

December 3, 2008

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.

CITIZEN PETITION

The Prescription Project,¹ a program of Community Catalyst, Inc., a non-profit consumer health care advocacy organization based in Boston, Massachusetts, submits this petition under §4(d) of the Administrative Procedure Act, 5 U.S.C. § 553(e), as well as under 21 C.F.R. §§ 10.25 & 10.30, and 21 U.S.C. § 352, to request the Commissioner of Food and Drugs to take action to address the growth of online/Internet advertising, such as online video advertisements posted on www.YouTube.com and other such websites, promoting prescription drugs regulated by the FDA's Center for Drug Evaluation & Research (CDER) and medical devices regulated by FDA's Center for Devices and Radiological Health (CDRH), as described herein.

ACTION REQUESTED

In order to protect the health and safety of consumers nationwide, the Prescription Project requests that the FDA:

1. Send a letter to all major prescription drug manufacturers and restricted medical device manufacturers, advising and reminding them that online/Internet drug and device advertisements and promotions are subject to the same requirements as promotions in other media, and recommending that all such manufacturers and distributors review online advertisements published, posted or otherwise distributed by them, or by third parties, agents, subcontractors and the like on their behalf or at their direction or request, to assure compliance with current disclosure requirements.
2. Issue a Draft Guidance on Consumer-Directed Broadcast Advertising of Prescription Drugs and Restricted Devices on the Internet, soliciting public comment and scheduling a public hearing on the contents and scope of such guidance. This guidance should clarify that Internet promotions are encompassed in the definition of broadcast advertisements in 21 C.F.R. §§202.1(e)(1) and (l)(1), and it should further describe the requirements for such online advertisements under 21 U.S.C. § 352.

¹ The Prescription Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession, and funded by the Pew Charitable Trusts, to advance policies to ensure safe and effective drugs for consumers and reduce the countervailing influence of industry marketing. More information is available at www.prescriptionproject.org.

STATEMENT OF GROUNDS

I. Increasing Market Competition fuels online DTC advertising of medical devices and prescription drugs, putting consumers at risk.

The advent of new medical technology, coupled with increased direct-to-consumer (DTC) advertising, may create significant risks to consumers. For instance, DTC advertising of medical devices presents consumers with extremely complex medical information in a limited advertising format. In testimony before the U.S. Senate Special Committee on Aging this past September, Dr. William E. Boden, chief of cardiology at Buffalo General Hospital, emphasized that the decision to use a “specialized medical device...requires a very sophisticated medical understanding” that few could gain through DTC advertising.²

Given this complexity, and the high stakes due to the significant risks associated with any medical devices implanted through surgery, DTC ads for medical devices are potentially even more problematic than such ads for prescription drugs.

In addition, the pharmaceutical and medical device industries, like others, are increasingly employing public relations (PR) firms to create sponsored, prepackaged video segments designed to mimic independent television news reports. These are called ‘video news releases’ or VNRs.³ PR firms have shifted from their successful targeting of TV news broadcasts to a new focus on online sources⁴. As a result, online sources, such as blogs, podcasts, video posting websites and newspaper websites, may account for more VNR use than TV broadcasters.⁵ Some warn that this shift allows PR firms to more closely target their audiences, but avoid government oversight.⁶ Critics have noted that, regardless of the medium, health-related VNR’s are especially problematic, because they make it easier to overstate and misrepresent the benefits of a health product.⁷

A. Numerous examples of device advertising are present on YouTube.com, and other such websites.

The three Citizen Petitions submitted simultaneously with this petition each document examples of medical device advertising on YouTube.com that are not compliant with current disclosure requirements.

One petition⁸ addresses four (4) video advertisements⁹ posted on YouTube.com directly by Abbott Laboratories, the manufacturer of the XIENCE V drug-eluting stent

² Boden, William E., MD, Testimony before the U.S. Senate Special Committee on Aging, September 17, 2008, page 7, available at <http://aging.senate.gov/events/hr202wb.pdf>, last visited 11-18-2008.

³ Peter Phillips et al, Project Censored, Censored 2008: the Top 25 Stories (2007) at 275.

⁴ Id. at 278.

⁵ Id. at 283.

⁶ Id.

⁷ Id.

⁸ Citizen Petition filed with FDA by the Prescription Project re Abbott’s XIENCE V product, submitted, December 3, 2008, available at http://prescriptionproject.org/assets/pdfs/Abbott_Petition_XIENCE-V.pdf.

medical device. None of these four videos included any of the required disclosures of the device's indicated use or risks.

The second petition¹⁰ notes that a YouTube video¹¹ promoting the PRESTIGE Cervical Disc was posted by VNR-1 Communications, a private PR firm specializing in the design and placement of promotional video content. The PRESTIGE Cervical Disc device is manufactured by Medtronic (NYSE: MDT), which has professional ties to VNR-1. This YouTube video also failed to include the required disclosures regarding indicated uses or risks.

The third petition¹² describes how the medical device distributor Stryker, through their PR firm MediaLink, posted a video¹³ misbranding the Cormet Hip Resurfacing System, another medical device.

YouTube is but one of many current online outlets that may become increasingly utilized for the dissemination of prescription drug or medical device video advertisements directly to consumers.

B. Device and drug manufacturers may not evade disclosure requirements through the use of third party promoters.

Two of the above examples document device promotional content placed on YouTube by PR firms hired by, or with business ties to, device manufacturers. When such content is posted on websites by an agent or actor on behalf of a manufacturer, then the disclosure requirements under 21 U.S.C. § 352 et. seq. clearly apply.

In a guidance or regulation, FDA should address the financial and other roles that manufacturers and distributors of medical devices and prescription drugs may play in the creation and distribution of promotional video news releases and other video content intended for broad public distribution. This should delineate the agency's thinking on the relationship between drug and device manufacturers and privately-retained PR firms, and the types of possible disclosures that may be required regarding the production of promotional material in which they both take part.

C. FDA has the authority to regulate advertising of the prescription drugs and restricted medical devices on the Internet.

FDA's has the authority to regulate advertising of all 'restricted'¹⁴ medical devices under 21 U.S.C. §§ 352(q) and (r). FDA has the authority to regulate the advertising of

⁹ See <http://www.youtube.com/watch?v=d8k32MZ-Tb8>, <http://www.youtube.com/watch?v=HM6Y6KunFhg>, <http://www.youtube.com/watch?v=bGbNnP5xGRo> and <http://www.youtube.com/watch?v=CpmEhAEwcrk>.

¹⁰ Citizen Petition filed by the Prescription Project re the Medtronic PRESTIGE device, submitted, December 3, 2008, available at http://www.prescriptionproject.org/assets/pdfs/Petition_re_Prestige_device_by_Medtronic.pdf.

¹¹ See http://www.youtube.com/watch?v=vde_qcZmiwU.

¹² Citizen Petition filed by the Prescription Project re Stryker's Cormet device, submitted, December 3, 2008, available at http://www.prescriptionproject.org/assets/pdfs/Petition_re_Cormet_device_by_Stryker.pdf.

¹³ See <http://www.youtube.com/watch?v=Q4tZVHxZArI>.

prescription drugs under 21 U.S.C. § 352(n), as further clarified by 21 C.F.R. § 202.1, and the 1999 Guidance on Broadcast Advertising of Prescription Drugs.¹⁵

Advertising is not defined by statute. By regulation, FDA has defined advertising of prescription drugs to “include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media *such as* radio, television, and telephone communication systems.”¹⁶ As this definition is illustrative, video presentations broadcast on the Internet fit squarely within the scope of this definition of advertising. As a result, FDA has applied the existing regulatory framework for broadcast advertising requirements to online advertisements.¹⁷ However, the FDA has not issued or revised any Guidance to address specific requirements or compliance concerns for online advertisers under the relevant statutes and regulations. (By contrast, the Federal Trade Commission, which regulates the advertising of, among other products, Over-the-Counter medications, has issued a Guidance on online advertising.¹⁸)

The time has come for FDA to provide clarity to the medical device and prescription drug industries, and help ensure that consumers are protected from unfair or misleading information concerning prescription drugs and medical devices. Therefore, the requested guidance should address the application of the brief summary, fair balance, major statement, and adequate provision requirements to advertisements in online media.

1. Application of the *fair balance* requirement to online ads needs clarification.

Under 21 U.S.C. §352(a) and (q) a drug or device may be misbranded if its advertisement is ‘misleading.’ A failure to provide a balanced presentation between intended uses and associated risks, or *fair balance*, is misleading. The requested guidance should address the meaning of ‘fair balance’ as applied to online information and promotion of medical devices and prescription drugs. In particular, it should address the difference between a traditional broadcast advertisement, which is inherently limited in duration, with Internet communications, which, even more so than print ads, offer greater ease and opportunity for inclusion of more complete risk and benefit information in any advertising.

¹⁴ A restricted device is one whose “sale, distribution, or use [requires] the written or oral authorization of a practitioner licensed by law to administer or use such device, ... if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.” 21 U.S.C. §360j(e)(2008).

¹⁵ FDA, Guidance for Industry - Consumer-Directed Broadcast Advertisements, (Aug. 1999) available at <http://www.fda.gov/CDER/GUIDANCE/1804fnl.htm>.

¹⁶ 21 C.F.R. 202.1(l)(1) (2008).

¹⁷ See, e.g., FDA Warning Letter (Sept. 25, 2008) http://www.fda.gov/foi/warning_letters/s6936c.htm, (citing YouTube ads for the prescription drug Adderall XR under 21 U.S.C. §352(n) and 21 C.F.R. 202.1).

¹⁸ FTC, Facts for Business: Dot Com Disclosures (2000), <http://www.ftc.gov/bcp/edu/pubs/business/ecommerce/bus41.pdf>.

2. Application of the *brief statement, major statement, brief summary, and adequate provision* requirements to online ads needs clarification.

Sections 21 U.S.C. § 352(a) and (n), and 21 C.F.R. §202.1 list the disclosure requirements for prescription drug ads, as further described by the FDA's 1999 Guidance on DTC ads. 21 U.S.C. §§ 352(q) and (r), list the disclosure requirements for medical device ads. But none of these statutes or regulations address online promotions. Thus there are numerous issues in need of clarification regarding online advertising for both prescription drugs, and especially for medical devices, for which no regulation or final guidances have been promulgated.

For instance, how can the "adequate provision"¹⁹ requirement be met in an online context? Under the "Guidance for Industry: Consumer-Directed Broadcast Advertisements" for prescription drugs, such adequate provision may be made by providing a "[d]isclosure in the advertisement of an Internet web page (URL) address that provides access to the package labeling."²⁰ But it is unclear, for instance, what is the maximum permissible number of links between an online advertisement and an online version of the package labeling, or how prominently on a webpage a link to the package labeling must be.

3. Distinction between 'advertising' and 'promotional material' as product labeling is unclear as applied to online information.

An exemption from the advertising disclosure requirements for restricted medical devices²¹ and prescription drugs²² is allowed for promotional "printed matter... the Secretary determines to be labeling" The definition of 'labeling' sweeps broadly to include "[b]rochures, booklets, mailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, . . . sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and . . . for use by medical practitioners . . . and which are disseminated by or on behalf of its manufacturer, packer, or distributor."²³

It is unclear whether such "printed matter" encompasses documents posted and made freely available online. If it does encompass such electronic online versions of documents, how this 'printed matter' exemption applies to web pages is unclear. For instance, a particular document may be *intended* "for use by medical practitioners," but may also be posted on a website accessible to the general public. It is also unclear whether the exemption applies, for instance, when such "labeling" is distributed in a

¹⁹ Which arguably is only permissible for prescription drug ads, since the Draft Guidance for Industry and FDA: Consumer-Directed Broadcast Advertising of Restricted Devices (Feb. 10, 2004, available at <http://www.fda.gov/cdrh/comp/guidance/1513.html>) remains a draft. 21 U.S.C. §§ 352(q) and (r) constitute the totality of current legal requirements for consumer-directed broadcast advertisements of restricted devices, and those sections require full disclosures, rather than the acceptable substitute in the drug context of a "major statement" and "adequate provision."

²⁰ FDA, Guidance for Industry: Consumer-Directed Broadcast Advertisements (August 1999), <http://www.fda.gov/CDER/GUIDANCE/1804fnl.htm>.

²¹ Under 21 U.S.C. § 352(r) (2008).

²² Under 21 U.S.C. § 352(n) (2008).

²³ 21 C.F.R. § 202.1(l)(2) (2008).

manner easily accessible to lay consumers. Such “labeling” materials have the capacity and likelihood to confuse and mislead consumers, and the requested guidance should address these issues.

4. The applicability of disclosure requirements to online advertisements produced and disseminated by public relations firms, external vendors and other agents and third parties, on behalf or at the direction of device and drug manufacturers and distributors should be clarified.

As described, we have identified in the accompanying Citizen Petitions several instances of manufacturers or distributors employing public relations firms that specialize in the creation and placement of ‘video news releases’ that are designed to mimic independent news presentations. The applicability of disclosure requirements to such advertisements, when there is any agency or financial relationship between the manufacturer/distributor and the PR firm/advertisement producer, should be made explicit.

II. Conclusion

With the online presence of DTC advertising and consumers’ reliance on the Internet for drug and device information both increasing, the FDA has a vital role to play to ensure that consumers are provided with information that is accurate in its content, and not deceptive in its presentation. The current regulations and guidances are inadequate to address the unique characteristics of online media.

We urge the FDA to act to protect consumers from unsafe or misleading information disseminated by drug and device manufacturers or distributors, and their promotional agents or affiliates. We urge FDA to issue a guidance, or promulgate regulations as appropriate, to address and clarify the application of current advertising and labeling disclosure requirements to the online medium. This is increasingly necessary, in light of consumers’ use of online media to research and understand complex health treatment options, and in light of the increased promotion of products by their manufacturers and associated promotional agents through online media.

We request that the FDA promulgate a Draft Guidance as soon as possible, inviting public comment and scheduling a public hearing for interested parties to make their views on these subjects known.

ENVIRONMENTAL IMPACT STATEMENT

We believe that the action requested herein is exempted from the requirement of an environmental impact statement pursuant to 21 C.F.R 25.30(a).

ECONOMIC IMPACT STATEMENT

(Not required upon initial submission.)

CERTIFICATION

The undersigned certifies on this Third day of December, 2008, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

(Signature)

Allan Coukell, Director of Policy
The Prescription Project of Community Catalyst
30 Winter Street, 10th Floor
Boston, MA 02108
(617) 338-6035