemented by the fifth package soon to be issued, containing more nutrition quality guidelines and a proposed food fortification policy.

Surge in Nutrition Labeling

It is especially pleasant to be able to report that application of the central regulation (nutrition labeling) is well under way. Nutrition labels of prescribed format and accuracy appear on over 100

separate foods, and the labels of well over 60 food companies. One survey reports that perhaps 40% of products that might bear nutrition labels already do so (General Accounting Office (GAO)). I would place this estimate slightly lower; however, new labels are observed by our local staff or district officers each month when they survey grocery shelves. Also, the list of companies with some nutrition labels on the shelves strongly suggests that many other products will soon follow because they are offered by these companies.

Nutrition labels appear on nearly every kind of food—canned, frozen, dry-processed, or baked. One supermarket chain (First National) nutrition labels nearly all its private brands. This store has about 80 different kinds of bread with nutrition labels! A second chain (Grand Union) is well advanced in nutrition labeling its private brands, and several other chains are rapidly converting their labels.

Several major food manufacturers have labeled essentially their whole line of products. This includes those who process fruits and vegetables, as well as those who deal in foods that already bore nutrition information of one kind or another.

The breakfast cereals are interesting because they have long carried nutrition information. Most of these already have converted to the standard nutrition labeling format. Some have taken advantage of their high nutrient content by being marketed as dietary supplements.

The extra problem of many small producers in developing data for proper nutrition labels has been handled successfully by their trade associations. For example, a group of canners in the midwest and one in California joined in an effort by the National Canners to generate data and know-how for nutrition labeling.

The Milk Industry Foundation mounted a major effort in developing analytical data for milk and milk products. They have provided a comprehensive labeling manual for their members. In this way the costs attendant on label design and analyses have been spread over several billion (9.3) dollars worth of products.

So, where do we stand in nutrition labeling? We have a workable regulation, the product of close cooperation of industry, universities, government, and the consumers. Labels are common on most grocery shelves and are increasing rapidly. Thus, we have achieved part of our goal. We have provided for accurate nutritional information on the labels of packaged goods.

Public Awareness

Now it is time to consider the next step—making sure that that information is being put to some useful purpose. We are sure that several useful purposes have been accomplished. There is no doubt that the American people are increasingly "nutrition" conscious. Also "nutrition" conscious are the food technologists who develop product lines and the marketing men who sell them.

We do not have a record of the number of food analyses made this past year. It is fair to guess, however, that it surpasses that of any year in history. This nutrition consciousness, and accurate new data on food composition, are already reflected in the marketplace. We hope such use will continue and will expand. To this end, we are cooperating in efforts by various groups, and particularly the Nutrition Consortium, to establish fair and accurate informational messages that may be used on labels and in labeling. We have cooperated with the Federal Trade Commission (FTC) in its efforts to establish such messages in advertising. Our major aim must be to persuade consumers to use this new tool—nutrition labeling.

National Survey

A responsible agency must try to measure the effectiveness of its actions. To that end, we ran a nationwide survey of base line consumer nutrition knowledge. The views and habits of food buyers also were carefully investigated. We felt that American consumers had succeeded in raising generally healthy families, often in times of depression and even food shortage. Therefore, the survey was designed to avoid asking questions that would require a professional answer.

Our own professionals and two well-known advisors (Paul LaChance and Joan Gussow) were pleasantly surprised to find that the American grocery buyer is fairly knowledgeable in a working-type test. For example, a majority were able to select suitable substitute foods if one were ruled out. Many knew the main functions and contents of a few nutrients of various common foods. They were far less sure of the usefulness of some of the more exotic vitamins. We would conclude that there is a fairly solid basis of fact in the minds of many consumers. This augurs well for educational efforts.

A purpose of the survey was to find keys to needed education and clues to motivation. Although the results are not final, we do have some ideas. For example, the respondents were asked to rate themselves as to their nutrition knowledge on a scale of 1 (nothing) to 10 (professional). Their self-perception is remarkably well correlated with their actual knowledge scores. Two very interesting groups appeared, however. The first includes those who rated themselves far too high; the second includes those who rated themselves far too low. Our staff is now studying these groups to develop easy-recognition signals. This is of considerable importance since the educational approach to these two groups should be very different.

Public Rates Value of Labeling

We also investigated how interested the public was in nutrition labeling. The questions were very carefully structured to avoid giving the respondent a bias. The results are clear—over three-fourths of all grocery shoppers want nutrition labeling, and even claim they woud be willing to pay for it. About three-fourths prefer it to recipe information, and nearly two-thirds preferred nutrition labeling to ideas on how to develop a balanced meal or menu with the given product.

To sum up, an evaluation of our status at this stage of development is satisfying. Surveys show an active and growing interest on the part of consumers, on which the success of the program must inevitably be built. Surveys also show a sufficient state of knowledge to permit effective use of the information offered on the labels. Nutrition labels are already on the shelves from so many major companies that we have reason to infer early extension of the trend to cover most of the important foods on which the nation's nutritional status is

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based. To date problems encountered by the FDA in implementing the regulations have been minimal. We have been gratified but not entirely surprised to find that the problems encountered by the industry have been less than many of them expected. This includes the problem of cost.

Fruits and Vegetables

The one problem area of real significance has been that of fresh fruits and vegetables. The resistance of this segment of the industry has caused the regulations to be temporarily stayed in their application to these commodities. It is important in this context to recognize what this stay means and does not mean. The key regulation, Section 1.17, provides, in effect, that if nutritional information is presented concerning a product, it must follow a prescribed format if it is not to be considered misleading and therefore illegal. The provision for this information is mandatory only if pure nutrients are added or if nutritional claims are made with regard to the product. Obviously, pure nutrients are not added to fresh fruits and vegetables, so nutrition labeling would not be so triggered. The exemption afforded by the stay of the regulation, therefore, means only that nutrition claims can be made without requiring full nutrition labeling in the prescribed format. Exemption from the regulations, however, does not confer exemption from the Federal Food, Drug, and Cosmetic Act. Any claims regarding the nutritive value of fresh fruits and vegetables must be met by the product offered or they are obviously false and actionable under the law. Also, of course, there is nothing to prevent the purveyor of a branded perishable from labeling his product in accordance with the regulation even though its application has been stayed, and his label would then have the same regulatory status as any other label.

All in all, we in the Food and Drug Administration feel that our expectations with regard to nutrition labeling have been met to date in terms of acceptance by industry and consumers and in terms of rate of implementation. Obstacles have been few and not too serious. A more meaningful assessment will come a year from now after a great many more labels have appeared on the shelves and the impact of educational programs has had a chance to make itself felt.

[The End]

USDA Nutritional Labeling Regulations and the Growth of Voluntary Nutritional Labeling on Meat

By HARRY C. MUSSMAN

Dr. Mussman Is Deputy Administrator for Scientific and Technical Service of the United States Department of Agriculture.

THE DEPARTMENT OF AGRICULTURE (USDA) is the federal agency responsible for the safety and wholesomeness of our nation's supply of meat and poultry products—as well as their truthful labeling. This responsibility is carried out through some 9,000 inplant inspectors stationed in over 5,500 meat and poultry plants which operate in interstate commerce. States likewise may carry out meat and poultry inspection programs in those plants operating in intrastate commerce, provided their programs are operated in a manner at least equal to the federal program. Presently, 40 states meet federal standards. In those states not conducting such programs, USDA assumes full responsibility for the inspection of all plants.

Labels Checked by USDA

One of the unique aspects of USDA's inspection program is the requirement that all labels of meat and poultry products be given prior approval before they may be used in the marketplace. This affords us the opportunity to correct labeling errors before they reach the consumer. Last year, for example, our staff approved over 180,000 labels as part of an ongoing effort in this important area of consumer protection. About 15,000 labels had to be revised or altered significantly before their use on inspected products was granted.

Shortly after the publication of the FDA regulations on nutrition labeling, we established guidelines which permitted the meat and poultry industry to participate in nutrition labeling on a voluntary basis. We also followed up by publishing proposed regulations on nutrition labeling which were very similar to those published by FDA. Even though USDA regulations have not yet been finalized, there has been rather broad participation by the meat and poultry industry in this area—a participation which appears to be enjoying a healthy growth rate.

Meat Products Currently Labeled

Before going into our regulations regarding nutrition labeling, I thought you might be interested in a quick overview of the kinds of meat and poultry products that are being marketed with nutrition information as part of the labeling material. At the present time, we have close to 50 companies engaged in nutrition labeling or about ready to do so. Approximately 100 plants are involved, which account for nearly 500 labels in use. Frankfurters and other similar cooked sausages are the leading meat products which carry nutrition labeling. About 200 labels are used on this kind of product alone. Other products carrying nutrition labeling are pizza, heat-and-serve dinners, luncheon meats, stews, soups, hash, chili, margarine, and spaghetti and meat sauce. This list, I think, clearly points out how extensive nutrition labeling is and can be used on processed meat and poultry products.

Notable for their absence from this list are raw meat and poultry products. There has been substantial interest in the nutrition labeling of these raw products which require cooking in the home. However, as I mentioned, there are no approved labels in use at this time for this class of products. Many complexities are involved: changes during cooking, marked product variability, the question of dealing with inedible portions, and the inevitable random-size containers. All of these have been primary reasons why raw products have not as yet carried nutrition information on the label.

Consumer Use of Labels

One concern which we hear oft repeated by many companies and consumers alike is that although consumers express great interest in nutrition labeling few know what to do with it or how to use it. We

would agree. However, it is through efforts such as those being demonstrated here in this conference that this circumstance should begin to change. With the consumer education program bringing information on use of nutrition labeling to all consumers and with a continued increase in use of such labeling resulting in greater exposure of consumers to nutrition values, the time will come when the use of nutrition labeling will become almost second nature for the great majority of consumers.

Changes in Proposed USDA Regulations

As I noted earlier, USDA has published proposed regulations regarding the nutrition labeling of products under its jurisdiction. The comment period for these regulations ended April 19, and we are now in the process of preparing a final rule. The comments received from the public, as well as the experience we have gained over the past year, have given us the basis for considering several changes in the original proposal. Certain of these changes could materially alter the costs associated with nutrition labeling of meat and poultry products and could therefore increase industry participation—both the consumer and industry will benefit.

(1) We will encourage industry to work with us in the development of standard values for raw products. In our judgment, this can lead to meaningful nutrition information for consumers as well as rapidly expand the use of nutrition labeling to a broad range of products which at this time do not carry this information.

Our experience over the past year also indicates that a certain class of frankfurter, for example, one whose meat component is entirely beef, could be labeled with a standard value at this time. Certain requirements regarding use of ascorbates and a maximum processing temperature would also be necessary, but I think you can readily see that the adoption of legitimate standard values could result in rapid expansion of nutrition labeling over a broad range of products.

(2) We expect to permit the determination of protein declaration to allow for "weighting" protein contributions from plant and animal sources as a percentage of the Recommended Daily Allowances (RDA) contribution. We believe this more accurately reflects the protein contribution and is superior to one based on an average protein efficiency ratio value.

(3) It is our judgment at this time that our proposed requirements calling for nutrition information to be present on an "as purchased" and "as prepared" basis for raw products will be retained. However, if we can develop jointly with industry standard values for this class of product, we may be able to overcome some of the barriers that now exist.

(4) We are seriously considering requiring the US-RDA contribution to be declared to the nearest 2 percent increment at all levels. This simply will permit more accurate representation on the label.

Many of the issues that have been raised regarding USDA's nutrition labeling regulations grew out of several consumer briefings which were held recently. I point this out for the purpose of calling attention to the new approach that the Department is taking in exposing to the public those regulatory proposals which have a strong consumer interest. Some of you are aware of the public briefings we held regarding our proposal on net weight—others were held on nutrition labeling. We have had an overwhelming public response to continue this kind of dialogue with consumers. We are extremely pleased with the success we have enjoyed in opening new avenues of communication with consumers. There is little question but that we will be using this approach to inform consumers on other issues in the future.

In closing, I would like to reiterate my earlier comment—that continued exposure to nutrition labeling and related information will result in a populace conditioned to use it as if by second nature. Success in achieving this level of usage will not come overnight. However, the ultimate benefits to the consumer are such that even a slightly delayed success can be accepted with enthusiasm. We at USDA are doing what we can to shorten that delay by developing regulations which will encourage nutrition labeling. We will consider modifying our approach wherever necessary to help reach our goal.

I hope I have given you a better understanding not only of the approach that the USDA is taking in nutrition labeling, but also of the role it plays in the overall safety of our meat and poultry supply.

[The End]

Nutrition Information and Nutrition Advertising

By J. THOMAS ROSCH*

Mr. Rosch Is Director of the Bureau of Consumer Protection of the Federal Trade Commission.

AT THE PRESENT TIME, nutritional advertising does not measure up to the requirements of specific statutes which the Federal Trade Commission (FTC) has pledged to enforce, particularly Sections 5 and 12 of the Federal Trade Commission Act. Two major problems exist in current food advertising.

Lack of Nutritional Facts

The first is that most food advertising today does not disclose material nutritional facts about the products being advertised. Section 12 of the Federal Trade Commission Act requires full disclosure of material facts with respect to food products. Section 5, which broadly condemns unfair and deceptive trade practices, has also been interpreted by the Commission to require the disclosure of material facts. Facts are "material" under the Commission's view when their disclosure might influence a significant number of purchasing decisions.

Nutrition information appears to represent a material fact within the Commission's definition. That being so, Section 5(a) and Section 12 of the Federal Trade Commission Act would apply.

Furthermore, various surveys support the contention that most consumers feel such information pertinent and helpful. The same

* This is a summary of Mr. Rosch's extemporaneous remarks. The views expressed by Mr. Rosch are not necessarily those held by the Federal Trade Commission or its staff.

surveys show that consumers desire such information. In addition, the experience of the Kellogg company in a recent successful nutrition advertising campaign suggests such advertising might be of economic advantage to manufacturers.

Value Comparison

The second problem lies with current food advertising where there is disclosure of nutrition information but not in a manner that permits a value comparison. This difficulty is illustrated by a recent labeling ruling in which the Commission required disclosure of material facts in a manner which would permit consumers to make comparisons between products. Thus, a competitive framework is established for nutritional claims.

Sugar-Laden Products

A third possible problem is the advertising of sugar-laden products consumed primarily by children. Section 5 of the Federal Trade Commission Act broadly condemns unfair trade practices. Questions have been raised concerning whether there is substantial evidence that sugar-laden products present health hazards, particularly dental problems, but also others less widespread and potentially more harmful. Questions have also been raised concerning whether children are especially vulnerable to advertising for sugar-laden products. To the extent these questions are resolved in the affirmative, such advertising is also a problem.

A number of issues arise in confronting these problems. First, for the most part, there is no need for the Commission to do any pioneering in this area. FDA has broken paths, and now the Commission need only follow in them.

The only major exception may be the sugar problem. The Commission may want to address itself to sugar-laden food advertising before the FDA takes definitive action, especially since the FDA at the present time has no plan to investigate the sugar hazard. The Commission has the expertise to handle such technical matters; it does so at the present time.

Specificity of Nutrition Information

The second major set of issues relates to communications. The nutritional information which must be disclosed in order to satisfy the requirements of the Federal Trade Commission Act must provide a complete nutritional profile for the advertised food, and, what is more, it must enable consumers to make comparisons on the basis of that information. The nutrition information must be, first, fairly detailed and, second, brand specific. Unless it is fairly detailed the information would be incomplete. Unless it is brand specific it would not enable consumers to comparison shop on the basis of nutrition.

Where foods already bear nutrition labels it may not be necessary to provide the entire nutrition profile in the television advertisement itself. However, the mere bland admonition instructing consumers to read the label would be nothing more than white noise for most consumers and would be insufficient information, leaving only the alternative of a complete nutritional profile in the advertisement itself. Probably, however, sufficient methods can be developed for informing the consumer without having to include a complete nutritional profile in the advertisement.

Disseminating Public Information

Finally, issues arise concerning the costs of gathering and disseminating the required information. For those who are engaged in nutrition labeling there would be no additional costs in gathering the information. The information required for those who do not engage in nutrition labeling could be gathered at minimal cost.

Increased costs for disseminating the information would probably not result from any rule promulgated by the Commission because additional advertising would most likely not be required. Nutritional information would be provided in existing advertising through disclosure requirements.

At any rate, if there were increased costs, they would be far outweighed by the advantages of providing the consumer with nutrition information. **[The End]**

Questions and Answers

Nutrition Labeling

Q: Where does FDA stand on mandatory nutrition labeling regardless of what is advertised?

Dr. Wodicka: We have never asked for it.

Q: Concerning fresh fruits and vegetables, what additional claim would require FDA to require nutrition labeling for such items?

Dr. Wodicka: I think we have announced that it would have to be a claim attached to a particular brand or in some other way non-generic. In other words, if you want to say "oranges are high in Vitamin C," we can't very well argue with that or require labeling.

How could it be done? Well, there are a variety of ways. It doesn't necessarily require that there has to be a label. There can be labeling. In other words, there can be a placard or poster that goes along with food. Much perishable produce these days is prepackaged. These packages could be labeled just like any other food. So the execution can't be all that difficult.

Q: Is a ground beef patty—the institutional type, heavily fortified with TPP—covered under nutrition labeling?

Dr. Mussman: This is sort of a difficult question. It depends on how you are interpreting "fortification."

If we are talking about adding, for instance, amino acids to a vegetable protein to bring it up nutritionally to a level comparable to the meat which it is being substituted for or is replacing, then "fortification" may not carry the same kind of interpretation that it would have if you were talking about high levels of vitamins and minerals.

I think if we use the term as it is commonly employed, however, it means added vitamins and minerals. The interpretation today is that this would indeed trigger nutrition labeling.

Q: What will be the assumptions underlying USDA's "as-prepared" nutrition data? For example, preparation method, time, temperature and so on?

Dr. Mussman: I think the only answer here is that we would rely much on what would be considered a common or usual type of preparation for the product in question.

We simply want to give an example to the purchaser, as to what kind of nutrition value would be in that product subject to particular cooking conditions. We are trying to be as specific as possible in laying out what those times, temperatures and conditions might be.

For bacon, for example, it might be "to a crispy brown." I think everybody should have a good understanding of what a "crispy brown" is.

We don't have all the answers. It might be easier with something like a turkey where you can say so many minutes per pound, X number of degrees. Then under those conditions you would have this kind of nutrition value.

Q: Why do you feel that "as-purchased" and "as-consumed" labeling is superior simply to the "as-eaten?" Why couldn't "as-cooked" be more attractive to the consumer and the manufacturer? This represents the nutrient content of the product as consumed and therefore describes the product more accurately since some nutrients are partially lost in cooking.

Dr. Mussman: We are hoping, as I mentioned in the talk earlier, to retain the "as-purchased" and "as-cooked" for two reasons. The "as-cooked," as pointed out here, is the more attractive of the two to the consumer simply because it tells what he or she is getting at the point when it is going to be eaten.

Obviously, in many cases the caloric value and the fat content, for example, are going to be appreciably lowered. This is an attractive kind of information.

The "as-purchased" requirement which we have is primarily for purposes of complying with our requirements under the Act. We must have a means of determining whether or not the product as it leaves the manufacturing establishment does indeed comply with our regulation. There is no way to do it if it is done on the basis of what it is like when it gets into the consumer's hands at the point of cooking. So for that reason we are staying with dual labeling on certain products, one "as-purchased" and one "as-cooked."

Q: There are many major differences between FDA and USDA nutrition labeling requirements. When can we expect the two agencies to agree on one set of regulations—or can we?

Dr. Mussman: I think we have come very close to having one set of regulations; there are few exceptions where we differ. One differing area is the "as-cooked" and "as-purchased" basis for the labeling of certain products.

We also differ as to the requirements on the information panel, I believe. FDA has a particular letter size, whereas we require sufficient legibility to make it easily distinguishable.

The major difference, however, as we see it, is not what goes on the label necessarily, but in the compliance programs in our Acts. The Food and Drug Act and our Act are somewhat different in that respect. Therefore, we have certain requirements which we feel are necessary in this connection, whereas FDA has a different set of views.

However, apart from that, I don't think the regulations relating to the use of voluntary nutrition labeling are that far apart.

Q: How would a frankfurter with 30 per cent beef plus 70 per cent pork and/or 70 per cent beef and 30 per cent pork be labeled? This changes the iron and thiamine value.

Dr. Mussman: It is a matter of deciding which one you want to prepare and apply the appropriate nutrition label to the product. That would mean probably having two sets of labels for this product when there was a need for shifting relative proportions of these two meats, as is permitted under our regulations. If you differed significantly from what your nutrition label said you would have to go to the other labeling. At this point that would be the only answer I could give you.

Q: A company with 12 plants making frankfurters will be required to make up to 432 routine control analyses per year at a cost of $100,000 to $160,000 per year. The same company may have 400 other products to go. Is the USDA killing the program with excessive routine control requirements?

Dr. Mussman: I think I answered that to some extent in my talk; at least I hope that subject was addressed. One answer certainly is that the use of standard labels for products of such high uniformity—for example, frankfurters—might be very appropriate.

On the other hand, for products that may not achieve that uniformity, whether the company had 12 plants or 24 and the formulation and ingredients and all other things were equal, it probably

would be possible to consider ways in which one label could suffice for one kind of control program and suffice for all production at the various plants.

There are some problems with that. I don't want you to believe that to be the final interpretation. I think it needs to be explored. The possibility is there.

Q: It seems to me that the USDA is facing a problem with the labeling of fresh fruits and vegetables. Isn't it true that the nutrition community believes if this labeling is to be effective eventually, all products should be so labeled? And I'd like to know whether that is possible under the current rules and regulations.

Dr. Wodicka: I am not sure I understand fully. The problem of fresh fruits and vegetables has been less that of changes in nutrient composition upon cooking but more the contention of the fresh fruit and vegetable people that their product is more variable than the same products that are bought by the processor. Therefore, they are not able to underwrite the nutritional value of what they purvey. So let the buyer beware.

Q: How are nutritionally labeled canned foods measuring up to the mandatory compliance requirements regarding nutrient declaration of Class 2 foods?

Dr. Wodicka: Very well. All samples but one have met the criteria.

Q: Are you considering revising the portion of the USDA nutrition labeling with the regulation requiring a precise number of assays per year per product?

Dr. Mussman: Yes, we are considering a revision. In fact, we have made considerable progress along those lines. We are thinking seriously about relating the number of tests to the volume of product being produced.

In addition we are also considering ways in which closer control over the formulation of the products—in plant control of assembling the product, the ingredients and so on—might to a degree substitute for some of the testing which would be expected.

What we are leading up to here is a possible reduction of labeling costs, which we have recognized to be substantial. It is an attempt to get as many people into this program as possible for the benefit of all concerned.

Q: Why have a provision for a niacin equivalent in nutrition labeling?

Dr. Wodicka: The tryptophane conversion is sufficiently variable. We hesitated a long time in deciding that the uncertainties of leaving it out were less than the uncertainties of putting it in. We could change our mind some day. There is no active consideration of the question now in case anybody is hanging back on nutrition labeling on that account.

Q: How about protein quality concerning the amino acids profile? Should not this also be labeled? Otherwise the unaware consumer might equate jello protein with cheese protein. What are your thoughts?

Dr. Wodicka: We have considered various alternatives, such as some sort of a figure of merit to adjust the protein value for some measurable biological value. We finally decided that with all its faults the protein efficiency ratio in the Association of Official Analytical Chemists (AOAC) procedure was widely used so we would settle on that.

We called for a declaration of the protein content in grams per serving. However, we also called for the declaration of the protein content as a percentage of the Recommended Daily Allowances (RDA). A protein with a Protein Efficiency Ratio (PER) below 20 per cent is assumed to contribute nothing to the RDA. Anything that has a PER of 20 to 100 per cent would be computed using 65 grams as the base. So this is a rough division of protein into three classes of biological value and that is probably as precise as most of the other things we do.

Q: Nonnutritive fiber and the concept of fiber in our diets is becoming more important. Will the presence of fiber be in labels? How does FDA view fiber in food?

Dr. Wodicka: It is fairly obvious that indigestible residue is an important constituent of food from the standpoint of health, although, by definition, I suppose it can't be considered nutrition as long as it isn't digested. However, it is important even though it isn't nutritional.

One of the difficulties is that we don't know how to measure it. In other words, a typical crude fiber determination, even though it is on animal feed labels, does not bear any demonstrable relationship to the matter of undigestible residue left in the alimentary tract. We don't have any better methods.

So I think I can promise you that it is not going to be on the label soon, if only because we don't know how to measure it. That doesn't mean we don't consider it important.

Q: When will FDA revise its US-RDA in line with the 1974 RDA?

Dr. Wodicka: That obviously refers to the Food Nutrition Board. I would have to say that I don't know. However, I would also add, "not soon," because the changes that the Board made in the RDA's that were recently published are not all that dramatic in magnitude and we are not about to ask all those people who have been busily putting nutrition labels on to change them, not in the midst of all the campaign. We are not going to rock the boat.

Food Advertising Regulation

Q: Please go out on a limb and "guesstimate" when the Commission will propose the food advertising regulations.

Mr. Rosch: 30 to 45 days. But, candor requires me to tell you that I made that estimate in January, too.

Q: How does the rule define advertising? As paid media or any spoken word by anyone or educational materials?

Mr. Rosch: That is a very specific question. I will tell you this much: TV, radio, print advertisements, with some exceptions, should be covered in some fashion, in my opinion.

Q: If lack of nutrition information doesn't permit comparisons, i.e., prevents consumers from making comparisons, does nutrition labeling then have to be compulsory rather than a voluntary program for the Federal Trade Commission (FTC)?

Mr. Rosch: I think the answer to that is "no," but only insofar as the information is disseminated in some form at some time, in a fashion that does permit comparisons by consumers on the basis of nutrition.

In other words, to the extent this information can be effectively communicated in other forms of media besides the label itself, it would not have to be included on the label.

However, insofar as it is not, I would say the logic of the FTC law does suggest that the labeling would have to be mandatory.

Q: You appear to assume that food manufacturers will require no research outlay for the development of analytical data. Is a few billion dollars inconsequential?

Mr. Rosch: The answer to the latter question is "no." I could move on at that juncture, but I won't. Insofar as foods already carry nutrition labels, there should be no further burden in terms of pro-

ducing analytical data because that data would have to be produced to make the nutrition label anyway.

Insofar as foods are not nutritionally labeled, an effective rule may not need to entail the burdens and analytical data, in terms of cost and time which might be required to develop current labels or correct nutrition labels. However, I think it would be profitable for you to nutritionally label foods.

Q: Food products are advertised on children's TV because children exert substantial influence in their purchase. What effect do you feel that nutrition information advertising will have upon these children who actually make the purchase decisions at the supermarket, assuming that practical ways are found to effectively disseminate the required information through TV spots?

Mr. Rosch: The answer at this juncture I can't tell you precisely. My own judgment is that probably very little, at least for the group up to age 7. I think the Commission is going to have to treat the children's advertising question on a separate basis and I think it will do so in the near future.

Q: Similar information has had little effect on cigarette consumption to a more mature audience.

Mr. Rosch: I am not quite sure what is meant by "similar information." However, with respect to what has been done in the cigarette area I know that many people have dismissed it as relatively ineffective because statistics indicate that cigarette consumption is on the rise.

Frankly, I am not sure that this is an indication of an ineffective regulation. I have yet to see any indication of what those statistics would look like today had those regulations not been in effect. The rise might have been much more substantial than it is right now. So we don't really have any facts on what that regulation has done.

Q: Is there a specified group or party responsible for coordinating the FTC guidelines with those of FDA?

Mr. Rosch: The answer to that is "yes." There is a group of staff people in the National Advertising Division of the Bureau of Consumer Protection who have coordinated their efforts with respect to the staff nutrition proposal very, very closely with FDA from the beginning.

In fact, at the outset, we stole one of FDA's finest nutritionists, Judith Cook, to head our staff effort. Unfortunately, she died late last

year. However, she was very important indeed in putting together the basis of the current staff proposal.

Q: What input is the FTC seeking from nutritionists, the academic community and consumers?

Mr. Rosch: The answer to that is, enough to assure ourselves that there is a *prima facie* case.

However, I must reiterate that final judgments with respect to the issues which I discussed earlier must await full development.

Q: Please explain FTC's rule-making procedure.

Mr. Rosch: Generally speaking, what happens is that the proposed rule is issued in the *Federal Register* for comment. It doesn't always happen. Sometimes the Commission is not sufficiently confident in an area to actually set forth a proposal.

In that case, what it will sometimes do is simply pose a series of issues which it wants addressed. Comments are solicited. Comments are received in writing. On the basis of those comments the Commission decides whether and to what extent public hearings are appropriate; by that I mean hearings on the record with questions from a Trial Examiner.

After that happens, the Commission considers the evidence which is in the record to determine whether it is sufficient to make a decision. If the Commission decides that it is not, then it will order a new round of comments or perhaps public hearings and in the ordinary course publish a final rule.

Q: How do you define "malnutrition" and in what way do studies, especially the Penn State survey, indicate that malnutrition is widespread?

Mr. Rosch: I would say that most surveys show slight deficiencies in two or three nutrients in certain population segments, but not "widespread" or true malnutrition.

I think this has been the subject of several years of inquiry at FDA. I think the record was fairly evenly split in that proceeding. However, there was substantial evidence in my judgment in that proceeding that there was widespread malnutrition.

Q: Does the proposed food fortification policy set maximum levels for food products? Is it voluntary?

Dr. Wodicka: Yes, it does set maximum levels of fortification. Only in a sense voluntary; it is going to govern our actions.

Q: Will it apply to standardized or nonstandardized foods or both?

Dr. Wodicka: Both.

Q: Will it define "enriched," "fortified," "imitation," et cetera?

Dr. Wodicka: Yes.

Q: Someone has been kind enough to ask that "nutritionally equivalent" be defined when considering imitation foods.

Dr. Mussman: That is not an easy one. Perhaps Dr. Wodicka might have some views on it. I suspect the only way I could adequately define it, just on the basis of need to respond to this question, would be as follows: if, by using standard testing procedures, the imitation food elicits the same kind of response as the product which it resembles or imitates, in that sense then it would be nutritionally equivalent.

I expect that there probably would be some more sophisticated answer available if you went into it in somewhat greater detail, amino acid residue composition, et cetera.

Q: If we accept the premise that nutrition is more than the sum of its parts how can even a bright consumer know the combined total effect of a day's nutrition intake as to adequacy?

Dr. Wodicka: Well, actually the tendency, in view of the biological variation for food materials, will be that the whole will not be greater than the sum of its parts if you are talking about micronutrients which are stated in terms of percentages from the RDA.

Obviously, if somebody wanted to work at it, he could add up percentages of the RDA and see whether he would end up with 100 per cent.

However, we believe that the major uses of nutrition labeling are going to be in comparative shopping and in the selection of what foods to eat, rather than in terms of the detailed planning of days' menus.

Sugar

Q: What are some examples of sugar-laden foods?

Mr. Rosch: Ice cream, candy bars, soft drinks? I can't give you an accurate answer to that at this juncture. I think there is evidence that sugar-laden foods are more detrimental to health if they are consumed between meals as opposed to at meals. There is some other data which suggests the contrary. Therefore, I can't tell you what

precisely would be included within my definition of "sugar-laden foods." For instance, they might be objectionable in terms of advertising for children.

Q: Current research in sugar and dental caries, where cereals high in sugar, sugar added and not added were compared indicates that the cereals did not demonstrate any increased dental caries.

Dr. Hegsted: My only comment on that would be that if you start out with a very bad situation and don't make it any worse that is not a very good recommendation for a product.

I think the same study done somewhere else might yield quite different results. So I don't think that is very conclusive one way or the other.

Q: Since both the FTC and the FDA indicate that existing sugar use may be studied, will this accelerate the possibility that cyclamates may be reinstated for consumer and industrial use?

Dr. Wodicka: Let me say that the events are unrelated.

Q: Is any department considering the expanded use of corn sweeteners where assimilation is much slower?

Dr. Wodicka: Well, corn sweeteners is a vague topic, of course, because it can mean anything from high textron, low dextrose to substantially pure or at least hypothetically maltose to dextrose to essentially the equivalent of invert sugar. So it would be pretty hard to generalize about this.

This is one of the problems, of course, when I said we had too few facts on a similar question. This doesn't mean there aren't any facts. There are an awful lot of facts. However, they don't add up. You have to make up your mind, for one thing, as to what does one mean by "sugar?" Does it include glucose, maltose, lactose, galactose?

It makes a difference because sometimes you put in sucrose but you wind up consuming invert. The form of the product makes the difference, for example caries, which depends on retention against the tooth. There are facts, but to sort them out into consistent patterns so that one can draw conclusions is a substantial challenge.

Q: What is the FDA doing about the relation of sugar to health? The FTC seems interested. The FDA's position is not clear.

Dr. Wodicka: It seems to me the FDA's position is one of watchful waiting. I am quite interested in the FTC's proposal to resolve this

question, which will presumably be accomplished in a hearing before an Administrative Law Judge.

Our problem is that we don't have enough facts.

Consumer Participation

Q: How does the FDA select consumers for participation in its deliberations? Conversely, how or to whom do interested consumers express their interest in participating?

Dr. Wodicka: The FDA does not select consumers for participation in its deliberations. It opens up many of its operations to discussion and open meetings. In every instance, of course, it publishes proposed regulations in the *Federal Register* and makes them available for a comment period, usually 60 days. Consumers do write in comments on proposed regulations. They are to be written to the Hearing Clerk. The procedure and the address is given at every regulation proposal.

Otherwise, if the consumer has a question or an opinion or a fact to offer in a letter to the Commissioner or to me or to anybody else they know, the closest regional director will usually get an answer. We do get thousands of them.

Q: How large a group was surveyed and in which parts of the country? I am referring to the survey in which we found that three-fourths of the grocery shoppers wanted nutrition information. How much extra would these people be willing to pay? What was the education and age level of those questioned?

Dr. Wodicka: The sample consisted of 1,500 people, a probability sample from standard census districts in all parts of the country and extrapolatable to the entire U. S. Half of them would pay 50 cents a week, 66 per cent, 30 cents a week, 75 per cent, 10 cents a week.

Q: You mentioned a survey done in supermarkets to measure attitudes on nutrition labeling. Is this study available? How many consumers were queried? In what section of the country were the tests given?

Dr. Wodicka: The highlights of the study are going to be in our magazine, "FDA Consumer," next month; there will be three articles through the summer, the final report in about six weeks. **[The End]**

What Lies Ahead?

By HENRY E. MILLSON, JR.

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WHEN I WAS ASKED TO SPEAK on this subject, I realized the vast number of topics that could be touched on under this heading. So I decided to try to hit the highlights of three subjects: (1) The direction and future of state and federal drug reimbursement programs; (2) Poison Prevention Packaging Acts and problems that may arise in the future associated with the packaging of drugs and cosmetics; and (3) Controlled Substances Laws—prospects for the future under their implementing regulations.

PMA v. Brian

My first topic, the direction and future of state and federal drug reimbursement programs, begins in California. *PMA v. Brian* prohibited the California Department of Health from implementing established maximum rates of reimbursement to be paid to California pharmacists for drugs supplied to MEDI-CAL beneficiaries. The Superior Court of California ruled that the Department of Health denied interested parties rights to a public hearing and other procedural rights under the California Administrative Procedure Act. The Court also held that the Director of the Department of Health is not vested with the statutory authority to reduce the quality and range of drugs to MEDI-CAL recipients.

On December 6, 1973, the Department of Health adopted temporary emergency regulations re-establishing price ceilings for drug reimbursement in approximately 130 generic categories under the MEDI-CAL program, ostensibly to comply with requirements under the court ruling in *PMA v. Brian*. These price ceilings were substanially the same as those established under two earlier editions of MEDI-CAL regulations which had been declared to be not in compliance with the

judgment of the Superior Court. However, the December 6th regulations for the first time required the Department of Health to hold public hearings.

The MAIC

According to Section 51513.2, of the applicable Administrative Regulations, particularly subsections (f) and (g), the Maximum Allowable Ingredient Cost (MAIC) of a product is to be established by the Director based on substantial evidence presented at the public hearings that the drug product chosen is:

> "generally equivalent in quality to those drug products used by physicians throughout the state and available throughout the state to outpatient pharmacies through usual and customary distribution channels in sufficient quantities to meet the needs of the MEDI-CAL program."

"Equivalent in quality" means giving the same patient response as other drug products of the same generic drug type. "Substantial evidence" is defined as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate equivalence." If the Director is unable to obtain such evidence, he may rely upon a recommendation concerning comparative therapeutic effect made by the Medical Therapeutics and Drug Advisory Committee, and such recommendation will be considered to be substantial evidence. This Committee is made up of nine members. As currently constituted, there are five physicians of various specialties, and four pharmacists on the Committee. Following public hearings that took place in February of this year, the Committee reviewed approximately 100 recommended MAIC's in about 2½ hours and approved them all as submitted. Three days had been scheduled for the Committee's review. PMA called this unseemly haste a "Rubber Stamp," which it clearly was.

The provision giving the Director the right to consider a Committee recommendation as substantial evidence provides the Director with great leeway in accepting a drug under the MAIC program without any real proof of substantial evidence. Query: If the Committee renders a favorable opinion on a drug without any evidence of equivalence in quality to other drug products of the same generic drug type, and the Commissioner relies on this opinion as "substantial evidence," does this not constitute an arbitrary and capricious ruling and an abuse of administrative authority by the Commissioner?

Those aggrieved by a Department of Health ruling on an established MAIC may appeal to the Director. From an adverse ruling by the Director, further appeal may be made to the Superior Court of California.

The Department of Health has unofficially expressed an intention to amend the Regulations based on the information developed at the hearings, and, in fact, has already made a few amendments. However, the future of many drugs in California for MEDI-CAL price ceiling purposes is not completely clear at this moment. I have a feeling that we won the battle, but we are losing the war.

Future MEDI-CAL Developments

The significance of these developments in California for the future are threefold. First is the uncertainty of the fate of some drugs in California in relation to MEDI-CAL price ceilings. In California, a combination of political pressures to keep welfare costs down (this is an election year) and budget allocation problems will tend to sacrifice some high quality medications on the altar of administrative expediency. Second is a close scrutiny of California by other states who may use California's experience with welfare drug price ceilings as a model for similar programs. In fact, if California's present program goes unchallenged, other states may adopt California's MAIC drug selections without independent evaluation of these selections. Third is the effect of these developments in California on federal programs. I think it is not an overstatement to say that Secretary Weinberger's proposal is grounded at least in part on California's drug reimbursement program. As you know, Secretary Weinberger has proposed regulations to limit drug reimbursements under programs administered by the Department of Health, Education and Welfare (HEW) to the lowest cost at which a drug is generally available unless there is a demonstrated difference in therapeutic effect. In addition, the Kennedy-Mills National Health Insurance Bill (S. 3286 and H. R. 13870) seeks to establish a national insurance formulary committee to establish a formulary, and drug reimbursement would be controlled by the Social Security Administration. Here again, California's program could be useful to the Social Security Administration if this health insurance bill becomes law.

Packaging Pharmaceuticals and Cosmetics

The second topic I would like to comment on is the increasing number of problems in the packaging field and the effects of these

problems on the future of packaging pharmaceuticals and cosmetics. One problem is in complying with the Poison Prevention Packaging Act. The need for safety closures on a broad range of drug products has resulted in an inadequate supply of safety closures in some of the needed sizes. Added to the problems of closure manufacturers, in "gearing up" to meet the heavy demands of a relatively new technology, are the problems of obtaining the plastic raw materials needed to manufacture these closures. Some of these plastic raw materials are derived from petrochemicals, which are in short supply. There are in existence many state Poison Prevention Packaging Acts, but fortunately these are generally patterned after the federal Act and usually do not give rise to special compliance requirements.

Another pressure by the states may be added to existing dislocations in obtaining finished packaging supplies. At least one state, Minnesota, is attempting to pass a bill to require the preclearance of all packaging, including drug packaging. Enforcement of this act, if passed, would be under the Minnesota Pollution Control Agency, and would be grounded on the environmental impact of the waste packages. If trends such as this develop, changes in packaging will have to filter through state preclearance procedures, seriously eroding a drug manufacturer's ability to shift from one packaging material to another as short supply problems become acute.

Polyvinyl Chloride Under Attack

Yet another problem has surfaced recently for the beleaguered packaging manufacturer and drug company purchasing agent. As you know, vinyl chloride is under massive attack as a carcinogen; and polyvinyl chloride (PVC), used as a package liner for many drug products, is coming under fire. On May 7, 1973, the Commissioner of Food and Drugs concluded that the use of PVC for packaging of alcoholic foods may cause such foods to be adulterated, based on reports of possible vinyl chloride migration problems. Then on April 22, 1974, the Commissioner published a proposed order in the *Federal Register* to prohibit the use of vinyl chloride as an aerosol propellant and as an ingredient of a drug or cosmetic product. The Commissioner asked for extensive data to be submitted to the Food and Drug Administration (FDA) on the usage of polyvinyl chloride in packaging materials, and vinyl chloride migration from polyvinyl chloride

containers and liners. Also, data on the pharmacological effects of such migration were requested. The Commissioner further required on April 22nd that drug manufacturers required to register under Section 510 of the Federal Food, Drug and Cosmetic Act submit to the FDA a list of all human drugs containing vinyl chloride and a list of all human drugs packaged in polyvinyl chloride containers or in containers with polyvinyl chloride liners. Regulations rigidly controlling the drug products, particularly liquid drug products that may be packaged in contact with polyvinyl chloride, are almost certain to come. Also, if zero levels are established for vinyl chloride in drug products, polyvinyl chloride will probably cease to exist as a packaging material for the drug and cosmetic industry. The Occupational Safety Health Act (OSHA) has just proposed (Friday, May 10, 1974 *Federal Register,* p. 16896) a zero exposure level for employees of manufacturers of vinyl chloride. The existing temporary standard is 50 P. P. M. If this proposed order becomes final, it may well be that a zero level cannot be obtained within economic realities, and OSHA will have indirectly killed polyvinyl chloride. If PVC dies a regulatory death, added pressures will be brought to bear on petrochemical polymer packaging materials such as polyethylene and polypropylene.

A trend back to glass containers will probably develop if pressures on plastics continue to mount. However, glass bottle manufacturers have cut back sharply on production in past years due to increased use of plastics, and they too may not be able to meet heavily increased demands. The trend to glass will, of course, not alleviate problems with safety closures, for which no permanent solution to short supply problems is presently apparent.

Controlled Substances Laws

My third subject is the Controlled Substances Laws, the interplay of state and federal acts (the Comprehensive Drug Abuse Prevention and Control Act of 1970), and prospects for the future of drug products under these acts. Almost all the states have such acts, and these acts are patterned generally on the Federal Act. However, some state Schedules of Controlled Substances are more inclusive than the federal Schedules, and do not exempt or exclude all of the drug products exempted under the Federal Implementing Regulations. If faced with this problem, an argument that a drug product is exempt

or excluded under the Federal Act is given weight by the states, and unless their specific experience with the drug is contrary, this argument, plus supporting data, may result in an exemption being granted.

The philosophy under which drug categories and specific drug entities are included in both the federal and state Schedules seems to be changing with the passage of time. When these acts were first passed, the acts were meant to cover known addictive substances and substances having a potential for abuse with physical or psychological dependence apt to result. Even the criteria for listing a drug in Schedule V, the least controlled Schedule under the Act, requires that the drug have a low potential for abuse, a current medical use, and that *abuse may lead to limited physical or psychological dependence*. Under Section 202(b) of the Act, except for treaty obligations, a drug may not be placed in any schedule unless the findings required for such schedule are made with respect to the drug. Currently, the philosophy seems to have expanded to cover substances having a *theoretical* potential for abuse based on similarities in chemical structure of pharmacological activity to listed substances. The rationale for this philosophy is that if sources of known abused substances are dried up, other substances will be sought by the drug abuser.

I don't mean to set up a straw man, but the future may see a further expansion of the Schedules to include substances having no known dependence or abuse potential, but which have toxic reactions when taken in overdoses that *could* be appealing to the drug abuser. Query: Could this be rationalized within the criteria set forth in the Federal Act, particularly the criteria set forth in Section 201 (a), 201 (c) and 202 (a) and (b)? Specifically, these criteria require a finding of potential for abuse and at least a limited physical or psychological dependence.

It is hoped that a rational view of this whole subject will be taken by the enforcers of these acts so that highly theoretical and unproven concepts do not result in the listing of a large number of the drug products on the market today as controlled substances. Unnecessary controls over drug products not really shown to be subject to abuse are not in the best interests of the public, the medical profession, the pharmacist, or the drug manufacturer. The cost of a chain of compliance with these controls will, of course, ultimately be borne by the public. **[The End]**

The Interplay of Federal and State Regulatory Programs on the Distribution of Pharmaceuticals— The Legislative Aspects

By CLIFFORD C. DAVID

Mr. David Is Legislative Counsel for SmithKline Corporation.

WHEN BILL PATTON asked me to serve on this panel, at first I had a little trouble trying to get a handle on the subject assigned to me—"The Interplay of Federal and State Regulatory Programs on the Distribution of Pharmaceuticals—The Legislative Aspects." Giving further thought to the matter, I realized that the "Legislative Aspects" have a great deal to do with the problem. This is where the interplay all starts. When states pass laws which differ from each other or the federal law, there are bound to be problems for companies doing a national business. One of the main objectives at the state level is to try to keep the laws uniform to the greatest extent possible. Although, as I will mention later, this doesn't mean we won't have problems even if the laws are identical. One's first question may well be—what's the problem? After all, don't we have uniform laws whose very purpose is to have the identical law in each state, which in turn is patterned after federal law?

Uniform Laws

The answer, of course, is yes, we have many uniform laws. I might mention that, in addition to uniform laws, there are also

"model laws" which as far as I can determine are really the same as uniform laws. The difference is a distinction without substance, the only difference being in which organization prepares and sponsors the law. Uniform laws have been proposed on many subjects. I'm sure you are familiar with many of them. In the drug area we have to mention a few: Uniform Food, Drug & Cosmetic Act (FD&C), Uniform Controlled Substances Act, Model Poison Prevention & Packaging Act, Truth in Advertising Law (Printers' Ink Model Statute). It is true that many of these uniform or model acts have been adopted by many states, and you would therefore not expect any differences in administration from one state to the next. Unfortunately, this is not the case. A bill may be the exact uniform bill when introduced but by the time it is considered by two or more committees and is worked over by the House and Senate and lobbied vigorously by interested groups, it is unlikely that by the time it goes to the Governor for his approval, it will be the same as when introduced.

Even though laws may be identical or at least portions thereof, it still does not mean that our problems have been solved. The same statutory language may be interpreted one way in one state and differently by the regulatory agency in another state. Another problem with uniform laws is that states are not uniform in updating them; important variations may exist for years. One thing we can say about uniform laws is that where we have them, we are likely to have fewer problems than if we didn't have them, but we still do have problems.

Conflicts Between State and Federal Laws

For a number of years, I have been involved in state and federal legislative matters not only for SmithKline Corporation but also for the Pharmaceutical Manufacturers Association (PMA). My interest or perhaps, more accurately, my concerns have not been as broad as the various interests represented here today, but they have fairly well covered the pharmaceutical industry and I don't imagine other areas differ too much. We have long realized that any time Congress passes a law and one or more states or even two states enact legislation on a particular subject, there are bound to be differences and eventually problems. One way to solve the problem would be to eliminate all state and local governments leaving only the federal government to regulate. This would surely do away with inconsistencies and con-

flicts. This does not, however, appear to be a practical solution. Perhaps Henry Millson can look into his crystal ball and tell us whether such a possibility lies ahead. If in a federal/state situation there is a clear conflict and it is impossible to comply with both, the federal requirements will of course prevail. Many times, however, there may be differences in the federal and state law. However, it is not impossible to comply with both. It may present some problems and be expensive and burdensome, but it can be done. In cases where conflicts or differences exist in state laws, neither prevails and both must be complied with.

Manufacturer Identification

Let us turn now to examples of legislation where there are differences:

(1) The first area and one that many of us are wrestling with right now is that of manufacturer identification. The federal law requires that the name of the manufacturer, packer or distributor appear on the label. This is the way it is in the Uniform FD&C Act and this was the requirement under most if not all state laws until a year or so ago.

Several states have now decided that this was not enough and they have passed laws which require the name of the manufacturer of the final dosage form to be identified. Two states require this information to appear on the label, but provide that in lieu thereof the statute may be complied with by filing the information with the appropriate state agency. In the third state, California, the regulations provide that the information shall be included in the labeling "on or within the package from which the drug is dispensed." There is no provision permitting the filing of the information with a state agency; the PMA is working on an amendment to the law to allow this. What would appear to be a small difference in the law in one state actually raises many questions:

(a) Who is the manufacturer of the final dosage form? In some instances this can be a difficult question to answer.

(b) Where should the information appear? On the label, the package insert, or both?

(c) As a practical matter, can compliance be limited to California or must it be done on a national basis?

(d) What problems are there under the federal law? Is a supplemental New Drug Application (NDA) required? If compliance is to be limited to California by stickering only those products in a branch which supplies California, is it necessary to register the branch with the Food and Drug Administration (FDA)?

These are some of the questions raised by the California law. It is to avoid these problems and because it would be more meaningful for the pharmacist to have this information prior to purchasing the product that the PMA is seeking a filing amendment.

The situation may soon become even more confused. I have just learned that the legislature in Florida has passed a bill providing that a prescription drug will be misbranded unless the *label* bears the name of the manufacturer of the finished dosage form *and* the name of the packer or distributor. I really haven't had an opportunity to consider the interplay of the federal, California and Florida laws—I don't see how it can help but cause more confusion.

Controlled Substances

(2) A second area where many states have "uniform acts" is controlled substances. In the introduction to this uniform act, it states:

"To assure the continued free movement of controlled substances between states, while at the same time securing such states against drug diversion from legitimate sources, it becomes critical to approach not only the control of illicit and legitimate traffic in these substances at the national and international levels, but also to approach this problem at the state and local levels on a uniform basis."

Who can argue with this objective? However, when we look at what we now have, four years after the federal act was passed, we find we have:

(a) A few states require triplicate prescriptions for Schedule II drugs while most states do not. The Bureau of Narcotics and Dangerous Drugs (BNDD) (now the Drug Enforcement Administration (DEA)) as well as a number of states considered a triplicate prescription requirement, but, after having weighed the pros and cons, decided against it.

(b) Prohibitions against the sampling of all controlled substances exist in some states. Although the federal Act

has a number of provisions controlling sampling, several states thought something more was needed—the only thing left was to ban them. Even where the statutory ban is identical, there are, however, inconsistencies. In one state where sampling is prohibited, it has been interpreted as prohibiting the sending of a personal use supply when requested by a physician. Another state does not consider this to be a sample and permits it.

(c) Differences between records of samples and what the physician must do to obtain samples.

(d) Research provisions relating to controlled substances vary widely. Some require submission and approval of a protocol for research of Schedule I substances. Separate registration for investigators may be required. In one state, the controlled substances act contains six schedules rather than the usual five. Schedule VI includes all prescription drugs not covered in other schedules. An Investigational New Drug (IND) type requirement applies to research of all controlled substances and thus all Rx drugs. Other states are limiting or banning research for all drugs by regulating on a piecemeal basis. Pennsylvania and a number of other states have banned all testing in prisons. Now Pennsylvania has proposed regulations which, as written, would permit research in mental health facilities. If this trend continues, it will make it more difficult to undertake the research that the FDA requires.

(e) Variations in the scheduling of drugs. On an individual basis, states are transferring drugs from one schedule to another or adding new drugs to one of the schedules.

As you can see, there is a lot of nonuniformity in the Uniform Controlled Substances Act which leads to marketing and distribution problems.

Drug Formularies

(3) A subject of major interest to pharmaceutical companies, who are faced with more and more legislation at both the state and federal levels, is drug formularies. Some states have had formularies for a number of years (Pennsylvania, for example), but these have

been used to determine what drugs would be reimbursed under the medical assistance programs in the state and have not been too much of a problem. However, starting in 1970, Massachusetts, after a number of unsuccessful years of trying, passed a law which established a drug formulary commission and required the commission to prepare "a formulary of generic or chemical and brand names of drugs and pharmaceuticals considered by the Commission as therapeutically equivalent." This law also required physicians who prescribed by brand name a drug listed in the formulary to also include the generic name. The stated purpose was to give the consumer a choice and the sponsor of the bill, Representative Serlin, was quoted in the paper as saying: "If he's stupid, he'll buy the trade name. If he has any common sense, he'll buy the generic name." It was clear that the purpose of the bill was to force physicians to prescribe by generic name and to require pharmacists to substitute on prescriptions, and thereby save the people of Massachusetts a million dollars a year.

Apparently, the law is not accomplishing the purpose that its supporters intended. After four years efforts are still being made to amend the bill to make it more workable.

Wide-Based Support for Bill

This bill was one of the first state bills in the drug area to have serious support from labor and consumer groups, normally formidable opponents to say the least. After this victory in Massachusetts, the word spread to other states and a rash of bills were introduced, several of which did pass. Each bill tried to improve on, and overcome the difficulties of the Massachusetts law and as a result, the other states which now have formularies are all different. The criteria for determining what drugs will be included in the formulary, how equivalency is determined, when substitution may be made and what the pharmacists must do if he does substitute, vary from state to state and create marketing and distribution difficulties. I believe that we will see more and more state laws dealing with formularies, generic prescribing and substitution, and as a result, the situation will become more confusing. I suppose there is even a possibility of federal legislation in this area. It will be interesting to see what happens if this should come about.

Laws Concerning Lobbying Activities

(4) Most states have laws relating to lobbying which require that persons engaged in activities which tend to influence legislation register with the appropriate authorities and in some cases submit periodic expense reports. These laws of course vary from state to state.

I am not going to discuss them today and I only mention them to point out how ridiculous the situation can get. In 1973, the board of supervisors of Orange County, California, adopted an ordinance governing the registration and disclosure of lobbyists. The ordinance became effective January 1, 1974, and requires registration, the listing of compensation and expenses and the identification of the people he represents. He must also disclose gifts and the cost of meals or entertainment furnished to county employees. The county counsel has ruled that under the ordinance as written, salesmen calling on the county purchasing department fall within the definition of "government advocate" and, therefore, must comply with the ordinance if his employer is to do business with the county.

Is There Hope for Uniform Laws?

I could mention a number of other legislative areas where differences exist either from state to state or state to federal which lead to problems for the national manufacturer, but I believe what I have mentioned indicates the problems. As you can see, the situation is confusing at best and sometimes much worse. Is there any real hope that sometime we will have consistency from state to state and uniformity with federal laws? Our efforts with uniform bills have not proved too successful, although the situation is generally worse where there are none. Arguing that companies doing business on a national basis have serious problems unless there is consistency has not made much of an impression. One approach would seem to be at least a partial answer. This is federal preemption. For many years there was a strong states rights block in Congress and it was difficult, if not impossible, to have preemption provisions included in a federal act. However, the situation seems to be changing somewhat and several recent federal acts have included limited preemption provisions. This may make things easier. The Consumer Product Safety Act and the Safety Closure Act both have preemption provisions.

One of the stated purposes of the Consumer Product Safety Act is to minimize the number of state and local regulations in conflict with the federal act. When a standard becomes effective under the federal act, no local jurisdiction may establish or continue in effect any regulation governing the same risk associated with that product, unless the local requirements are identical to the federal standard or unless the commission grants an exemption. Such an exemption may be granted if the proposed local rules impose a higher level of performance than the federal standard, if such is required by compelling local conditions and if it does not unduly burden interstate commerce. The pending device legislation bills include preemption language.

Preemption Provisions

The recently introduced Kennedy Bill (S. 3441) includes among other provisions a requirement that pharmacists post a list of prices of the most frequently sold drugs. The bill further provides, "It is declared to be the express intent of Congress to supersede any and all laws of the states or political subdivisions thereof, insofar as they may now or hereafter provide for the display of information which is different from the information required to be displayed under this section. . . ." It then goes on to exempt statutes which impose a standard of performance equivalent to or higher than that established by this section.

These preemption provisions may not be completely to our liking, but I really believe they will be helpful.

One last item of interest concerns a report that the FTC staff has proposed for consideration by the commission that the commission void all state bans on drug price advertising by declaring such bans an unfair trade practice. This to me is a novel way to preempt a field. Whether it is legal or not, I'm not prepared to say. It certainly presents a number of interesting legal problems. My purpose in mentioning this is to express concern that, if the FTC should void the state bans and the decision is upheld by the courts, what can we expect from the FTC in the future?

At the moment preemption appears to be the best hope for uniformity. It won't solve all of our problems, but it should make life easier for many of us. **[The End]**

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