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FTC, NOT FDA, SHOULD REGULATE ONLINE FOOD INFORMATION

by

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The Food and Drug Administration ("FDA") plans to "proceed on a case-by-case basis in determining what is 'labeling'" on the Internet and will not "exempt Internet information of food companies from labeling requirements," according to the Agency's November 1, 2001 response to the Washington Legal Foundation's ("WLF") April 13, 2001 citizen petition. Letter from Margaret Dotzel, Associate Commissioner for Policy, FDA, to Daniel J. Popeo and Paul D. Kamenar, WLF (Docket No. 01P-0187/CP1) (Nov. 1, 2001). *See also* WLF, Citizen Petition to Exempt Internet Information from FDA Labeling Requirements (Docket No. 01P-0187/CP1) (Apr. 13, 2001).

WLF's citizen petition was filed after the Agency sent a January 19, 2001 Warning Letter to Ocean Spray Cranberries, Inc., in which FDA threatened to seize the company's inventory because information on its website and related hyperlinks connected ingredients in Ocean Spray juices with the prevention/mitigation of certain diseases, and thereby failed to conform to FDA's food labeling requirements. The Agency's response presents legal and practical difficulties because: (1) regulation of Internet information as labeling is outside the scope of the Agency's authority under the Federal Food, Drug and Cosmetic Act ("FFDCA"); (2) regulation of Internet information as labeling is inconsistent with the First Amendment, as the courts have determined Internet communications should be given the highest level of protection from government intrusion; and (3) proceeding on a case-by-case basis to determine what Internet information is labeling continues to leave the regulated industry without well-reasoned guidance and chills further speech.

FDA Regulation of Internet Information as Labeling Is Inconsistent with the FFDCA. FDA's designation of certain Internet information as labeling exceeds its congressionally-authorized authority to regulate labeling. Congress defined "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) *accompanying such article.* 21 U.S.C. § 321(m) (emphasis added). The Agency asserts in its response to WLF's citizen petition that the progeny of cases emanating from the decision in *Kordel v. United States*, 335 U.S. 345 (1948) supports its contention that information about FDA-regulated products disseminated over the Internet by or for regulated entities meets the definition of labeling.

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The *Kordel* court determined that brochures disseminated by a maker of health food products, which were intended to be read by consumers while using the product, were labeling even though they were distributed separately from the products. As explained in WLF's citizen petition, however, the Court clarified the meaning of the term "accompanying" by explaining that the brochure "was used in the sale [of the product]," "[n]owhere else was the purchaser advised how to use [the product]," and distribution of the brochures "constituted an essential supplement to the label attached to the package." *Id*. at 348. Consequently, the Court determined that "the products and literature were interdependent." *Id*.

In the overwhelming majority of cases, Internet information about FDA-regulated products is not directly used as part of on-line sales, purchasers have access to information on how to use the products from other sources, and the Internet information is not an "essential supplement" to product labels (*i.e.*, the Internet information is available elsewhere). The sale of FDA-regulated products and related Internet information are not, therefore, interdependent. Because there is no direct nexus between product sales and Internet information, such that the Internet information properly can be considered part of an "integrated distribution program," it does not constitute labeling. *See id*. As set forth in FDA's response to WLF's petition, however, the Agency's unduly broad definition of labeling is indistinguishable from advertising. In distinguishing these terms in the FFDCA, however, Congress plainly did not intend this result.

Moreover, *Kordel* was decided in the era of the mimeograph, not the computer, and its teachings are somewhat antiquated in light of the volume of and access to product information in today's marketplace. Unlike the retail settings of 1948, where consumers had limited access to static information about products — primarily at the point of purchase (*e.g.*, from the product label, in-store displays, etc.) — today's consumer has instantaneous access to a vast array of evolving information about products in various contexts, including more extensive product labels, independent peer-reviewed ratings services (*e.g.*, Consumer Reports), on-line scientific/medical databases and information services (*e.g.*, Medline, WebMD, Medscape, DrKoop.com, etc.), and consumer chatrooms. In particular, consumers who utilize the Internet are relatively sophisticated about accessing product and health information, and are able to identify misinformation because of multiple sources of information. Moreover, unlike consumer exposure to product labels and in-store displays, Internet information is neither passively accessed nor generally available at the point of purchase. Consumers proactively seek out most Internet information.

Apart from *Kordel*, FDA offers in its response to WLF's petition four additional cases decided over thirty years ago — that, by definition, do not reflect contemporary facts and ideas about product information — as support for a broad interpretation of the term "accompanying" and, in turn, its conclusion that Internet information is labeling. These cases, however, describe situations in which the questionable information was, in contrast to most Internet information, closely tied to and interdependent with the sale of the products. In *United States v. Diapulse Manufacturing Corp. of America*, 389 F.2d 612, 614 (2d Cir. 1968) the "labeling" consisted of sixteen pieces of printed and graphic matter provided with the medical device (found in a practitioner's office). In *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 38 (1st Cir. 1957), *cert. denied*, 77 S. Ct. 1383 (1957) the "labeling" consisted of leaflets and newsletters comprising a sales kit that "was shown to be an integral part of the selling process." In *United States v. 47 Bottles, More or Less, Jenasol RF Formula "60"*, 320 F.2d 564, 568 (3d Cir. 1963) the "labeling" consisted of promotional leaflets that "unquestionably" were to be used with the product for sales purposes. Finally, in *United States v. Guardian Chemical*, 410 F.2d 157, 161 (2d Cir. 1969) the "labeling" consisted of brochures sent to doctors "as part of an integrated program which included the sale and distribution" of the product.

Assuming that Internet information concerning FDA-related products is not labeling, it is either advertising, which falls under the primary jurisdiction of the Federal Trade Commission ("FTC") consistent with the longstanding FDA/FTC agreement, *see* Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, Part III., 36 Fed. Reg. 18539 (Sept. 16, 1971), or unregulated speech. The FTC uses the more flexible standard of "prior substantiation" in regulating

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advertising. This is consistent with the First Amendment, and arguably better suited to assessing the appropriateness of Internet information. Moreover, the FTC has more relevant expertise to regulate Internet information about FDA-regulated products given its considerable experience in regulating broadcast advertising and developing Internet-related guidance.

FDA Regulation of Internet Information as Labeling Violates the First Amendment. As set forth in WLF's citizen petition, FDA's regulation of Internet information as labeling also violates the First Amendment rights of manufacturers to disseminate truthful information, and the First Amendment rights of consumers to receive such information. As support for this position, WLF documented recent precedent, such as in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), where the courts have determined that FDA has violated the First Amendment by unnecessarily limiting speech concerning FDA-regulated products. In *Thompson v. Western States Medical Center*, 535 U.S. __, 122 S. Ct. 1497 (2002), the Supreme Court reinforced this message to FDA, explaining that "[i]f the First Amendment means anything, it means that regulating speech must be a last — not first — resort." *Id*. at 1507. In the aftermath of *Western States*, FDA has sought public comment to ensure that its regulations, guidances, policies, and practices comply with government First Amendment case, but the Agency's Federal Register notice neither acknowledges the issues raised in WLF's citizen petition nor mentions Internet communications in any respect. *See* Request for Comment on First Amendment Issues, 67 Fed. Reg. 34942 (May 16, 2002).

The courts have also held more generally that Internet communications should be given the highest level of protection from government interference. In the litigation surrounding the Communications Decency Act of 1996 ("CDA"), for example, the courts, recognizing the unique and important characteristics of the Internet, determined that certain provisions of the CDA were unconstitutional as prohibitive of free speech. In *Reno v. ACLU*, 521 U.S. 844, 873, 883, n.30 (1997), for example, the court determined that First Amendment precedent requires a "medium specific" approach to analyzing the regulation of mass communication, and concluded that the Internet — as "the most participatory form of mass speech yet developed" — is entitled to "the highest protection from governmental intrusion."[1] Similarly, in *Zeran v. America Online*, 129 F.3d 327, 330 (4th Cir. 1997), the court acknowledged, consistent with the explicit language of the CDA, that the Internet and interactive computer services offer "a forum for a true diversity of political discourse, unique opportunities for cultural development, and myriad avenues for intellectual activity," and that it is "the policy of the United States . . . to preserve the vibrant and competitive free market that presently exists for the Internet and other interactive computer services, unfettered by Federal or State regulation." *See* 47 U.S.C. § 230(a)(3); *see also Kathleen R. v. City of Livermore*, 87 Cal. App. 4th 684, 697 (2001) ("Section 230 [of the CDA] was enacted, in part, to maintain the robust nature of Internet communication and, accordingly, to keep government interference in the medium to a minimum").

Internet information concerning health care, including truthful information about the health benefits of food products, is widely accessed by consumers and advances an important public health goal. The 13th annual PULSE™ Survey — the largest private survey of U.S. consumer healthcare utilization patterns based on the responses of 100,000 households — revealed in March 2000 that approximately 10% of all U.S. households used the Internet to access health information. *See* Medstat, Results Released from National Consumer Survey of Healthcare Utilization – 13th Annual PULSE™ Survey Largest of Its Kind (Mar. 21, 2000), at http://www.inforumonline.com/news/pressrel.cfm?currletter=2. By the end of 2002, it is estimated that more than 100 million Americans will be using the Internet to access health care information. Given the

[1]The court further explained the unique and important characteristics of Internet communications as follows: "Four related characteristics of Internet communication have a transcendent importance to our shared holding that the CDA is unconstitutional on its face. … First, the Internet presents very low barriers to entry. Second, these barriers to entry are identical for both speakers and listeners. Third, as a result of these low barriers, astoundingly diverse content is available on the Internet. Fourth, the Internet provides significant access to all who wish to speak in the medium, and even creates a relative parity among speakers." *Reno v. ACLU*, 521 U.S. 844, 873, 883, n.30 (1997).

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important health and societal benefits associated with improved diets (*e.g.*, prevention of life-threatening diseases, reduced malnutrition, etc.), providing unfettered access to accurate Internet information about foods and nutrition is vital. Because the science of nutrition is rapidly evolving, this information cannot be effectively conveyed through food labeling.

FDA's contention that Internet information about foods should be considered labeling is yet another instance in which the Agency's overly-paternalistic attitude towards the dissemination of health care information threatens to subvert an important public health goal. Unlike drugs and Class II/III medical devices, there are relatively few safety issues associated with legally-marketed foods, and consumers are not apt to forego established drug/device therapies based on favorable information about foods. Moreover, as noted, the relatively sophisticated consumers who access information about foods on the Internet can readily verify or supplement that information with the click of a mouse.

Particularly in recent years, Congress has sought to override FDA's paternalistic speech restrictions in numerous areas. For example, with the passage of the Dietary Supplement Health and Education Act of 1994, the burden is on FDA to demonstrate that dietary supplements are not safe for use, rather than requiring manufacturers to demonstrate that they are safe. Likewise, several provisions in the FDA Modernization Act of 1997 ("FDAMA") were intended to provide consumers and health care providers with greater access to unregulated health information. Section 113 of FDAMA requires FDA, in cooperation with other agencies in the Department of Health and Human Services, to establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions, and to disseminate the information from this data bank to the public through information systems such as the Internet. Moreover, Sections 401 and 114 of FDAMA were intended to facilitate the dissemination of information about (1) the safety, effectiveness, or benefits of uses not described in the approved labeling of a drug or device to health care practitioners, pharmacy benefit managers, and health insurers, and (2) health care economic information about drugs to hospitals and other institutional formulary committees and similar entities, respectively. Given these and other similar directives, Congress likely would be equally skeptical of FDA's efforts to regulate Internet information as labeling.

FDA's Case-by-Case Approach Leaves the Regulated Industry without Guidance and Chills Speech. In its response to WLF's citizen petition, FDA stated that "if a company were to promote a regulated product on its website and allow consumers to purchase the product directly from the website, the website is likely to be 'labeling,'" and that it will "proceed on a case-by-case basis in determining what is 'labeling.'"

The Agency's planned case-by-case approach will continue to chill important speech. Absent guideposts on the scope of health and nutrition information that can be provided on-line in different contexts, conscientious food manufacturers and marketers will remain unnecessarily conservative in communicating information about their products.

FDA is correct that a narrowly-construed, labeling-focused "rule or guidance would be quickly outdated due to the ongoing rapid changes in the Internet and its use." *See* Letter from Margaret Dotzel, Associate Commissioner for Policy, FDA, to Daniel J. Popeo and Paul D. Kamenar, WLF (Docket No. 01P-0187/CP1) (Nov. 1, 2001). The solution, however, is not for the Agency to continue to use old paradigms for regulation of new technologies. The FTC has had no difficulty in applying the more flexible standard of "prior substantiation" to Internet information, and providing understandable guidance to on-line companies. FDA should step aside and allow FTC to regulate health and nutritional information about food products on the Internet.

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