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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: First Amendment Issues, Docket No. 02N-0209

Johnson & Johnson appreciates the opportunity to provide comments to the Food and Drug Administration ("FDA") regarding the compliance of FDA's regulations, guidance documents, policies, and practices with First Amendment jurisprudence. Johnson & Johnson is the world's most comprehensive and broadly based manufacturer of health care products for the consumer, pharmaceutical, and medical devices and diagnostics markets.

As a member of both the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Advanced Medical Technology Association ("AdvaMed"), Johnson & Johnson agrees with the comments and legal analysis that these organizations are submitting to this docket. We are writing separately to emphasize the importance of areas of specific interest to Johnson & Johnson companies.

I. GENERAL COMMENTS

Johnson & Johnson urges FDA to institute more rigorous internal and external processes designed to safeguard First Amendment freedoms whenever its actions regulate the speech of the pharmaceutical, device and diagnostic industries. Such processes should seek to achieve FDA's public health mission while simultaneously allowing the free flow of accurate and non-misleading information to health care professionals, institutional providers, and patients.

FDA should ensure that its actions are consistent with governing First Amendment case law, and it should explicitly consider the impact on speech that its actions are likely to have prior to instituting any action. FDA should make an assessment before FDA creates policy, interprets or promulgates regulations, issues guidance documents, or enforces laws and regulations related to labeling, advertising or the exchange of scientific information.

It would be inappropriate for FDA to pursue enforcement actions against companies when FDA knows, or should know, that the enforcement action could not survive a legal

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challenge. Therefore, the legal rationale must be established and well-documented prior to any enforcement action.

II. SPECIFIC AREAS OF INTEREST

In response to the request for specific FDA policies and regulations that should be reevaluated in light of the First Amendment case law, we suggest the following areas.

A. REPRINTS AND SCIENTIFIC EXCHANGE

FDA has a legitimate interest in preventing companies from making false and misleading claims about their products, including unsupported claims that fall outside of the approved indication for the product. Physicians and health care providers should be able to rely on the labeling claims of a product without having to conduct their own scientific research every time they prescribe a product. However, in accordance with First Amendment case law, when speech about a lawful activity is not misleading, FDA must satisfy the requirements of *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980) in order to justify a restriction on the speech. FDA's restriction must (1) promote a substantial government interest, (2) directly advance that interest, and (3) be no more extensive than necessary to achieve the asserted government interest.

While we acknowledge FDA's interest in ensuring that the health care community and patients have access to accurate information upon which they may rely in making treatment decisions, any policies and enforcement actions that FDA takes must directly advance that interest and be no more extensive than necessary to achieve that interest. In practice, any restriction on the dissemination of information on off-label uses should be explicitly balanced against the equally important interest of companies and the medical community in the exchange of scientific information about products and diseases.

Companies should be allowed to present truthful and non-misleading data about off-label uses of a product as part of legitimate scientific exchange. FDA should create standards regarding off-label promotion that ensure that data is presented in a fair and balanced manner, and that allows health care practitioners to make decisions about treatment based on the data that is available, even if the treatment decision is to use a product for an indication or use that has not been approved by FDA. Appropriate disclosures that accompany information on off-label uses should inform practitioners that the product has not been approved, and information provided should not be misleading.

Consistent with First Amendment law, companies should be able to distribute to healthcare providers and physicians reprints of articles from the medical literature that contain information considered to be off-label as long as:

(1) the product is approved by FDA; (2) the article has been published in a peer-reviewed, scientifically credible journal that is independent of the company; (3) the content of the article is not false or misleading; and (4) the article is accompanied by appropriate disclaimers informing the reader that the product has not been approved for the use discussed.

B. DIRECT TO CONSUMER ADVERTISING

1. Summary of Comments

Johnson & Johnson agrees with PhRMA and AdvaMed that direct to consumer advertising (“DTC”) is a form of commercial speech that is protected by the First Amendment. FDA may only impose restrictions on DTC consistent with its designated statutory and legal authority, and in accordance with the case law, including the *Central Hudson* case and its progeny. FDA may not impose restrictions on speech that is not misleading or inherently false, and that serves the legitimate purpose of educating consumers about disease and treatment.

There are numerous benefits to DTC advertising. Better patient outcomes can often be achieved due to awareness and interest created by DTC. Physicians, although often skeptical of the merits of DTC, welcome the new patient awareness and increased opportunity for patient dialogue and discussion it creates.

2. Restrictions on DTC are Not Constitutionally Permissible

DTC advertising is like other forms of commercial speech that are constitutionally protected. Except as provided below, we believe that it is not constitutionally permissible to impose special restrictions on DTC which is truthful and not misleading. Although FDA has not imposed any special restrictions on DTC advertising, we are aware that FDA has recently been exploring the imposition of additional regulation.

FDA should be mindful that it is not permissible to suppress truthful speech for fear that the speech will cause its audience to respond irrationally. *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S.484, 503 (1996); *Virginia Bd of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 772. Courts have consistently held that such a view undermines the public’s ability to make rational decisions based on truthful information. Social science data (referenced below) demonstrates that consumers and physicians are able to comprehend and retain important information provided through DTC, and that they act rationally with regard to demand for, and prescription of, advertised products. Therefore, FDA should not impose restrictions on DTC advertisements that provide valuable information to consumers in a manner that is truthful, fair and balanced.

3. FDA Must Act Within Its Legal Authority When Placing Restrictions on DTC

FDA is empowered by statute only to regulate advertising of prescription drugs and restricted devices.¹ FDA does not have the statutory authority to regulate or to take enforcement action related to the advertisement of non-restricted medical devices, OTC prescription products, or cosmetics. Rather, the Federal Trade Commission ("FTC"), which is authorized by law to protect consumers from deceptive or misleading messages in advertisements, should enforce violations of consumer protection laws in these categories.

For those advertisements over which FDA has legitimate statutory authority, the agency should adopt a process of enforcement that is modeled after FTC's enforcement approach, focusing on substantiation of claims, lack of deception and fairness. It should establish a forum in which challenges may be brought by the FDA on the grounds that advertisements are false and misleading, and manufacturers are afforded the opportunity to respond, before enforcement action may be taken.

This type of forum would be especially helpful in the realm of DTC television advertisements. Currently, if FDA is concerned about the content of a DTC television advertisement, it requests that the advertisement be immediately removed by the sponsor. If the sponsor fails to remove the advertisement, FDA will notify the networks that the advertisement violates the law. On this advice from a federal agency, the networks immediately withdraw the advertisement. At a minimum, FDA should provide companies an opportunity to meet with FDA to discuss FDA's concerns with the advertisement, prior to contacting the networks.

4. DTC Advertising Provides Benefits to Patients and the Medical Community

a. Patient Benefits

FDA has recognized the benefits of DTC advertising, which include better patient compliance with medication regimens, and the increased willingness of patients to seek treatment for under-diagnosed diseases.² Along with AdvaMed and PhRMA, we agree that

¹ Note that it is arguable that FDA has the legal authority to restrict a device through the premarket approval ("PMA") process, as opposed to through the issuance of a regulation. CDRH has taken the position that all PMA devices are restricted devices, and includes language to that effect in approval letters.

² Center for Drug Evaluation and Research, Attitudes and behaviors associated with direct-to-consumer (DTC) promotion of prescription drugs; main survey results. Rockville, Md., Food and Drug Administration, 1999. (Visited 9/12/02) <<http://www.fda.gov/cder/ddmac/dtcindex.htm>>; Presentation by Kathryn Aikin, Ph.D., Division of Drug Marketing, Advertising and Communications, Food and Drug Administration, (April 18, 2002) (visited 8/19/02) <<http://www.fda.gov/cder/ddmac/DTCnational12002a/sld001.htm>>.

broad dissemination of truthful information serves both the public good and the medical community, by improving compliance and appropriate treatment.

For example, both formal and informal studies have shown various benefits to consumers who are exposed to DTC advertising.³ DTC encourages patients to seek appropriate medical care, and to actively participate in their care once they seek it. At least one study has shown that patients with common, chronic diseases such as allergies, diabetes, and ulcers, value DTC advertising, and have been encouraged by exposure to DTC to seek ongoing care and advice from their physicians.⁴ DTC that is fair and balanced encourages patients to actively participate in decision-making about their health care, by increasing awareness of therapeutic options and by encouraging patients to seek more information and actively participate in their health care.⁵

It is clear that active patient involvement in seeking advice, treatment, and care ultimately leads to better outcomes for patients.⁶ However, many patients with certain “stigmatizing” diseases such as sexual dysfunction, HIV, depression and cancer are reticent to seek care or advice about their conditions. Through DTC, such patients are learning important information about available treatment options, and individuals are seeking advice from their physicians, friends or families.

Patients have reported that they have sought advice from their physician about a condition that they had not previously discussed, in part, because they were motivated by DTC.⁷ An internal Johnson & Johnson company DTC study has demonstrated that patients with HIV may seek information and advice on their disease, by showing a print advertisement to someone else who has the same condition, by saving a copy of the advertisement, or by discussing the advertisement with a spouse or partner.⁸

³ Blankenhorn, Nancy Duckwitz, et al, *Power to the People*, MEDICAL MARKETING AND MEDIA, August 2001. (citing to Gallup and IMS studies of DTC); F.F. Gonul, F. Cater, et al., *What Kinds of Patients and Physicians Value Direct-to-Consumer Advertising of Prescription Drugs*,” HEALTH CARE MGT. SCIENCE, 3(3):215-26 (2000).

⁴ Gonul and Wind, *supra* note 3; Wm. Zachary 3rd, and D.B. Ginsburg, *Patient Autonomy and the Regulation of Direct to Consumer Advertising*, CLINICAL THERAPEUTICS, 23(12):2024-2037 (2001); NATIONAL HEALTH COUNCIL, DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING, OVERVIEW AND RECOMMENDATIONS (2002).

⁵ Zachary and Ginsburg, DB *supra* note 4.

⁶ Zachary and Ginsburg, DB, *supra* note 4, at 2033. *See also*, NATIONAL HEALTH COUNCIL, *supra* note 4.

⁷ Blankenhorn, Duckworth et al., *supra* note 3; Joel S. Wissman, PhD, David Blumenthal, MD, et al, *Recent Research on Health Effects that Result from Direct-to-Consumer Patient Advertising*, Presentation at AAAAI Annual Meeting, New York City (March 3, 2002).

⁸ Data on File, April 2002.

Minority populations may also benefit from more DTC advertising. The National Medical Association, which represents black physicians, has called for more DTC advertisements, particularly when these advertisements show more culturally diverse commercials in media outlets that target minorities.⁹

b. Benefits to the Medical Community

Although some medical practitioners view DTC with skepticism, many physicians appreciate DTC as a tool to improve interaction with patients.¹⁰ The American Public Health Association supports DTC for its role in increased disease awareness and active participation by patients, provided that the physician-patient relationship remains strong, and advice is properly filtered.¹¹ A FDA study demonstrated that most patients who had been prompted to discuss an advertised product with their physician reported that the physician welcomed their questions and discussed the product with them to their satisfaction.¹² Physicians and patients have also reported greater patient compliance with drug or disease regimens due to reminders provided by DTC.¹³

c. DTC Does Not Lead to Overutilization of Pharmaceutical or Medical Products

FDA has expressed concern that DTC leads to overutilization of prescription products, by encouraging consumers to take prescription products they do not need, and by encouraging physicians to overprescribe such products based on patient demand.

The notion that physicians will overprescribe advertised products is unfounded. Physicians are independent professionals who are bound by ethics, insurance laws, consumer laws, and fraud and abuse laws to prescribe medically necessary products for their patients. Cost-containment measures and patient cost-sharing mechanisms, such as copayments, deductibles and formularies, incentivize patients to seek care and prescription products only when medically

⁹ AP, *Prescription Drug Commercials – They Work* (visited April 30, 2002) <<http://cnn.health.printthis.clickability.com/pt.printThis?=&printThis&fb+Y&u.../2002>>.

¹⁰ Gonul and Wind, *supra* note 4.

¹¹ Zachary and Ginsburg, DB, *supra* note 4.

¹² Center for Drug Evaluation and Research, *supra* note 2.

¹³ NATIONAL HEALTH COUNCIL, *supra* note 4.

necessary. Arguably, physicians choose prescription products primarily based the patient's insurance coverage or cost-sharing provisions, and not on patient preference arising from DTC. This is true even if the patient became aware of, and asked for, a branded product, because the patient was exposed to DTC.

Physicians are also required by ethics and laws governing professional practice to assert their best medical judgment in prescribing the most appropriate products for a patient, based on the condition, medical history, and circumstances presented by that patient. The physician, as a "learned intermediary," is the actor who possesses the greatest knowledge of the particular patient's needs, the medical and clinical knowledge of the patient's disease state, and the medical and clinical knowledge that will lead to the prescription of appropriate products to meet the patient's needs.

Educated consumers are capable of giving informed consent to their treatment, if they have been provided fair and balanced information. DTC advertisements are required to provide consumers with balanced information about prescription products, and research indicates that consumers understand and retain the information provided.¹⁴ Of those who asked for an advertised prescription product, only fifty percent (50%) of adult patients reported that they received a prescription from their physicians for the product.¹⁵ Sixty percent (60%) reported that their physicians mentioned a non-drug therapy instead.¹⁶ Clearly, physicians work with patients to select appropriate treatment based on what is medically optimal, and not on DTC.

C. EXHIBIT HALLS/TRADE SHOWS

FDA should reassess and clarify its position concerning the dissemination of medical information by regulated companies in convention exhibit halls and trade shows. To date, FDA has provided virtually no written guidance to industry on this issue, in direct contravention of its own Good Guidance Practices. Agency representatives have provided some verbal guidance, in the form of public comments, indicating that regulated companies face restrictions on their ability to disseminate "off label" information in such venues. This verbal guidance is lacking in clarity and direction, and is at times contradictory. This lack of meaningful and consistent written guidance chills medical speech that is protected by the First Amendment as well as by Congressional directive,¹⁷ and creates great confusion in the regulated industry.

¹⁴ Center for Drug Evaluation and Research, *supra* note 2.

¹⁵ *Fifth Annual Survey of Consumer Reaction to Direct-to-Consumer Advertising of Rx Medicines* PREVENTION MAGAZINE (March 2002).

¹⁶ *Id.*

¹⁷ See 21 U.S.C. 360aaa-6(a).

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¹⁷ Sec 21 U.S.C. 360aaa-6(a).

FDA should promptly issue written guidance making clear that regulated companies are free to respond to requests for medical information by visitors to exhibit hall booths, provided that: (1) requests for information are not prompted by the company; and (2) the responses are balanced and not misleading.

FDA should also issue written guidance clarifying its position with regard to dissemination of information at international trade shows and conventions. FDA should clarify that manufacturers may promote approved uses of its products to attendees, provided that promotional activities are clearly directed toward residents of the country where promoted uses have been approved. This principle should apply even when international trade shows and conventions are held in the United States.

III. ADDITIONAL AREAS OF INTEREST

Johnson & Johnson would also like the FDA to consider the following additional areas of interest to its companies.

A. COMPARATIVE CLAIMS IN ADVERTISING

FDA's current policy requiring two adequate and well-controlled clinical trials to support comparative claims about prescription drug products is too restrictive. FDA should acknowledge that in some circumstances, advertising claims may be justified by one large, multi-center study.

B. "GENERAL" VERSUS "SPECIFIC" CLAIMS

CDRH should review current policies on "general" versus "specific" claims related to the use of medical devices. Many devices are approved for general uses, such as ablation of soft tissue in a particular system. However, manufacturers are prohibited from making claims about the use of devices on specific organs within that system, without prior approval from CDRH. This position seems counterintuitive, and may warrant renewed scrutiny.

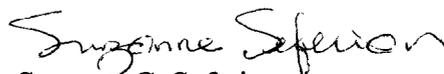
C. DISSEMINATION OF PRESS MATERIALS

FDA may also wish to examine current policy on press releases and other press materials. FDA should provide further guidance on the distinction between pre-approval press releases containing truthful, non-misleading scientific information, and press releases related to new intended uses of an approved product.

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Once again, we thank you for this opportunity to provide comments on First Amendment issues. We look forward to working with FDA on issues of specific interest to Johnson & Johnson companies.

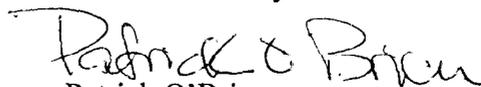
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