Health Claims for Infant Formulas and Foods: U.S. Regulations

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Food label claims are statements on a product label or in accompanying materials such as consumer brochures or information manuals for health care professionals. Health claims, one type of food label claim, describe the relationship between a food substance and a disease or health-related condition. Their use must be consistent with FDA regulations. Sound science is an essential component in making decisions to permit health claims. In this chapter, I highlight some of the issues that commonly arise in the decision-making process whereby sound scientific principles and evidence are integrated into the general regulatory requirements for health claims. I also discuss some of the specific and unique challenges in applying general health claim principles to infant formulas and foods.

LABEL CLAIMS: GENERAL REGULATORY FRAMEWORK

There are two regulatory categories for infant formulas in the United States. One category is "regular" infant formula—products intended for use by the general population of healthy infants. These formulas must be nutritionally complete and be capable of supporting healthy growth in infants when consumed as the sole source of nutriment during the first year of life. The other regulatory category is "exempt" infant formula. Exempt formulas are intended for use by infants with inborn errors of metabolism, low birth weight, or with other unusual medical or dietary problems. An example would be products specifically formulated to be low in or free of the amino acid phenylalanine for use by infants with phenylketonuria (PKU). These types of formulas may need to be exempted from some of the nutritional requirements for the general population of healthy infants because of special nutritional or dietary management needs of infants with medical and health conditions. Additionally, because these formulas may not meet the nutritional needs of healthy infants, they could pose a safety concern if not used under close medical supervision.

For the purposes of this discussion, "infant foods" include foods intended for use by infants and toddlers less than 2 years of age. Infant foods may be intended
for use by the general population of healthy infants (e.g., infant cereals and juices). Additionally, some infant foods may be specifically designed to be used in the dietary management of a disease or health-related condition that has distinctive nutritional requirements. These latter types of infant foods are regulated as "medical foods" and must be used under close medical supervision.

Label claims for infant formulas and foods come under general food law requirements that label information be "truthful and not misleading." This means that not only must a label statement be truthful, but the statement may also need to include "material" information that is necessary to prevent a truthful statement from being misunderstood by consumers. For example, a statement on a regular infant formula that the formula meets 100% of the calcium requirement of an infant, or that it has more calcium than other infant formula products, although factual, would be misleading without a clear indication that all infant formulas have adequate calcium to meet the nutritional needs of infants and that calcium intakes significantly in excess of the requirements do not provide any added benefit and may, under certain conditions, cause harm.

Several types of label claims on infant formulas and foods also come under the Nutrition Labeling and Education Act (NLEA). This is the 1990 amendment to the Food, Drug and Cosmetic Act (hereinafter, the act) that governs, among other things, nutrient content claims (e.g., "high protein" or "low fat") and health claims (e.g., "diets low in sodium may reduce your risk of hypertension") on foods for the general population. Health claims can be made only when the FDA has promulgated regulations and the claim meets specified criteria, such as: use of defined terms, prescribed message components, and the conditions that a food must meet before it is eligible to bear a claim. There is a petition process by which an interested person can request that the FDA amend existing or authorize new health or nutrient content claim regulations.

Infant formulas and foods, to bear nutrient content and health claims, must follow the same general principles as foods for the general population. However, NLEA-type health claims for foods for the general population cannot be used on infant formulas and foods unless they have been specifically authorized for these foods. For example, the authorized health claim for sodium and hypertension cannot be used on infant formulas and foods because there is no specific provision in the authorizing regulation for its use on products marketed for infants.

In this chapter, I limit my discussion to NLEA-type health claims for "regular" infant formulas intended for use by healthy, full-term infants and to those infant foods marketed for the general population of healthy infants. To date, there are no authorizing regulations for health claims for infant formulas and foods under the NLEA provisions of the act. Claims on exempt infant formulas and medical foods are outside the scope of this chapter, because they are exempted from NLEA requirements. Additionally, claims that a product is useful in the diagnosis, cure, treatment, mitigation, or prevention of a disease could cause a product to be regulated as a drug and are also outside the scope of this chapter.
HEALTH CLAIMS: GENERAL ISSUES

What is a health claim under NLEA? A health claim has two components: the food substance that is the subject of the claim and the disease or health-related condition that is affected by consumption of the food substance. Reference to the disease or health-related condition may be explicitly stated or implied through use of symbols or other means. Examples of implicit claims include "third party" endorsements (e.g., the American Heart Association recommends . . . ), written statements (e.g., a brand name including a term such as "heart healthy"), symbols (e.g., a picture of a heart), or vignettes that would likely be understood to assert a claimed benefit for the product.

The scientific standard that a food substance/disease relationship must meet to be authorized for use as a health claim is defined as "significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." This agreement must be based on the totality of the available scientific evidence. Any data that are used to develop this regulation must be publicly available. The underlying scientific evidence does not have to be in peer-reviewed journals, but it must be in the public domain and available through the FDA’s public docket when a regulation is proposed or finalized. Review of a potential health claim topic can be initiated through action of the Food and Drug Administration or, more commonly, by a petition from an interested person.

To understand health claims for infant formulas and foods, it is necessary to understand health claims as applied to foods for the general U.S. population. Health claims on foods differ in several ways from the dietary management/special nutritional needs claims of medical foods/exempt infant formulas and disease-related drug claims. Food health claims usually describe risk-reduction benefits for the general population of healthy people. With health claims, the food substance/disease relationship must be described within the context of a total daily diet (e.g., diets low in fat may reduce the risk of some types of cancer). Intakes needed to achieve the expected benefit do not need to be provided by a single serving of a food or single product but can be achieved by selecting multiple servings from "good sources" of the targeted substance (i.e., more than 10% of the RDI per reference serving) if that substance is a "positive nutrient" (e.g., calcium) or "low" sources of a "negative nutrient" (e.g., fat).

For food health claims, the expected benefit is often a future benefit, delayed in its effect (e.g., high calcium intakes in adolescent years may reduce the risk of osteoporosis in later years). The expected benefit often applies to some but not all persons. For example, with the fat and cancer health claim, not all persons are at equal risk of cancer, and not all cancer risks are responsive to lowered intakes of fat. Thus, the number of persons benefiting from a low-fat diet with respect to development of cancer is likely smaller than the number of persons following the general dietary guidance to consume low-fat diets for this purpose. Indeed, without practical ways for consumers to identify their risks and individual responsiveness to dietary guidelines, most health claims are broad-brushed, encouraging dietary
modifications for the general population. Conversely, for medical foods/exempt infant formulas and drugs, use is generally targeted to those persons who exhibit the signs and symptoms associated with a disease or health condition. Persons unlikely to benefit are not likely to be exposed to the substance of interest.

HEALTH CLAIMS: INFANT FORMULAS AND FOODS

There are unique characteristics of regular infant formulas that raise questions about how best to apply the NLEA health claims provisions to these formulas. In the United States, we have requirements that all regular infant formulas meet certain nutrient composition and bioavailability criteria. All of these formulas are required by regulation to meet the nutritional needs of rapidly growing infants when consumed as the sole source of nutrition. Therefore, the question arises: If health claims would give some infant formulas "specialness" over other marketed formulas because of a contained substance that is claimed to have advantages relative to an infant’s risk of a disease or health condition, what should the substances be? If all marketed formulas are nutritionally adequate, does that mean that health claims should be used only for substances other than essential nutrients? If health claims are focused primarily on reduction in risk of future health problems or disease conditions, what role do they serve in infant formulas? At this time, one can only speculate as to the kinds of conditions that might be forwarded as possible topics for health claims on infant formulas and foods because, to date, the FDA has not received any petitions for these claims. Would it be appropriate to allow health claims on infant formulas containing substances that will reduce the risk (i.e., incidence, severity, or duration) of common infant illnesses (e.g., childhood viruses, ear infections, or diarrhea) or decrease the likelihood of developing or delay the onset or severity of food intolerances and sensitivities (e.g., protein allergies)? Are health claims appropriate for other common conditions of young infants (e.g., colic, spitting-up, and regurgitation)? These issues will undoubtedly provoke considerable debate in the next few years.

One question in reviewing health claims for infant formulas and foods will be an identification of who will benefit? If there is convincing substantiation that the food substance/disease relationship is valid and there are no unresolved safety concerns, there are at least four possible scenarios as to who benefits. The first is the case where all infants would benefit. In this case, the health claim needs to be authorized expeditiously because failure to do so would deny provision of an optimum formula. However, this scenario also suggests that the regulatory nutrient requirements for all infant formulas be revised to require mandatory addition of the documented beneficial substance to all marketed formulas. Moreover, if the result is that all infant formulas must contain the substance of interest, this quickly becomes a situation where a health claim is inappropriate because it implies differences among formulas that are no longer the case.

The second possible scenario is that there is no demonstrable benefit under the conditions in which the formula would be used, but there are data from quite different
conditions of use (e.g., higher-risk subgroup or larger intakes). To implement a health claim under these conditions requires extrapolation of results from one condition to a quite different, more general condition of use. Extrapolations of this type, although requiring a great deal of judgment, are commonly encountered challenges, particularly where it may be impractical or costly to substantiate a benefit under conditions that more closely mimic actual use. The key need is to define what principles and criteria should be followed for making data extrapolations from one context to another when evaluating the validity of a food substance/disease relationship for infant formulas and foods. This is currently, and is likely to remain, a very controversial issue.

The third possible scenario is the case where a subgroup of healthy infants would benefit, and health care providers or parents can accurately indentify those children. In this case, label information may be useful for targeting the groups that will benefit and those that will not benefit. To date, this scenario has been rarely encountered.

Finally, a common scenario is a subgroup of infants that is likely to benefit, but the health care providers or parents in that subgroup cannot reliably identify their infants as responders or nonresponders. In this case, safety of exposure to the test substance must be documented for all infants, regardless of expected benefit, because all could be exposed.

SAFETY

A single formula product frequently serves as the sole source of nutrition for several months or more in young infants who are undergoing a very rapid and crucial period of growth and development. Additionally, the intake of infants and, consequently, the exposure of infants to substances in that formula, is higher on a per-kilogram body weight basis than at any other stage of the life cycle. With these high exposures and developmental vulnerabilities, there is simply no room for error. We can’t allow a claim that would cause a manufacturer to be motivated to make an unsafe product. We also cannot allow a claim that would motivate parents to use a product in an unsafe way. Unlike foods consumed as part of a mixed diet by adults, infant formulas and foods have a much narrower tolerance for mistakes. Consequently, safety evaluations done for ingredients for the general food supply may need to be reexamined for infant use because of the higher exposures and more immature physiological systems of young infants.

Potential safety concerns should be resolved before health claim topics are evaluated. Often, people tend to address the possible benefits and give relatively little attention to safety questions. However, it cannot be assumed that a study designed to show benefit is an adequate basis to establish safety. For example, a larger sample size is often needed to document safety than to document a benefit. Moreover, safety problems may be undetected or undocumented if the study design and conduct fail to identify and systematically monitor endpoints related to safety.

Safety concerns are of two types: (a) the ingredient source that provides the substance of interest and (b) the substance that is being added for a particular benefit.
Nutrients and beneficial food substances are rarely added solely as nutrients or isolated substances. Rather, they are added as food ingredients that contain other substances. Sometimes, a nutrient is the major component of the source material (e.g., vitamin B₃ from pyridoxine hydrochloride). Sometimes, it is a minor component of the source material (e.g., linoleic acid in an oil ingredient). For ingredients’ sources, a key question is what else comes with the targeted nutrient/substance? Many ingredients have a long history of use in infant formulas and raise no concerns. However, increasingly, manufacturers are interested in adding ingredients without a history of use. These ingredients may be produced by novel means or from novel sources (e.g., fungal/algal sources of LC-PUFAs) or may be added in fairly large amounts (e.g., oils, sources of fatty acids).

Ingredient additions rarely result in unidirectional change, i.e., in increasing the food substance of interest without changing anything else. The new ingredient frequently dilutes or replaces other ingredients and, as noted above, brings other substances with it. The new ingredient may change ratios among nutrients (e.g., among fatty acids or amino acids), may result in interactions that alter the bioavailability of the food substance or other nutrients/desired substances in the formula, or may displace another substance with an unrecognized benefit. Thus, to minimize the likelihood of unintended and unexpected adverse effects, adequate evaluation of safety is an essential prerequisite to health claim evaluations for infants.

The safety of the food substance per se may also need to be addressed. These are presumably biologically active substances, and, as such, they can produce benefit and/or risk. A frequent assumption is that adding a food substance to formula at the same level as is found in human milk is adequate assurance of safety. However, similar chemical composition does not necessarily equal biological equivalence in terms of both benefit and risk. For example, if infant formula is designed to contain the same level of iron as human milk, the infant would receive inadequate iron nutriture. If ratios among fatty acids are significantly modified, they may alter eicosanoid production, resulting in adverse effects on immune function. Thus, chemical equivalence of a food substance in a formula to human milk is a necessary part of the safety evaluation but may be an insufficient basis for evaluating safety. Biological effects in the consuming infant will also need to be evaluated.

SCIENTIFIC EVIDENCE

The nature of health claims (e.g., risk reduction or future benefit in currently healthy infants) presents scientific challenges that must be resolved with sound evidence. A current controversy relative to health claims on food products in the United States is what kind of research is needed, how many studies are needed, and how best to integrate information from different types of studies. These knotty questions will likely be debated for some time.

Science generally follows a continuum from hypothesis to consensus. The legal concept of “significant scientific agreement” occurs somewhere between these two
poles. If we authorize health claims with very preliminary data, we will have many claims, but there will be little motivation for manufacturers to do more research. Thus, the state-of-the-art knowledge base likely will not progress beyond a very preliminary level. If health claims are prematurely authorized, the expected benefits may not be real, and parents will be misled. Moreover, if the data are preliminary, unexpected safety concerns may arise under conditions of widespread use. Conversely, if scientific standards are too high, it will be too costly to carry out the research, and this will discourage funding of research needed to substantiate new claims.

Regardless of the philosophical and legal arguments as to what types and numbers of studies are needed, available evidence relied on to make health claims decisions must be consistent with sound scientific principles of study design and conduct. In evaluating evidence from studies, including clinical trials, documentation of such elements as the randomization scheme, attrition rates and causes, adherence to study protocol, and long-term follow-up is essential for evaluating the quality of the science. Asking questions about these types of study issues doesn’t mean that a drug standard is being imposed for food health claims. Good science is good science. It is not unique to drugs. The difference between foods and drugs should not be that food claims are allowed to be based on bad science while drug decisions must rely on good science. Rather, the differences between the underlying science for foods and drugs evolve from differences in the nature of the hypotheses posed, the test substances used, the target population and conditions of use, and the nature of the endpoints examined. Being able to describe elements of good study design and conduct is good science for health claims for foods as well as for drugs.

SUMMARY

Health claims are food label claims, authorized by regulation, that describe a relationship between a food substance and a disease or health-related condition. To date, no health claims have been considered for infant formulas and foods. In this chapter, the regulatory frameworks and some likely scientific challenges underlying the making of such future decisions are discussed.

REFERENCES

From the 21 Code of Federal Regulations

Part 101: Food Labeling
Subpart A: General Provisions
§101.14 Health claims: General Requirements.
Part 107: Infant Formula
Subpart A: General Provisions
§107.3 Definitions
Subpart B: Labeling
§107.10 Nutrient information
Subpart C: Exempt Infant Formulas
§107.50 Terms and conditions
Subpart D: Nutrient Requirements
§107.100 Nutrient specifications

From the Federal Register

Food labeling: general requirements for health claims for food. FR 58(3) 1993 (Jan 6):2478–2536.

DISCUSSION

Dr. Perman: To what extent is the process collaborative, and to what extent is it judgmental? And does it have to be judgmental and adversarial, even legalistic, by its rules and regulations?

Dr. Yetley: We have an open-door policy for persons who want to come in and talk with us. We also have very limited staff resources, so there is always a limitation on how much time we can spend with individuals. The process does have to occur by rule making, however. Once the petitioner has sent in a petition, the FDA has 100 days to decide whether or not to file the petition in the public docket. During this first 100 days, the petition remains confidential. Within this period of confidentiality, the FDA may inform the petitioner if the agency has particularly serious concerns about the quality or completeness of the petition. The petitioner then has the opportunity to withdraw the petition and consider resubmitting at a later date. By 100 days, however, a decision must be made by the FDA as to whether the petition is complete enough to be filed or whether it should be denied. If it is filed, then the petition becomes public. Ninety days later, the FDA has to either deny the petition or publish a proposed regulation. Once it is proposed, a regulation is open for public comment. The final regulation must address the issues raised in the comments received.

Dr. Uary: The standards that are being applied now may be different from those that have been applied over the last decade or so. Do you undertake review of existing approvals, or is something that got in 10 years ago no longer subjected to review?

Dr. Yetley: Once the FDA has promulgated an authorizing regulation, it is published in the Code of Federal Regulations. Rule making is required to amend or delete it. The FDA would normally go back and review an existing health claim regulation only if there were significant new data. At this point, either the FDA or a petitioner could decide to reexamine the original decision and evaluate the need for revision. If the new data were compelling enough to determine that the original decision needed updating, the FDA would revise the existing regulation through rule making. I also note, however, that the legal authority and implementing regulations for health claims only came into place in January 1993. To date, there are no regulations for health claims for infant formulas and foods.

Dr. Iber: Could you speak of the use of outside consultants and the resources that you have in house to do these reviews if they are complex?

Dr. Yetley: We work very closely with other members of the Public Health Service, for example, with the National Institutes of Health, the Centers for Disease Control, and other Centers within the Food and Drug Administration. We also can go to the FDA Food Advisory Committee (or an ad hoc working group of that Committee) or contract with an external authoritative group (e.g., the Food and Nutrition Board of the Institute of Medicine). The use
of individual outside consultants can also be done on an ad hoc basis but requires that they be brought on as special government employees. This means, among other things, that they must be free of conflicts of interest. It may also trigger requirements for open public meetings.

Dr. Whitehead: I wonder if you could just clarify for me how you decide whether or not something is going to be dealt with as a food or as a drug. For example, melatonin is an anomaly: it is sold in a small capsule but dealt with as a dietary supplement when it is quite clearly a drug. Also, how do you differentiate between a health claim and what one might call a medicinal claim? In other words, what happens if a product is added to a food that is supposed to either prevent a disease or indeed cure it? It seems to me there is quite a big difference between the American way of looking at this and that of the European Union.

Dr. Yetley: Under certain circumstances, melatonin is currently being marketed in the United States as a dietary supplement. As such, it is covered under the Dietary Supplement Health and Education Act, which allows dietary supplements to be marketed without any premarket approval or review by the agency, and which exempts ingredients in these products from FDA’s food additive provisions, providing the supplement product is properly labeled and meets all applicable legal requirements. The legal requirements for dietary supplements differ significantly from requirements for infant formulas and foods. As for differentiating between a drug versus a food claim, if you have a product that is labeled “For the dietary management of diarrhea in infants,” that product may be an exempt formula or a medical food because it is marketed for the dietary management of a disease and is to be used under close medical supervision because you are dealing with a sick child. If the claim is for “reducing the risk of diarrhea,” the product is presumably for consumption by a healthy child, and there is the expectation that, at some time in the future, use of this product will be protective against getting the disease or will reduce the severity of the disease if it is contracted, then this product may be regulated as a food, perhaps as a regular infant formula for which a health claim must be authorized through rule making. Label information suggesting usefulness in the treatment, mitigation, cure, or prevention of a disease renders the product a drug, and it would be regulated under drug provisions of the law. Thus, it is the “intended use” of a product, as defined by accompanying label/labeling information from the manufacturer or retailer, that primarily determines the regulatory status of a product.

Dr. Rey: The FDA is in a very difficult situation with the law because it cannot oppose a claim for a dietary supplement unless it can prove that it causes harm. The burden of proof lies with the administration, not the producer. Have you authorized any health claims for regular infant formula?

Dr. Yetley: We have not received a petition for a health claim for an infant formula, and we have not authorized any such claims for infant products. Again, however, infant formulas are not under the same regulatory provisions as dietary supplements.

Dr. Lucas: The current interest in infant nutrition is no longer nutritional, in a sense. That is a slight exaggeration, but by and large, we know how to meet infant nutritional needs, and we have guidelines for ranges of nutrient intakes. The current excitement in the field is the impact of nutrition on health, that is, within that range of acceptable nutrients, we may in fact be altering long-term health outcomes in children. That type of research is expanding rapidly. It is highly likely that, in the future, a number of medical claims, which you have defined under FDA regulations as drug-type claims, will be made for infant food. I would reckon that for normal infant formulas, that is likely to happen in the next 5 years; it is already happening for specialized formulas. How equipped is the FDA to deal with that as it arises—for instance, modulation of the energy content of formulas could produce significant effects on later body composition that might have implications for obesity? How well are
you going to be able to deal with proper randomized intervention research that meets all your
criteria but that actually makes a drug-type claim for healthy infant foods in terms of disease
prevention.

Dr. Yetley: I think this comes back to my earlier answer—that we will very quickly search
out the necessary expertise from other sources; we have extensive expertise in the National
Institutes of Health, in other branches of the Public Health Service, and in other FDA Centers.
Experts from these agencies have been very helpful. We also have statutory deadlines to
meet, so we have to get health claim petitions and infant formula notifications reviewed and
done within the statutory time lines. It is the notifier’s or petitioner’s responsibility to collate
and document the scientific evidence to facilitate FDA’s review of new or modified infant
formulas and health claim petitions. Moreover, all authorizations of health claims are finalized
through a public rule-making process in which FDA proposes an action and describes the
basis for each of the proposed provisions. The proposal is then open for public comment.
After the comment period, FDA finalizes the regulation based on acceptance or justified
rejection of the public comments. This public notice and comment process, itself, can provide
considerable input from scientists if they choose to participate.

Dr. Yolken: Formulas have additions and modifications that are based on the composition
of breast milk. Does the FDA have any regulations or guidelines on the eventual advertising
of claims concerning a formula’s resemblance to breast milk?

Dr. Yetley: Advertising is controlled by the Federal Trade Commission rather than the
FDA. There are really two issues here. One issue is the claim that says the formula is more
like breast milk. This is really outside the health claim purview and falls into the “truthful
and not misleading” criteria. The second issue is a scientific one, where the claim is that a
formula product is improved over other similar products, and the improvement takes it nearer
to breast milk in quality. This is a difficult scientific question in terms of what you use for
a control group and how you evaluate the evidence. If you wanted to make a claim of this
type, you would likely need to compare infants consuming your formula both to infants
consuming the formula that is being replaced and to breast-fed infants.

Dr. Yolken: If advertising is dealt with by a different agency, is there any way in which
you can try to make sure that health claims made in advertising balance the ones you have
approved?

Dr. Yetley: The Federal Trade Commission regulates advertising, but FDA and FTC do
coordinate on a number of issues. We have a memorandum of understanding to try to be as
consistent as possible and as harmonious as possible in terms of how we deal with health
claims and other nutrition labeling issues.

Dr. Clarke: To my mind, the ultimate health claim is that “breast-feeding provides the
best nutrition for your baby,” and, in compliance with the WHO code, we are required to
claim this in Europe on every product label for infant formulas. I think that is a health claim,
but philosophically, it is rather strange to have a health claim for a product which has no
label attached to it. In Europe, we are required to have a very densely packed label stating
the social and economic disadvantages of changing to infant formula feeding and so on. My
question is, is soy formula considered to be exempt or not?

Dr. Yetley: Generally, soy formulas are considered to be regular formulas.

Dr. Rey: The directive that regulates infant formula in Europe was published in 1991, and
we have accepted only six claims so far. These are all descriptive claims: “lactose-free,”
“sucrose-free,” “lactose-only,” “low-sodium,” “iron-enriched,” and “protein-adapted”
(if the whey protein:casein ratio is not less than 1 and if the total amount of protein is less
than 2.5 g/100 kcal). According to the directive 96/4/EC amending the directive 91/321/EEC,
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reference to "reduced allergen or antigen" properties is now allowed, but several conditions warranting the claim are required. For us, the major one is that the scientific evidence behind the claim should be available to the authorities. So if a company has made a large number of studies to demonstrate or try to demonstrate that the incidence of eczema is reduced with hypoallergenic formula, they can write on the label that the formula is adapted to decrease the incidence of allergy, but if the company has never made any studies to prove such an advantage, it should be under obligation to prove it.

Dr. Fairchild: Dr. Yetley, you talked about three different categories of infant formula claims—the exempt, the health claims, and regular formulas not making health claims—that would be judged on whether the claims were truthful and not misleading. In the area of health claims, we have a name for the standard of substantiation, we call it "significant scientific agreement." In the other two areas, there is no name for the level of substantiation. I wonder if you could say something about the nature of the difference in the data you would expect to see in those three categories.

Dr. Yetley: There are no formal definitions or guidelines. Currently, these other claims are evaluated on a case-by-case basis.

Dr. Lucas: It seems to me that legislation is potentially out of key with what is about to happen or is happening in research in the field. Let us suppose, for instance, that two studies involving over 2000 babies had shown that iron improves neurodevelopment. A formula company involved in both studies could claim legitimately in scientific terms that a formula with iron improves neurodevelopment. As I understand it, legislation prevents that claim from being made in the United States. Why is that?

Dr. Yetley: That is not necessarily true. I don't know exactly how the agency would deal with a claim for neurodevelopment—whether we would call it a health-related condition, in which case it would be covered in the health claim rules, or whether we would deal with it under the "truthful and not misleading" provisions. In either case, the agency would look at the totality of the evidence and would ask what conclusions the qualified world experts would make with the same questions and the same available evidence.

Dr. Glinsmann: Because the infant formula may be the sole source of nutrition for the infant for a period of time, there should not be any formulas that are not supplemented with iron because iron is necessary for neural development. I think eventually the agency must rethink the composition of infant formulas and perhaps have that as a requirement.

Dr. Yetley: The information on the label has to be not only truthful, but not misleading, and it could be that if you simply said it was useful for neural development, it could be very misleading.

Dr. Rey: Dr. Glinsmann already has given a good answer to Dr. Lucas's question. If a nutrient improves the neurodevelopment of a child, it is mandatory to add this to the formula. But in the case of iron, there are two possibilities: the producer can add iron or not add iron in the formula, and if iron is added, he can say that iron is added to the formula. So I think the situation is very clear.

Dr. Przyrembel: There seems to be a major difference between claims on infant formulas in Europe and the United States. In Europe, it is sufficient to say there is iron in a formula, not that it is required for neurodevelopmental function and so on. We expect the people who want to buy it or the doctors who want to prescribe it to know the reasons for doing so. The same is true for LC-PUFAs. Nobody is allowed to say that LC-PUFAs are good for your brain or for your visual acuity.