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December 11, 2002

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

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

Dear Sir or Madam:

Pfizer Inc. ("Pfizer") hereby submits (Exhibit A) proposed regulations concerning one facet of the Food and Drug Administration's ("FDA's") First Amendment inquiry--a sponsor's right to respond to public statements by an independent third party concerning a drug that is subject to an approved or pending New Drug Application ("NDA") or Investigational New Drug ("IND") application. This is a particularly important and timely issue given the pending Supreme Court certiorari petition in *Nike v. Kasky*, 71 U.S.L.W. 3319 (Oct. 16, 2002). In that case, the petitioner seeks clarification of the circumstances in which a manufacturer's response to third-party attacks constitutes speech subject to strict scrutiny under the First Amendment, rather than commercial speech subject to intermediate scrutiny. Pfizer believes that providing FDA with specific proposed regulatory language safeguarding a manufacturer's right to respond to such third party attacks will assist the agency in considering whether and how to amend its regulations or guidances in order to conform with First Amendment principles. It will also demonstrate that codification of First Amendment principles is a feasible and natural outgrowth of the agency's current constitutional review and should be aggressively pursued by FDA. Although Pfizer has illustrated its proposal in the form of draft regulations, it would be equally appropriate for FDA to incorporate these safeguards in the form of a guidance.

Pfizer observed in its initial comments that the First Amendment embodies a "presumption that truth will best emerge from the collision of ideas that results from open channels of communication" and that "more speech," rather than less, is the best remedy for exposing misleading speech. Comments of Pfizer Inc. at 44 & n.155 (Sept. 13, 2002) ("Pfizer Comments") (quoting *Whitney v. California*, 274 U.S. 357, 377 (1927), *overruled in part, Brandenburg v. Ohio*, 395 U.S. 444 (1969)). These principles apply with particular force to prescription drugs. "Given the benefit and risk calculus involved in the use of any drug, there is ample room for public debate over drug use and constitutional value in letting all speakers play an equal role in that debate." Pfizer Comments at 45. Thus, First Amendment interests are best served when all interested

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speakers are allowed an equal opportunity to debate publicly the merits and risks of a drug product. This is at least as important—perhaps even more important—than a debate about the ethics and legality of Nike’s labor practices in third world countries at issue in the *Kasky vs. Nike* case.

As Pfizer stated in its initial comments, however, FDA’s current regulations single out drug manufacturers as the only class of speakers who cannot join freely in this public debate. Instead, manufacturers are governed by “pervasive, extensive regulations that tightly control what manufacturers may say about their products and attempt to transmogrify advertising and other promotional communications into comprehensive instructional messages.” *Id.* at 111. “FDA, by requiring manufacturers to include an exhaustive list of a product’s risks as well as its benefits, ... hampers drug manufacturers’ ability to respond truthfully to attacks on their products.” *Id.* at 113.

The agency’s regulations appear to be premised on the concept that the manufacturer is the only speaker concerning its drug product and that regulating manufacturer speech is the sole means of ensuring that physicians and consumers are fully advised about drug benefits and risks. This is largely not the case. There are myriad speakers—from medical journals to patient advocacy groups to HMO benefits managers to dietary supplement manufacturers—each of whom has differing motivations in initiating public debate concerning various prescription drugs and different messages that they would like to convey. *Id.* at 12-13. Once debate is initiated by an independent third party, the First Amendment commands reliance on the clash of conflicting views rather than government regulation to establish the truth. Thus, “[i]t simply serves no public health purpose to inhibit a manufacturer, who is likely to be the most knowledgeable source of scientific data concerning a particular drug, from providing useful information about the drug when that drug’s utility is thrown into public controversy by a third party.” *Id.* at 115.

Pfizer’s proposed regulations seek to level the playing field by affording manufacturers the right to respond to independent third party statements about their products without subjecting these responses to FDA’s stringent prescription drug labeling and advertising requirements. Such speech is not properly characterized as labeling or advertising because physicians will not rely on it to ascertain the operative instructions for the safe and effective use of a product. *See id.* at 71-74. Nor can the speech be deemed commercial speech. Far from doing “no more than propose a commercial transaction,” such speech constitutes the same type of scientific debate that others initiated concerning a particular drug product. *See Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376, 385 (1973). As neither labeling nor advertising, but rather scientific speech, such responses should benefit from full First Amendment protection.

Pfizer has carefully crafted its proposed regulations to ensure that manufacturers cannot evade FDA’s requirements by characterizing statements as responsive, when they are not or when a response is knowingly or recklessly is false. For example, where a

manufacturer knows that it is making a false statement or has serious doubts about its truth, that speech remains fully subject to FDA's otherwise applicable advertising and labeling requirements. Similarly, if the agency can establish that the speech at issue is not the type of responsive speech that the proposed regulation intends to cover because, *inter alia*, it does not respond to a specific statement made by another concerning a product, is not made in reasonable proximity to the time at which the need to respond to the public criticism of the drug arises, or is disproportionate in scope and in the extent of dissemination to the initial third party statement, FDA may subject that speech to its labeling and advertising regulations. These anti-evasion principles are borrowed from the law of self-defense, and would permit the manufacturer effectively to defend its products in the crucible of public debate on the same constitutional footing as the myriad other speakers in the marketplace.

Pfizer urges the agency to consider carefully the proposed regulations and to amend its regulations and guidances to reflect the approach taken in Pfizer's proposal. By so doing, FDA will remedy the inequity that currently exists between unregulated entities, who may attack drug products at will without being subject to any speech restrictions, and manufacturers, who are arguably in the best position to disseminate information concerning their products but who, under current regulations, may risk enforcement action if their response is not tightly controlled in ways that largely dilute the force of the communication without measurably enhancing the truthfulness of the message conveyed.

Respectfully submitted,

PFIZER INC.

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Exhibit A

Pfizer's Proposed Right of Response Regulation or Guidance

NDA and IND Holder's First Amendment Right of Response

Section 202.901. **Constitutional Exemption for Sponsor Responses to Public Debate.**

Where the sponsor of a pending or approved NDA or IND for a prescription drug disseminates statements in response to public statements disseminated by an independent third party which concern the nature, quality, utility or characteristics of that drug, including but not limited to safety or effectiveness, FDA shall not deem those statements to be labeling or advertising as defined, respectively, in 21 U.S.C. § 321(m) and Section 202.1(1)(2) of these regulations. FDA has determined that the First Amendment bars the agency from subjecting such responsive elements of public debate to any of the requirements governing prescription drug labeling or advertising under the Federal Food, Drug and Cosmetic Act or FDA's implementing regulations.

Section 202.902. **Anti-Evasion Safeguards.**

- (a) The exemption in Section 202.901 for responses to independent third-party statements shall not be used to evade otherwise applicable labeling and advertising requirements. In determining whether a communication is a responsive communication protected by Section 202.901, the Commissioner shall take the following factors into account:
1. **Specificity.** Whether the communication addresses with specificity, by identifying time and place, and, if applicable, title or subject matter of the relevant publication or utterance, the third party statements about the nature, quality, utility or characteristics of the sponsor's drug to which it responds.
 2. **Necessity.** Whether the communication identifies with particularity the need to respond to the relevant third party statements for the benefit of the audience.
 3. **Immediacy.** Whether the communication is disseminated in reasonably close proximity in time to the relevant third party statement given the nature of the media utilized in responding and the requirements for advance commitments for space and the like.

The need to respond may arise, *inter alia*, (a) at the time a third party statement is disseminated; (b) at the time that the sponsor reasonably learned about the statement; or (c) at the time the statement becomes a matter of serious public importance due to, for example, greatly expanded public dissemination.

4. **Proportionality.** Whether the scope and dissemination of the communication is proportional to the dissemination of the relevant third party statement to which it responds. The scope of the communication is proportional if it is reasonably tailored to address the representations in the third party statement. The dissemination of the communication is proportional to the dissemination of the public criticism if the audience reach and frequency of publication of the media used to respond is comparable to the audience reach and frequency of the media used to disseminate the criticism in the first instance.

- (b) A statement shall not be deemed to be covered by Section 202.901 if the Commissioner establishes that the sponsor disseminated it with actual knowledge that a representation of fact was false or with substantial awareness of its probable falsity or a serious doubt about its truth.

Authority: United States Constitution, Amendment I.