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A Regulatory and Enforcement View of Retail Medicine

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A Regulatory and Enforcement View of Retail Medicine

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I. Introduction and Overview

The purpose of this paper is to identify issues related to the regulation of health care products, such as foods, including dietary supplements; drugs, and medical devices and their relationship to "retail medicine" as defined by David W. Hilgers in his paper titled "The Rise of Retail Medicine: Adding New Complexity to the Practice of Health Care Law". This paper will attempt to provide an introduction and overview to the laws and regulations governing the manufacturing, advertising, marketing, possessing, using, and selling of such health care products and how these laws apply to retail medicine. As retail medicine has developed and expanded, so have the number of regulatory and enforcement actions as a result of the marketing of medical services and health care products using retail marketing strategies without proper attention to the federal and state laws and regulations governing these health care products and services.

The United States Supreme Court recognized that the "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) (internal quotation marks omitted). Despite the prominence of the States in matters of public health and safety, the United States Congress in 1906 first enacted a significant public health statute, the Food and Drug Act of 1906 to prohibit the manufacture or shipment in interstate commerce of any adulterated or misbranded food or drug. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1986) tracing the development of federal public health law. Similarly, the Texas legislature, in 1911, under their police powers to legislate for the protection of the public health and safety passed Title 71, Chapter 3, Articles 4470-4473, Vernon's Texas Statutes, entitled Food and Drugs, which has subsequently been codified at Chapter 431.001 *et. seq.* of the Texas Health and Safety Code as the Texas Food, Drug, and Cosmetic Act ("TFDCA"). This act has been amended to track the changes (except for parts where the States are preempted) in Section 301 *et. seq.* of the Federal Food, Drug and Cosmetic Act ("FFDCA"). In addition to tracking the federal statute, the TFDCA contains a prohibited act for false advertising that is not contained in the FFDCA. (See §431.021(f) of the TFDCA.)

Another area in which both the federal and Texas legislatures have acted to protect their citizens is the area of false, deceptive, or misleading advertising, acts, and practices. On the federal level, Congress created the Federal Trade Commission ("FTC") who regulates and prosecutes false advertising pursuant to15 USCA §55. In Texas, as in the majority of states, the legislature passed the Deceptive Trade Practices Act ("TDTPA") which is found in Chapter 17 *et.seq.* of the Texas Business and Commerce Code. These laws, in combination with the FFDCA and the TFDCA regulate the advertising and marketing of products in the health care industry in Texas, including foods, dietary supplements, drugs, and medical devices.

II. Regulation of products or services under the FFDCA and the TFDCA

Before the relationships between healthcare products and retail medicine can be examined to determine if the ventures into retail medicine trigger the applicability of the FFDCA and any state food and drug laws, like the TFDCA, a basic understanding of the definitions of foods, dietary supplements, drugs, and medical devices is necessary. Other states have "mini-FFDCA" acts and within these states, the level of enforcement varies greatly with Texas being one of the most active in the enforcement area. If a health care product or a medical service involving one of these products is being sold in the retail medicine setting, then compliance with these food and drug safety laws must occur to avoid regulatory and enforcement actions.

A. Foods, including dietary supplements

The definition of "food" under both the FFDCA and the TFDCA is identical. Both §201(f) of the FFDCA and §431.002(16) of the TFDCA define food as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. Under Texas law, a dietary supplement is not separately defined so it is regulated as a food pursuant to the TFDCA although, of course, all the claims that can be made under federal law (pursuant to section 403(r) of the FFDCA can also be made for dietary supplements in Texas. The term "dietary supplement" is defined in §201(ff) (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); (2) means a product that (A)(I) is intended for ingestion in a form described in section 350(c)(1)(B)(I) of this title; or (ii) complies with section 350(c)(1)(B)(ii) of this title; (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (C) is labeled as a dietary supplement. Under the definition of drugs in §201(g), certain claims are allowed to be made for a dietary supplement in accordance with section 403(r)(6) of this title, but otherwise, dietary supplements under federal law shall be deemed to be a food within the meaning of this chapter. FDA has adopted regulations at 21 C.F.R §101 *et.seq.* for food labeling, including nutrition labeling (21 C.F.R §101.9), nutrient content claims (21 C.F.R §101.13), health claims (21 C.F.R §101.14), misbranding of food (21 C.F.R §101.18), and nutrition labeling of dietary supplements (21 C.F.R §101.36). Both the Federal Food and Drug Administration ("FDA") and the FTC have issued guidance documents related to dietary supplements.[1]

B. Drugs

The term "drug" is defined in §201(g)(1) of the FFDCA as (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). This section states that certain claims are allowed to be made for a dietary supplement in accordance with section 403(r)(6) of this title without misbranding the dietary supplement as a drug. The definition of "drug" under §431.002(14) of the TFDCA tracks the definition in the FFDCA except that the state definition excludes a

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[1] FDA guidance documents on dietary supplements include, but not limited to an "Overview of Dietary Supplements" at www.cfsan.fda.gov/~dms/ds-oview.html; "Claims That Can Be Made for Conventional Foods and Dietary Supplements"at www.cfsan.fda.gov/~dms/hclaims.html; "Label Claims: Structure/Function Claims" at www.cfsan.fda.gov/~dms/labstruc.html; "Food Labeling Guide, Appendix C for Health Claims, Appendix A for Nutrient Content Claims, and Appendix B for Relative (Comparative) Claims" at www.cfsan.fda.gov/~dms/flg-6a.html;and FTC guidance documents on dietary supplements at www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm .

reference to the “official Homoeopathic Pharmacopoeia of the United States”.

C. Devices

The term “device” is defined in §201(h) of the FFDCA generally to mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The definition of “device” under §431.002(13) of the TFDCA tracks the definition in the FFDCA, except in section §431.002(13)(c) which references “principal intended purposes” rather than “primary intended purposes”.

D. Licensing Requirements and Authority to Inspect

Under the TFDCA, food manufacturers, food warehouse operators, and food wholesalers have to be licensed to operate in Texas under §431.222 of the TFDCA, with a separate license for each place of business. To operate as a food manufacturer, food warehouse operator, or food wholesaler without a license is a prohibited act pursuant to §431.021(y) of the TFDCA.

Under the FFDCA, drug and device manufacturers and wholesalers, pursuant to §510(a), (b), and (c) of the FFDCA, have to register with the FDA and are subject to inspection under §510(h) of the FFDCA. A refusal to permit inspection (§301(f) of the FFDCA) and to allow access to records, to permit copying of records, or failure to establish or maintain records §301(e) of the FFDCA) are violations of the prohibited acts in §301 of the FFDCA. Wholesale drug distributors have to file a licensing statement pursuant to §431.202 of the TFDCA, and it is a prohibited act under §431.021(x) of the TFDCA to operate as a wholesale distributor of drugs without filing the licensing statement. Device manufacturers and device distributors have to be licensed under §431.272 of the TFDCA and to operate without these licenses is a violation of prohibited act §431.021(x) of the TFDCA.

Section 431.042 of the TFDCA authorizes the Commissioner of Health or his authorized agent or a health authority to inspect an establishment where a food, drug, device, or cosmetic is manufactured, processed, packed, held for introduction into commerce, or held after the introduction. This provision is not limited to an establishment that is licensed, but can be used to inspect any establishment as defined to protect the health and safety of the public. TDSHS can also access records to show movement in commerce pursuant to §431.044, pursuant to the licensing provisions listed above, and to §431.043 of the TFDCA for those required to maintain records by Chapter 431 of the TFDCA or Section 519 or 520(g) of the FFDCA.

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