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FDA's Revised Medical-Foods Policy Impedes Care and Violates the First Amendment

by Sarah Roller and Katie Bond

In May of this year, the Food and Drug Administration (FDA) issued a final version of "Frequently Asked Questions About Medical Foods: Second Edition."[1] Despite numerous comments questioning how the draft guidance defined "medical foods," the final version retained the definition. FDA's narrow interpretation is at odds with the broader and more flexible statutory definition of medical foods and will impede the communication of truthful, well-substantiated information concerning the benefits of food products designed to serve the nutritional needs of disease sufferers. The guidance not only fails to provide an adequate framework for the development and marketing of medical foods, it violates the First Amendment rights of manufacturers and consumers.

Regulatory History of Medical Foods. Medical foods are a subset of "foods for special dietary use."[2] A misbranding provision in the original 1938 Food, Drug, and Cosmetic Act (FDCA) granted FDA authority to regulate the labeling of foods for special dietary uses. FDA has not promulgated rules pursuant to this authority. In 1988, Congress sought to encourage the development of, *inter alia*, medical foods in the Orphan Drug Act Amendments (ODA).[3] The amendments defined "medical food" for the first time to mean:

> [A] food which is formulated to be consumed or administered internally under the supervision of a physician and which is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.[4]

In 1990, Congress passed the Nutrition Labeling and Education Act (NLEA), which created the "health claims" regime for foods for the general population.[5] Medical foods were explicitly exempted from the NLEA requirements.[6] This carve-out preserved the agency's authority to tailor labeling requirements for these specialized products in a manner that is appropriate, accounting for both the disease-related conditions of use and the role that physicians and other health care professionals play in supervising the use of medical foods.

Unfortunately, in the agency's regulations implementing NLEA, the agency significantly narrowed the field of foods that are exempted. In contrast to the statutory definition, FDA's regulation, § 101.9(j)(8), exempts a medical food *only if* it satisfies the following criteria:

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[1] *See* 81 Fed. Reg. 29,866 (May 13, 2016). FDA had previously issued two versions of the first edition in 1997 and 2007.
[2] 21 C.F.R. § 105.3(a)(1). FDA originally enacted this provision in 1941. *See* 6 Fed. Reg. 5921 (Nov. 22, 1941); *see also* 61 Fed. Reg. 60,661 (Nov. 29, 1996) (discussing regulatory history of foods for special dietary use).
[3] *See* Pub. L. 100-290.
[4] 21 U.S.C. § 360ee(b)(3).
[5] *See* Pub. L. 101-535.
[6] 21 U.S.C. §§ 343(q)(5)(A)(iv), (r)(5)(A).

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> (i) It is a specially formulated and processed product for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
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> (ii) It is intended for dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of diet alone;
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> (iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
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> (iv) It is intended to be used under medical supervision; and
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> (v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.[7]

FDA's Updated Guidance on Medical Foods. In the recently issued second edition of FDA's medical-food guidance, the agency states that the criteria in § 101.9(j)(8) "clarif[y] the statutory definition of a medical food."[8] FDA's new guidance also further constricts the category in ways not reflected in the statutory definition. Particularly problematic is FDA's cramped interpretation of the intended use element of the statutory medical-food definition.

The statute specifies that a medical food is "intended for specific dietary management of a disease or condition" for which there are "distinctive nutritional requirements."[9] Whereas "distinctive nutritional requirements" can reasonably be construed to mean virtually any nutritional requirement that differs from the nutritional requirements of the general population, FDA has layered over this element the additional requirement that management of the distinctive nutritional requirement "cannot be achieved by the modification of diet alone."

Discussions of pregnancy and diabetes in the guidance demonstrate how this interpretation can vastly limit the scope of allowable medical foods. The guidance explains that pregnancy is not "a condition for which a medical food could be labeled and marketed" given the requirement in § 101.9(j)(8)(ii) that the distinct nutritional requirements accompanying a condition cannot be managed "by the modification of the normal diet alone."[10] The guidance posits that "generally the levels of micronutrients necessary for pregnancy can be achieved by the modification of the normal diet alone," and "[i]t is generally practicable for women who are pregnant or planning to become pregnant to follow the IOM [Institute of Medicine] and FDA recommendations for nutrient intake within a normal diet."[11] The new guidance also relies on § 101.9(j)(8)(ii) to bar labeling medical foods for use to treat diabetes. The guidance takes the position that a medical food may not be sold for diabetes because "[d]iet therapy is the mainstay of diabetes management" and that "a regular diet can be modified to meet the needs of an individual affected by DM [diabetes mellitus] (along with appropriate drug therapy if necessary)."[12]

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[7] 21 C.F.R. § 101.9(j)(8).

[8] FDA, Frequently Asked Questions About Medical Foods: Second Edition, at Q&A 2 (May 2016).

[9] 21 U.S.C. § 360ee(b)(3).

[10] *Id.* at Q&A 24 (emphasis added).

[11] *Ibid.*

[12] *Id.* at Q&A 26. Consistent with the new final guidance, FDA warning letters have characterized the § 101.9(j)(8) exemption criteria as part of the definition of a medical food and have pointed to the narrowing language from § 101.9(j)(8)(ii) in concluding that certain products are not medical foods. *See, e.g.*, FDA Warning Letter to NVN Therapeutics (Dec. 26, 2013); FDA Warning Letter to Metagenics, Inc. (Aug. 13, 2013); FDA Warning Letter to Focus Laboratories, Inc. (June 3, 2016).

Narrowed Definition Bars Management Claims for Specialized Foods. FDA's narrow interpretation of medical foods subjects specialized products to the regulatory framework that applies to foods for the general population. Most notably, if FDA concludes that a specialized food fails to meet the agency's narrow criteria for "medical foods," the food will be subject to FDA's regimes for health claims and structure/function claims.

According to FDA rules, a "health claim" is "any claim made on the label or in labeling of a food" that expressly or implicitly "characterizes the relationship of any substance to a disease or health-related condition."[13] This broad definition presumably includes claims for any substance that is authorized to be added to food regardless of whether it plays a role as a nutrient. Health claims require prior FDA review and approval[14] and may discuss only reduction in the risk of disease, not the "diagnosis, cure, mitigation, or treatment of disease."[15] Given the broad definition of "health claim," and the concomitant narrow field of disease-prevention claims eligible for approval, a specialized food is effectively barred from being promoted with any claims to manage a disease or other condition unless the food meets FDA's narrow criteria for medical foods. This is the case even if the food, in fact, aids in managing the distinctive nutritional requirements of a disease or condition.

FDA's overly narrow construction of the medical-foods definition combined with the restrictions on health claims means that structure/function claims are the only available option to communicate the benefits of specialized foods not meeting FDA's medical-food criteria. Structure/function claims are limited to claims that "describe the role of a nutrient or dietary ingredient intended to affect the structure or function" or that "characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function."[16] By contrast, specialized nutritional products are designed to meet the unique nutritional needs of people with certain diseases or conditions that fall outside of the "normal structure or function of the body." Structure/function claims, thus, cannot adequately convey the important and scientifically validated role such products play in the nutritional management of certain diseases or conditions.

The health and structure/function claims framework is not tailored for specialized products intended for disease. Yet, this is the regulatory framework that governs specialized products if they do not fit FDA's narrow, new interpretation of medical foods.

FDA's Narrow Interpretation of Medical Food Is Constitutionally Suspect. FDA's interpretation of medical food restricts the ability of manufacturers to disseminate information about their products as well as healthcare consumers' access to that information. The agency's failure to account for the First Amendment exposes the guidance to constitutional challenge. Several recent court decisions in the context of healthcare information bode poorly for FDA's odds of surviving such a challenge.

In *United States v. Caronia*, the US Court of Appeals for the Second Circuit reviewed a lower court's conviction of a pharmaceutical salesperson on charges of conspiracy to introduce a misbranded prescription drug into interstate commerce.[17] The conviction was based solely on truthful promotional statements about off-label use of the drug.

FDA argued on appeal that the FDCA empowers it to restrict the salesperson's truthful speech. The court assessed FDA's action under the Supreme Court's "*Central Hudson* test." Under that test, the government must (1) identify a substantial interest that justifies the restriction; and (2) demonstrate that the restriction "directly advances" the interest and is "[no] more extensive than necessary."[18] The *Caronia* court found that, rather than

[13] 21 C.F.R. § 101.14(a)(1); *see also* 21 U.S.C. § 343(r).
[14] *See* 21 C.F.R. §§ 101.14, 101.70. *See also* 21 U.S.C. § 343(r).
[15] FDA, Guidance for Industry: A Food Labeling Guide, at H1 (Jan. 2013).
[16] 21 C.F.R. § 101.93(f).
[17] 703 F.3d 149, 162 (2d Cir. 2012).
[18] *Bolger v. Young Drugs Prods. Corp.*, 463 U.S. 60, 69 (1983) (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980)).

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further any interest in drug safety or efficacy, prohibiting truthful off-label drug promotion in fact "paternalistically interferes with the ability of physicians and patients to receive potentially relevant treatment information."[19] The court, likewise, found that "[n]umerous, less restrictive alternatives are available" to promote the governmental interests in drug safety or efficacy.[20] The court thus chose not to construe the FDCA in such a manner that it would apply to truthful off-label promotion, and overturned the conviction.

In *Amarin Pharma, Inc. v. FDA*, the plaintiff sought a preliminary injunction barring FDA from taking enforcement action against its truthful off-label promotion.[21] The *Amarin* court rejected FDA's request that it limit *Caronia* to its facts, holding that the Second Circuit's ruling was anchored on firm statutory interpretation and constitutional grounds. It enjoined FDA from prohibiting truthful, non-misleading speech on the off-label use of Amarin's product.[22]

Caronia and *Amarin* significantly complicate any constitutional defense of FDA's medical-food definition. A court would likely agree that FDA has substantial interests in protecting consumers from unsafe foods and preventing misleading claims about foods. FDA's narrow interpretation of medical food, however, fails to directly advance either interest in a manner that is tailored to align with First Amendment requirements. Instead, FDA's interpretation prohibits companies from marketing or promoting entirely safe foods that are used under a physician's supervision and are actually helpful for a disease or condition that has distinctive nutritional requirements. If, in FDA's view, dietary management of the distinctive nutritional requirements could theoretically be accomplished using a conventional diet alone, the producer cannot label or advertise the product for a medical use. This prohibition sweeps too far, impeding entirely truthful commercial speech.

Medical-food consumers would also have ample standing to challenge FDA's guidance under the First Amendment. The guidance's definition prevents patients from accessing information to help manage their diseases. Patients might instead make impractical modifications to their normal dietetic patterns to meet their distinct nutritional requirements (*e.g.*, taking extremely high levels of dietary supplements) in the absence of appropriate medical supervision, which is required for "medical foods" under the ODA definition. For instance, patients with epilepsy may need to follow a ketogenic diet. If not executed properly and under medical supervision, the ketogenic diet can either be ineffective or unsafe.

Also, in reaction to FDA's speech restrictions, medical-food producers may make the economically rational decision to cease production or marketing of such products. That could have an adverse impact on public health. A consensus has developed among diabetes experts that FDA's guidance will prohibit products that are widely used for treatment. The Academy of Nutrition and Dietetics has "urge[d] FDA to reconsider the elimination of diabetes as a medical food indication" given the group's position that "diabetes-specific medical foods" are "clinically- and cost-effective."[23] The Healthcare Nutrition Council and International Formula Council, likewise, have asserted that FDA's "blanket determination about diabetes dietary management" is "inconsistent with how diabetes is managed across the country."[24]

Conclusion. FDA has impaired economic development, inhibited access to health care, and infringed upon Americans' First Amendment rights through its restrictive definition of medical foods. Perhaps by updating its policy to expand the medical foods category in line with the statutory definition as a "food" subcategory (distinct from a drug) and to align labeling requirements with First Amendment and appropriate FDCA requirements, FDA can better support the development and marketing of this important category of healthcare nutrition products.

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[19] 703 F.3d at 162.
[20] *Ibid.*
[21] Op. and Order, No. 15-3588 (S.D.N.Y. Aug. 7, 2015).
[22] *Id.* at *48.
[23] Comments by Academy of Nutrition and Dietetics (Oct. 15, 2013), at 1.
[24] Comments by Healthcare Nutrition Council and International Formula Council, at 14.

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