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FDA MUST CLARIFY DRUG MAKERS' ABILITY TO PUBLICLY DEFEND PRODUCTS

by

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In the context of the Food and Drug Administration's ("FDA") on-going First Amendment inquiry, *see* Request for Comments on First Amendment Issues, Docket No. 02N-0209 (May 16, 2002), a pharmaceutical maker recently asked FDA to codify a manufacturer's right to respond to critical public statements by third parties about a drug. *See* Pfizer Inc. Letter (Dec. 11, 2002), FDA Docket No. 02N-0209. FDA should give serious and timely consideration to this request and promulgate a new regulation or guidance addressing the ability of pharmaceutical and medical device manufacturers to respond to third party criticism.

FDA should be acutely sensitive to First Amendment values and a company's right to respond on an equal footing with its critics, particularly when the debate is initiated by others. *See, e.g.,* Marc Kaufman, *Hormone Replacement Therapy Gets New Scrutiny: Finding of Increased Risk Prompts Federal Effort*, WASH. POST, Aug. 14, 2002, at A-1 (discussing risks and benefits of hormone replacement therapy used by post-menopausal women after study finding serious side effects). This is a particularly important and timely issue now that the Supreme Court has granted the certiorari petition in *Nike, Inc. v. Kasky*, No. 02-575 (Jan. 10, 2003). In that case, the petitioner seeks clarification of the circumstances in which a manufacturer's response to third-party attacks constitutes core speech subject to strict scrutiny under the First Amendment, rather than commercial speech subject to lesser scrutiny.

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. *See e.g. 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 and medical devices. First Amendment interests are best served when all speakers are allowed an equal opportunity to debate publicly the merits and risks of a drug product or device. This is at least as important — perhaps even more important — than a debate about the ethics or legality of Nike's labor practices in third world countries at issue in the *Kasky vs. Nike* case.

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But FDA's current regulations single out drug manufacturers as the only class of speakers regarding drugs who cannot freely join in this public debate. Instead, manufacturers are governed by pervasive regulations that tightly control what they may say about their products. These regulations are premised on the outmoded notion that the manufacturer is the only speaker concerning its drug product and that tightly regulating manufacturer speech is the sole means of ensuring that physicians and consumers are fully advised about drug benefits and risks. In our Internet-empowered age, this is just *not* the case. There are myriad speakers, each of whom has differing levels of expertise and knowledge about the product, motivations in initiating public debate concerning various prescription drugs, and different messages that they would like to convey. 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, it simply serves no public health purpose to prohibit 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.

FDA should 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 relevant information for the safe and effective use of a product. 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). Being neither labeling nor advertising, but rather scientific speech, such responses should benefit from full First Amendment protection.

The principle that a manufacturer should have the right to participate in the public debate about the merits of its drug on an even footing with the critics seems self-evident. Remarkably, this becomes a novel proposition in the context of FDA's paternalistic regime of regulating virtually all manufacturer speech as either advertising or labeling subject to a plethora of prescriptive requirements intended to control every detail of the substance and format of the response. But responding proportionally, on the same terms, to public criticism initiated by a third party would be no more than an exercise of the privilege of self-defense that the law recognizes in a variety of contexts.

FDA should acknowledge, in a regulation or formal guidance, that a drug manufacturer has a First Amendment right of response. This would remedy the substantial inequity that now 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 and often solely capable, to disseminate information concerning their products. Under current regulations, however, the producers may risk FDA 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.