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EXCESSIVE FDA SCRUTINY OF DTC ADS UNDERMINES SPEECH RIGHTS

by

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As direct-to-consumer (DTC) television advertising of prescription drugs has become highly visible, criticism of such advertising has escalated. DTC drug advertising has increasingly been the scapegoat for rising drug costs. This rhetoric is now reaching its crescendo as the Food and Drug Administration (FDA) completes a two-year evaluation of its DTC advertising policies.

DTC advertising of prescription drugs has increased substantially since 1997, both in terms of overall spending and the number and types of products advertised. The factors contributing to this growth include changes in FDA policy, consumer interest in health care, the growth of managed care, and competitive forces in the marketplace. The potential advantages and disadvantages of DTC advertising — increased consumer awareness and higher prescription drug prices and use — have been well documented and continue to be debated.

FDA's review of its DTC policies should not focus on such economic concerns, which are outside the Agency's purview and expertise. Instead, FDA's review properly should focus on whether DTC advertising presents safety concerns, and whether consumers are adequately receiving and continuing treatment for illnesses and other conditions. Focusing on drug costs is not only improper for FDA, it ignores a practical explanation for DTC advertising's potential contribution to increased drug costs — consumers might simply be responding to the availability of new therapies that thankfully address their health conditions and improve their quality of life.

The attention to drug costs and increasing DTC advertising has overshadowed FDA's draconian enforcement efforts, which have increasingly focused on minutia in broadcast advertisements. As FDA's DTC advertising policies come under review, the Agency's actions should also be scrutinized, since they raise provocative constitutional and administrative law issues and may be ripe for challenge.

Regulation of Prescription Drug Advertising. FDA's authority for regulating prescription drug advertising is derived from the Federal Food, Drug and Cosmetic Act (FFDCA or the Act). The specific requirements that pertain to a prescription drug advertisement depend upon the vehicle. Broadcast advertisements must include a "major statement" of side effects and contraindications in the audio and/or visual as well as a brief summary of side effects, contraindications, and effectiveness, unless adequate provision is made for disseminating the drug's approved labeling.

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Historically, uncertainty about how to meet these requirements stifled the proliferation of broadcast DTC advertisements, resulting in marginally informative "reminder" or "help-seeking" commercials — providing only the name of the drug or information about a related disease/condition, respectively — designed to avoid regulatory requirements.

FDA largely resolved this ambiguity in its consumer-directed broadcast advertising guidance, that sets forth an approach for satisfying the adequate provision alternative to providing a brief summary. FDA, Guidance for Industry: Consumer-Directed Broadcast Advertisements Guidance (1999). FDA recommends that advertisers satisfy the adequate provision requirement by providing consumers with four opportunities through the advertisement to obtain a drug's complete labeling: (1) a toll-free telephone number, whereby consumers can either have the labeling read aloud or mailed to them; (2) concurrent, widespread print advertisements or brochures targeted to reach the exposed audience; (3) an Internet webpage that provides access to the labeling; and (4) a statement that additional product information can be provided by physicians, pharmacists, and other health care professionals. FDA's planned two-year evaluation of this policy is set to conclude in August 2001.

DTC Advertising of Prescription Drugs. In 2000, drug companies spent more than 2.1 billion advertising their products directly to consumers, a 17% increase over 1999. Julie Appleby, *Prescriptions Increase as Drugmakers Spend More on Ads*, USA TODAY, Feb. 21, 2001, at 6B. Consumers also purchased more drugs — prescriptions rose 6% and industry-wide sales increased 15% from $126 billion to $145 billion. *Id*. This increase may be the result of several factors, including new, more expensive drugs being introduced into the market, an aging population, and price increases. In turn, drug prices rose 3.9% in 2000. *Id*.

The ten prescription drugs most heavily marketed to consumers are indicated for allergies (Clartin, Flonase, Zyrtec, and Allegra), arthritis (Celebrex and Vioxx), ulcers/heartburn (Prilosec), erectile dysfunction (Viagra), depression (Paxil), and osteoporosis (Prempro). Id. Advertising expenditures for allergy and arthritis drugs continue to outpace other categories, with each representing about 10% of total DTC advertising spending. *Id*.

Recent FDA Enforcement Actions. To say that FDA has been active in enforcing DTC advertising requirements is a gross oversimplification. Untitled letters and Warning Letters certainly abound for DTC advertising violations, but this is to be expected given the increasing numbers of ads. The more insightful, and disconcerting, aspect of FDA's approach is the focus of its scrutiny.

While FDA's focus on the adequacy of information about side effects and contraindications may be warranted, the Agency has become exceedingly immersed in critiquing how imagery and the audio/visual information in broadcast ads convey information about risks and effectiveness. With limited resources, FDA has made the review of DTC television advertisements a priority. Some examples are illustrative of the Agency's approach:

> •FDA found a Celebrex advertisement misleading because "the totality of the images, the music, and audio statements . . .[including] supers such as ‘Bill-arthritic knees,' various multiple physical activities portrayed by arthritis patients (such as rowing a boat and riding a scooter), the soundtrack "Celebrate, Celebrate. Do what you like to do, [and an audio statement about relief from arthritis pain and stiffness]" overstate the effectiveness of Celebrex. Warning Letter from Spencer Salis, Pharm.D., Regulatory Review Officer, DDMAC, to Jerome M. Prahl, Associate Director, Regulatory Affairs, G.D. Searle & Co. (Nov. 14, 2000).
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> •An advertisement for Vaniqa (for slowing the growth of unwanted facial hair) was considered misleading by FDA because "the use of small type and ambiguous language . . .[including] ‘Works with current hair removal methods . . . inadequately communicates . . . the necessity of continued use of the patient's current hair removal techniques while using Vaniqa.'" Warning Letter from Cheryl Y. Roberts, M.S., J.D., Regulatory Review Officer, DDMAC, to Roma Plakyda, Regulatory Services Specialist, Bristol-Myers Squibb Company (Nov. 15, 2000).

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•A Sarafem (for premenstrual dysphoric disorder, or PMDD) advertisement — showing an exasperated woman struggling with a shopping cart with concurrent audio stating "Think it's PMS? It could be PMDD."— was deemed misleading because "the imagery and audio presentation of the advertisement never completely define or accurately illustrate [PMDD] and there is no clear distinction between premenstrual syndrome (PMS) and PMDD communicated." Warning Letter from Lisa L. Stockbridge, Ph.D., Regulatory Reviewer, DDMAC, to Gregory T. Brophy, Ph.D., Director, U.S. Regulatory Affairs, Eli Lilly and Company (Nov. 16, 2000).

Marketers often repeatedly run afoul of FDA scrutiny when the issues involve an advertisement's audio/visual presentations, even after submitting ads to FDA for review. While FDA has only requested one corrective action campaign stemming from television advertising, (Warning Letter from Minnie Baylor-Henry, Director DDMAC, to Wayne Yetter, President and CEO, Novartis Pharmaceuticals Corporation (Jan. 21, 1999)), some companies have been inclined to voluntarily broadcast corrective DTC ads where the Agency has been particularly vigorous in its criticism. In response to the Agency's concerns with the Celebrex advertisement, for example, Pharmacia ran a corrective advertisement with a new jingle "Celebrate, Celebrate. Come on and celebrate," and added the disclaimer "individual results will vary." *Merck, Pharmacia Broadcast Corrective Direct-to-consumer Television Ads*, FDA ADV. AND PROMOTION MAN., Jan 2001, at 1.

The Agency's intense scrutiny of DTC ads is unlikely to diminish in the future. FDA Division of Drug Marketing, Advertising and Communications (DDMAC) Director Tom Abrams announced that a key advertising/promotion regulatory initiative for 2001 will be to evaluate the use of brief summaries in DTC advertisements, and the extent to which they provide for adequate and accurate disclosure of product risk information. Abrams has also indicated that alternative approaches for providing risk information to consumers may be considered.

FDA Orientation Towards DTC Advertising. FDA's stated mission is "to promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use." Notably absent from FDA's mission is protecting the public from economic injury. This is relevant because, in many cases, FDA's scrutiny of imagery and audio/visual information in DTC ads that speak to drug effectiveness present economic, not safety, issues. DDMAC Director Abrams recently summed up the Agency's impetus for closely regulating DTC advertising as follows: "We don't think public health is being served if the public is being exposed to unbalanced messages." Chris Adams, *FDA Scrambles to Police Drug Ads' Truthfulness*, WALL ST. J., Jan. 2, 2001. While inadequate information in an advertisement may present a safety issue, the converse is not necessarily true with respect to an overstatement of effectiveness. Just because an advertisement potentially overstates a drug's effectiveness does not mean the ad lacks sufficient safety information — this is not a zero-sum game. FDA's enforcement of balanced messages when the potential for injury is purely economic, is arguably outside the Agency's authority.

As detailed above, the most heavily advertised prescription drugs are intended to improve quality-of-life — such as for the relief of arthritis and allergy symptoms — not serious life-threatening conditions. FDA's focus on imagery and audio/visual cues in DTC ads that involve the effectiveness of these medications seems misplaced. What ill is FDA trying to prevent? If a consumer — after consulting with his or her physician and receiving a prescription — starts taking a COX-2 inhibitor and cannot, thereafter, "ride a scooter" to the extent shown in the ad, what injury, other than the additional cost of the medication, has the consumer experienced? Dashed hopes? These medications are generally more effective — and may be safer — than the over-the-counter alternatives.[1] And consumers are not naïve — they understand there is a certain amount of puffery in all advertisements, even those for drugs. Senior citizens viewing such ads may not expect, or desire, to ride a scooter, but may be grateful to learn of a treatment for arthritis that would make it easier to walk a few blocks.

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[1]COX-2 inhibitors such as Celebrex and Vioxx may present a lower risk of serious stomach problems than non-steroidal anti-inflammatory drugs such as ibuprofen and acetaminophen.

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Legal and Strategic Options for FDA and Industry. FDA usually orders violators to pull or alter their DTC ads or, in a minority of cases, to run corrective advertising. Companies generally comply because they fear reprisals in both the drug marketing and approval contexts, but the Agency lacks the authority to levy fines for such noncompliance, and it has not exhibited the fortitude to initiate product seizures or injunctions where companies do not heed its advice. FDA and industry, therefore, are at a regulatory crossroads, and it is unclear who has the determination to choose a fork in the road.

While the Federal Trade Commission (FTC), which regulates the advertising for certain FDA-regulated products, has considerable experience regulating advertising directed to consumers, FDA has very little such experience, and its guidance and enforcement often reflect this. FDA has a tendency to apply labeling solutions — such as detailed requirements for making claims — to promotional issues. In light of its increasing criticism of DTC ads, there is a reasonable chance that FDA could institute more elaborate requirements for broadcast advertisements, making them unworkable for industry.

The pharmaceutical industry could continue to let FDA set the agenda for DTC advertising requirements, but it also has several opportunities to take the lead on this issue. Instead of permitting FDA to institute more stringent brief summary requirements, the industry could propose its own DTC advertising standards emphasizing the protection of patient safety. These standards could be based on the generally more flexible FTC advertising requirements. The development of industry standards could prove useful in negotiating with FDA on potentially more rigorous brief summary requirements, as well as in political circles. More importantly, perhaps, individual companies and/or the industry as a whole could seek to challenge the legality of FDA's regulation of minutia in broadcast DTC ads.

Courts may view such a challenge favorably, given that in several well-publicized cases the courts have frowned upon FDA's paternalistic regulation of health care product information, including that directed to consumers. Particularly germane to FDA's regulation of minutia in DTC advertising are the decisions in the *Pearson v. Shalala* case. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). Commensurate with FDA's refusal to authorize the Pearson plaintiff's dietary supplement health claim for folic acid, the U.S. Court of Appeals for the D.C. Circuit held that FDA had to consider less restrictive means of regulating health claims, such as adding disclaimers to make health claims non-misleading. *See Pearson*, 164 F.3d 650. FDA subsequently found the folic acid claim inherently misleading — even with clarifying disclaimers — but exercised its enforcement discretion to propose four alternative qualified claims, each of which was approximately 60 words long. The U.S. District Court for the District of Columbia found that even a cursory examination of the scientific literature that FDA relied upon in making its decision — including a clinical intervention trial involving over 2,000 women who took supplements containing 0.8 mg of folic acid — revealed that FDA's determination that the claim was inherently misleading and could not be cured by disclaimers was arbitrary and capricious. *Pearson v. Shalala*, 2001 U.S. Dist. LEXIS 1253, 1282 (D.D.C. 2001). Because the Court found that the plaintiff's claim was only "potentially misleading" (and thus not denied First Amendment protection), it ordered the Agency to draft "more appropriately short, succinct, and accurate disclaimers" to be used by dietary supplement marketers. *Id.* at 1299.

The *Pearson* holdings demonstrate that it is possible to successfully challenge FDA on its micro-management of promotional messages, particularly if a company has the right data. If a company has data that demonstrates, for instance, that a DTC ad properly communicates to consumers the scope of the effectiveness of its drug, it could challenge FDA assertions to the contrary. Using available marketing research methodologies, it is possible to develop valid and reliable data that address these issues. Initially, such a challenge might involve a strong response to a relevant untitled letter or Warning Letter, but if FDA refused to relent, a court challenge could be brought. A court challenge may not efficiently address a company's goals concerning a particular short-lived DTC ad, and the added benefit of a stronger effectiveness presentation may not be worth the time or cost. But as blockbuster drugs continue to be critically important to the long-term financial survival of pharmaceutical companies, such a challenge may be worthwhile if it curtails overzealous FDA intervention.

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