

ORIGINAL

Before the  
U.S. Food and Drug Administration  
Rockville, MD

In the Matter Of:

Help Seeking and  
Other Disease Awareness  
Communications by or on  
Behalf of Drug and Device Firms

Docket No. 2004D-0042

SUPPLEMENTAL COMMENTS OF PFIZER INC

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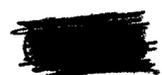
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## TABLE OF CONTENTS

	Page
I. FDA’S EFFORT TO IMPOSE RISK DISCLOSURE ON CERTAIN NON-PRODUCT MESSAGES THROUGH AN AMORPHOUS “LINKAGE” THEORY COULD INADVERTENTLY IMPEDE DISSEMINATION OF EFFECTIVE DISEASE AWARENESS COMMUNICATIONS .....	4
A. FDA Should Encourage Maximum Dissemination of Privately Funded— and Indisputably Useful—Help-Seeking Messages.....	5
B. The Help-Seeking Guidance Identifies Only a Vague Definitional Test That Sets No Clear Boundary on Disclosure Requirements .....	7
II. THE HELP-SEEKING GUIDANCE FAILS TO RECOGNIZE THE POTENTIAL BENEFITS OF THE COMMON ELEMENTS THAT ALLEGEDLY LINK DISEASE AWARENESS MESSAGES OR TO SUBSTANTIATE ANY PURPORTED HARM CAUSED BY THEM.....	12
III. THE GUIDANCE DOES NOT ATTEMPT TO TAILOR DISCLOSURES TO ADDRESS ANY PURPORTED HARM CAUSED BY ARGUABLY LINKED MESSAGES.....	16
IV. THE GUIDANCE RAISES SIGNIFICANT FIRST AMENDMENT ISSUES.....	17
CONCLUSION.....	20

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**SUPPLEMENTAL COMMENTS OF PFIZER INC**

Pfizer Inc (“Pfizer”) hereby supplements its initial filing in this docket in order to address at greater length the issues presented by the draft Guidance titled “Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms” (the “Help-Seeking Guidance” or “Guidance”).<sup>1</sup> That document properly “encourages drug and device manufacturers to develop disease awareness communications, particularly ... for serious or life-threatening diseases or health conditions that are under-diagnosed or under-treated.”<sup>2</sup> Pfizer is on record with its firm support for consumer-directed communications, which evidence shows serve a valuable purpose in building awareness of disease conditions and empowering consumers to seek appropriate treatment. We therefore are encouraged by FDA’s recognition that help-seeking messages and other disease awareness communications are an important part of a

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<sup>1</sup> FDA, *Guidance for Industry, “Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms* (posted Feb. 4, 2004), available at <http://www.fda.gov/cder/guidance/6019dft.doc>. Pfizer’s initial comments focused on the Draft Guidance titled “Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements” and were submitted on May 7, 2004, shortly before the initial deadline for comments to be submitted in this proceeding. FDA subsequently extended the comment period until August 10, 2004. See *Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions; Availability; Reopening of Comment Period*, 69 Fed. Reg. 30945 (June 1, 2004).

<sup>2</sup> Help-Seeking Guidance at lines 156-159.

broader effort to provide consumers with beneficial health information about conditions and available treatments to address them.<sup>3</sup>

Unfortunately, in broadly targeting so-called “linkage” between disease awareness and product-specific messages, the draft Guidance and follow-up comments to the industry by FDA indicate that the agency may limit delivery of effective disease awareness messages by finding them to be unlawful for lack of product advertisement disclosure standards.<sup>4</sup> Pfizer is concerned that the Help-Seeking Guidance in its current form would unnecessarily narrow the existing “safe harbor” regulatory exemption for disease awareness communications, leaving only antiseptic formats that may communicate public health messages less effectively. At the same time, this new approach would also tread on First Amendment values.

To convert communications outside its jurisdiction into regulated product communications, the draft Guidance relies heavily on a theoretical construct about implicit messages that has not yet been empirically tested. Because the linkage concept has no grounding in factual data, however, it seems to have no logical stopping place—short of operating as a *de facto* ban on the use of any visual or aural element in disease awareness messages that may also appear in product advertising. The amorphous test for “linkage” is so vague that it might dissuade at least some manufacturers from supporting disease awareness communications for fear of inadvertently subjecting themselves to misbranding allegations. This, in turn, likely would thwart FDA’s efforts to encourage greater dissemination of disease awareness information

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<sup>3</sup> According to the Help-Seeking Guidance, the term “disease awareness” messages includes, but is not limited to, “help seeking” messages directed at consumers. Because nothing in the document explains why regulatory concerns in this area should arise in the context of professional audiences, Pfizer’s comments here focus principally on the consumer-directed messages—as the Guidance itself appears to do.

<sup>4</sup> See, e.g., Tericke Blanchard, *Disease Awareness Ads Indistinct From Product Ads Could Be Viewed As Promotional, FDA Says*, “The Pink Sheet” DAILY, May 28, 2004.

that can be “particularly important for under-diagnosed, under-treated health conditions, such as depression, hyperlipidemia, hypertension, osteoporosis, and diabetes.”<sup>5</sup>

By raising concerns about the scope of the Draft Guidance, Pfizer does not seek to disable the FDA from challenging cases of classic “bookending”—*i.e.*, the practice of running a help-seeking message and reminder ad in tight physical proximity. As we have noted before, “a close nexus between two such ads in time or space” could well justify the conclusion that the help-seeking ad was conveying a brand message.<sup>6</sup> Other federal agencies have successfully implemented narrow, specific prohibitions on certain presumptively improper practices. FDA policy could be limited to similarly targeted enforcement actions.

The Help-Seeking Guidance, however, goes well beyond a few limited and egregious situations. It appears to call into question any use of “perceptually similar” visual and aural elements between disease awareness communications and advertising of all sorts, including straightforward product ads that fully comply with the applicable risk disclosure requirements. Indeed, the Guidance appears premised on the notion that there are no public health benefits, but only harms, that could arise from any type of linkage. The draft reflects no understanding that the use of similar presentational elements across many types of product and non-product communications can be an effective means of delivering important, FDA-sanctioned health information to consumers; such stylistic techniques can help the messages break through the commercial clutter that often distracts or numbs consumer attention.

Before FDA puts the many benefits of help-seeking communications at risk, the agency should develop a factual record that would help set understandable boundaries that a successful

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<sup>5</sup> Help-Seeking Guidance at lines 28-30.

<sup>6</sup> See Comments of Pfizer Inc, Request for Comment on Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements, Docket No. 04D-0042, at n. 54 (FDA filed May 7, 2004).

and defensible policy in this area would need. FDA should begin by considering evidence as to whether linked messages offer benefits or pose harms to the public health. If any as-yet unidentified harm is substantiated, the agency—mindful of the constitutional limits on its power—must turn to the task of tailoring any proposed disclosure remedy to address it. Pfizer urges FDA undertake these necessary steps before the agency either enforces the new Guidance in individual cases or finalizes it.

**I. FDA’s Effort to Impose Risk Disclosure on Certain Non-Product Messages Through an Amorphous “Linkage” Theory Could Inadvertently Impede Dissemination of Effective Disease Awareness Communications**

The Help-Seeking Guidance identifies—and distinguishes between—product advertising and promotional labeling, which are subject to FDA regulation, and disease awareness messages, which do not refer to regulated products and therefore are beyond the agency’s statutory jurisdiction. The Guidance expresses FDA’s view that the latter nonetheless can be brought within the agency’s authority if the messages are “combined” with either reminder advertising (which identifies a product but makes no claim about it) or with product ads (which include both the product name and efficacy and safety claims and are subject to FDA’s full risk disclosure mandates).<sup>7</sup> The combination at issue is not a literal merger of two separate communications but rather an implied linkage between messages that remain distinct in time or space. The Guidance maintains that certain amorphously defined combinations may, by virtue of their effect on consumer perceptions, effectively import product claims into disease awareness messages.

The discussion below explains that, in its current state, the Help-Seeking Guidance could discourage at least some manufacturers from disseminating more, and better, unbranded health communications. First, the Guidance inadvertently undercuts the public/private dynamic that has

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<sup>7</sup> Help-Seeking Guidance at lines 111-116.

spurred the development of the disease awareness communications that the FDA applauds.

Second, the “factors” that FDA proposes to use to identify improper linkages are so vague that they appear to bestow virtually unlimited discretion on the agency to draw connections that would trigger enforcement actions. They thus impose a high and unnecessary degree of risk on the dissemination of the disease awareness communications that the agency seeks to encourage.

**A. FDA Should Encourage Maximum Dissemination of Privately Funded—and Indisputably Useful—Help-Seeking Messages**

As noted above, the positive effect that privately funded help-seeking messages and other disease awareness communications have had on the public health is indisputable. Consumer-oriented help-seeking messages broadly expose large segments of the public to important health information in, typically, short and attractive print or electronic presentations that capture the attention of laypersons who might not otherwise seek out the data. Help-seeking messages convey not merely information about diseases or conditions but also drive home the point that health problems can be effectively treated under the direction of a licensed professional.<sup>8</sup> These communications act as a stimulus that results in diagnosis and treatment of diseases and conditions, some of which are serious or even life threatening.<sup>9</sup>

Manufacturers are motivated to fund disease awareness messages for several interlocking reasons. First, as participants in the health care system, manufacturers seek the best outcomes

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<sup>8</sup> FDA already has heard testimony indicating that health messages resonate powerfully with consumers when the communications also extend hope for treatment. *See* Hearing Transcript, Direct-To-Consumer Promotion Public Meeting, at 174-175 (Sept. 23, 2003), *available at* <http://www.fda.gov/cder/ddmac/DTCmeetingTranscript2.doc> (Dr. Mike Magee of Pfizer Inc. explaining that product advertisements, which inform patients of a specific treatment option, work to empower patients and motivate them to speak to their physicians about possible treatments.).

<sup>9</sup> The facts before the agency in its Consumer-Directed Promotions docket plainly demonstrates that direct-to-consumer (“DTC”) messages generate appropriate doctor/patient communications that lead to appropriate therapy decisions—which may or may not involve a drug produced by the manufacturer who funded the message. *See* Comments of Pfizer Inc, Request for Comment on Consumer-Directed Promotion, Docket No. 03N-0344, at 14-23, 28-34 (FDA filed Dec. 1, 2003) (summarizing data) (hereinafter “Pfizer Consumer-Directed Promotions Comments”).

for consumers and providers and recognize that increased disease awareness may be critical to early detection and effective treatment. Second, dissemination of disease awareness messages by identified manufacturers can build institutional goodwill with consumers and the health care community. Third, better recognition of disease and health condition symptoms can prompt consumers to seek necessary medical intervention and thus increase utilization of safe and effective drug treatment. The confluence of these motives produces a substantial disease awareness effort that delivers important public health benefits without any expenditure of public funds.<sup>10</sup> FDA, in our view, should direct its efforts to aligning its regulatory policies and these motives to preserve and expand disease awareness communication by manufacturers.

Unfortunately, the draft Help-Seeking Guidance may inadvertently diminish the manufacturers' incentives to disseminate useful, non-branded health information. Setting aside for the moment the many questions on exactly what the Guidance prohibits, it clearly suggests that FDA would expect any disease awareness message that shares some of the look, sound or feel of product ads to be directly accompanied by a full set of risk disclosures. Importing such information, however, necessarily requires naming the drug whose risks are being disclosed—which could well turn off those consumers who habitually resist product advertising and thereby prevent them from ever absorbing the health information. If help-seeking messages can remain outside product disclosure requirements only if they are stripped of all “perceptually similar” stylistic elements that would potentially identify a relevant drug treatment, at least some

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<sup>10</sup> As Pat Kelly, President of Pfizer U.S. Pharmaceuticals, recently said, “The unspoken truth about advertising of medicines is that it constitutes one of the largest and most successful public health campaigns in U.S. history.” See *FDA Preparing New Prescription Drug Ad Guidelines*, Reuters Health, Sept. 23, 2003, available at <http://12.42.224.225/HealthNews/reuters/NewsStory0923200317.htm>.

manufacturers might opt instead to shift resources to product ads where the regulatory requirements are clear.<sup>11</sup>

The resulting losses to the public health would be twofold. Pfizer knows that people tend to differ in their responses to various types of health messages, which is why diverse types of health education communications have the broadest possible impact. To the degree that some consumers would have responded more readily to foregone non-product messages, an opportunity to disseminate important information would be lost. Moreover, given the constraints inherent in both traditional advertising and non-product messages, if disease awareness communications were required to be supplemented with risk and benefit information, then a certain amount of time or space once devoted to details about the symptoms and long-term implications of diseases and conditions would be sacrificed. In other words, some “pure” information about a disease or condition would not reach consumers and entrusted professionals.

It appears from the text of the Guidance that FDA has not considered the full deterrent effect of its proposed new policy. Pfizer urges the agency to refashion its approach in a way that does not risk the loss of any of the valuable advertisement time and space currently devoted to help-seeking messages and other disease awareness communications.

**B. The Help-Seeking Guidance Identifies Only a Vague Definitional Test That Sets No Clear Boundary on Disclosure Requirements**

The Help-Seeking Guidance states that FDA may rely on two broad factors in determining whether “two communications together qualify as promotional labeling or

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<sup>11</sup> In fact, Novartis Pharmaceuticals recently indicated that concerns expressed by FDA over an unbranded Novartis ad campaign regarding available treatments for hypertension might deter the company from engaging in further disease awareness promotion. *See Novartis Unbranded Hypertension Ad Cited For Link To Diovan Promotion, “The Pink Sheet,”* July 26, 2004.

advertising” and thus fall within the agency’s regulatory power.<sup>12</sup> The factors are “perceptual similarity” in appearance and/or sound and “close physical or temporal proximity.”<sup>13</sup> The agency does not further define either factor, but it notes that perceptual similarity—which FDA considers the “determinant issue”—may include “thematic, graphic, visual and other presentation elements.”<sup>14</sup> The Guidance simply states that FDA may take enforcement action against a disease awareness message and a product ad “presented in combination ... in a way that causes the audience to perceive the two pieces as one advertisement or promotional labeling piece.”<sup>15</sup>

But, even assuming *arguendo* that FDA could accurately determine audience perceptions in these situations, the Guidance offer no clear boundaries to guide manufacturers who may wish to continue funding help-seeking messages when linkage could be asserted. In fact, certain public statements by the agency’s staff can be interpreted as imposing a *de facto* ban on the use of *any* similar visual or aural elements in help-seeking messages and product advertising.<sup>16</sup> By suggesting that this may be the only safe way to avoid enforcement actions, the agency appears to be making a sweeping —yet factually unsubstantiated—assumption about consumer perceptions.

The lack of clear directives for manufacturers appears to stem from the lack of factual evidence that might help determine the extent to which consumers actually do link Help-Seeking and branded messages. As the Guidance itself acknowledges, there is no data on record

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<sup>12</sup> Help-Seeking Guidance at lines 239-240.

<sup>13</sup> Help-Seeking Guidance at lines 221-224, 243-245.

<sup>14</sup> Help-Seeking Guidance at lines 247-253.

<sup>15</sup> Help-Seeking Guidance at lines 185-187.

<sup>16</sup> See Blanchard, *supra* note 3 (quoting DDMAC Director Tom Abrams as remarking that “You can keep things quite separate by just making sure that you don’t have similar presentational elements.”).

concerning the effect on consumers of perceptually similar help-seeking messages and product ads that are in some unspecified proximity to each other. FDA cites to some general psychological and market research that “suggests” how perceptual similarity may affect consumers who view advertising messages,<sup>17</sup> but it is not clear how these general insights might translate in reality—a reality that is complicated by the fact that the explicit content of a disease awareness message is not at all similar to a traditional advertisement. The Guidance acknowledges that it lacks any facts at all concerning the degree of “close physical or temporal proximity” that would warrant concern. FDA therefore appropriately calls for “comment on whether such data do exist or, in the absence of data, whether there would be utility in trying to develop specific criteria.”<sup>18</sup>

Development of an empirical record on both factors is not only useful but constitutionally necessary whenever the government proposes to act on the basis of *implied*, rather than explicit, messages. Pfizer notes that the FTC, with far greater general advertising expertise than FDA, routinely relies on adequate data-gathering procedures and standards to determine consumer perceptions about promotional messages before the agency acts upon them.<sup>19</sup> FDA itself has recognized the informative value of consumer survey evidence in the analogous context of analyzing health claims in food and dietary supplement labeling. There, the agency stated that it recognizes that survey data and other evidence will be helpful in evaluating whether consumers are misled by a particular claim.

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<sup>17</sup> Help-Seeking Guidance at lines 216-232.

<sup>18</sup> Help-Seeking Guidance at lines 255-257.

<sup>19</sup> See Comments of the Staff of the Bureau of Economics, et al., of the Federal Trade Commission, Request for Comment on First Amendment Issues, Appendix One: Building a Record on Advertising Meaning and Substantiation, Docket No. 02N-0209, at 3-4 (FDA filed Sept. 13, 2002) (explaining that “When the available extrinsic evidence is insufficient or flawed and the ad meaning is still uncertain, the FTC may proffer a copy test for the record. Copy testing is the most probative form of extrinsic evidence.”), *available at* <http://www.ftc.gov/os/2002/09/fdaappendix.pdf>.

For example, surveys, copy tests, and other reliable evidence of consumer interpretation can be helpful in assessing the particular message conveyed by a statement that FDA believes constitutes an implied claim.<sup>20</sup>

Survey evidence is also regularly relied on in false advertising cases under the Lanham Trademark Act, where jurists have long recognized that “the court’s reaction [to an advertisement] is at best not determinative and at worst irrelevant. The question in such cases is—what does the person to whom the advertisement is addressed find to be the message?”<sup>21</sup>

As it stands now, the Help-Seeking Guidance provides no practical help to manufacturers trying to answer that question. With respect to perceptual similarities, what precisely crosses the line? Would common coloration be enough? A common typeface for text? What if it were one or the other but not both? Similarly, with respect to physical or temporal proximity, how close is too close? In print, would the appearance of a help-seeking message and product ad in the same publication be too close? What if the publication was one edition of a newspaper but the two communications appeared in different topical sections, *e.g.*, sports and the feature section? If the publication were a magazine, would it matter if the issue had 30 pages or 300? If the medium were television, would it matter whether the two communications aired during the same program but during different commercial breaks? Would it matter if the two communications aired during different episodes of the same program—and would there be a distinction drawn between program episodes that air once a week versus those that are “stripped” across the same time period every weekday?

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<sup>20</sup> *Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability*, 67 Fed. Reg. 78002, at 78003 n. 1 (Dec. 20, 2002).

<sup>21</sup> *American Brands, Inc. v. R.J. Reynolds Tobacco Co.*, 413 F. Supp. 1352, 1357 (S.D.N.Y. 1976).

The conceptual difficulties surrounding the linkage construct go beyond those that arise in attempting to connect (or disconnect) two communications appearing in the same publication or program.<sup>22</sup> The Help-Seeking Guidance also suggests that a single-product company should be wary of ever disseminating a disease awareness message whether or not it engages in product advertising. While “not automatically disqualified” from engaging in such speech, such a firm nonetheless could face enforcement action if

FDA determines that a supposed disease awareness communication impliedly identifies a particular drug or device, *which may be the case when a communication relates to a drug or device that is the only drug or device in its diagnostic or therapeutic class or the only product manufactured by a company.*<sup>23</sup>

In other words, the FDA may determine a pre-formed linkage—based on its own perception and without regard to whether the audience knows whether a manufacturer sells only one product or offers the lone product approved for a particular condition.<sup>24</sup> As a practical matter, it seems that

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<sup>22</sup> Conflicting opinions on the general concept of linkages among FDA officials themselves illustrates the difficulty of drawing defensible distinctions without solid empirical data. Although the Draft Guidance expresses FDA’s position today that presentation of two linked advertisements “within the same 15 minutes of a one half hour program or the same half hour of a one hour program,” is problematic, Help-Seeking Guidance at lines 259-260, just five years ago FDA personnel indicated that the use of similar graphic or contextual images in reminder ads and product specific ads were not a cause for concern. *See FDA Response Time for DTC Ad Advisory Comments Has Doubled, Agency Says*, “The Pink Sheet,” Sept. 20, 1999 (quoting then-DDMAC Branch Chief Nancy Ostrove as remarking that FDA does not “worry about the linkages anymore,” and explaining “You can use the same graphic in the product ad and the ‘reminder’ ad as long as they don’t make representations about the product.”).

<sup>23</sup> Help-Seeking Guidance at lines 120-125 (emphasis added).

<sup>24</sup> The Guidance seems to imply that manufacturers should not help to build disease awareness for conditions for which there is only one drug therapy available because such communications would, by definition, indirectly promote the use of that one available product. This policy, therefore, discriminates on the basis of condition and discounts the public health benefit that would be lost if such communications were prohibited. If there is only one product available, it is inevitable that disease awareness communications will result in indirect promotion of the use of that product—but isn’t it desirable that consumers should use this product? Particularly if there is a new treatment available, why should policymakers not seek to inform the public and notify them that treatment is available for a condition from which they might suffer? Is FDA saying that consumers should only get the benefit of being able to learn about new treatments for health conditions when there is already more than one product available?

a single-product or category-exclusive company would have to eliminate references to the firm's name from the message in order to be assured that negative consequences would not attach.

Furthermore, the Help-Seeking Guidance does not make clear why this rationale would be limited to such firms. If any manufacturer heavily advertised a particular product, it is possible that consumers would associate the maker's name with that product, regardless of how many other treatment options existed for the condition or how many other drugs or devices the manufacturer marketed. Consequently, the same potential for pre-formed linkages would seem to exist. Does this mean that all manufacturers engaged in significant amounts of consumer-oriented advertising should take the precaution of eliminating the last vestige of their business identities—the firm name and logo—from their help-seeking messages?<sup>25</sup> Faced with the uncertainty, it seems more likely that such manufacturers could be dissuaded from engaging in disease awareness ads at all.

In sum, there is no obvious, logical stopping point to the linkage concept. Tracing out the logical implications of the Guidance's rationale illustrates why FDA must reconsider its proposed approach to supposedly linked communications. At the very least, the agency should gather and analyze data that could lead to development of a more workable and factually grounded policy.

## **II. The Help-Seeking Guidance Fails to Recognize the Potential Benefits of The Common Elements That Allegedly Link Disease Awareness Messages or to Substantiate Any Purported Harm Caused by Them**

Setting aside the practical difficulties of determining what perceptual similarities may creates linkages justifying extension of FDA authority, Pfizer is concerned about several key

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<sup>25</sup> Depending on how far the Guidance's prohibition on use of perceptually similar stylistic elements might go, the resulting message might create an impression among the public that the manufacturer was not being forthright in its consumer-directed communications.

policy assumptions that appear to have shaped the Guidance. Foremost among them is the unproven supposition that linkages between branded ads and disease awareness messages can offer no benefits to the public health but instead could pose only harm to consumers and professionals. The discussion below explains why FDA should not proceed on its unsubstantiated assumptions.<sup>26</sup>

With respect to benefits, there are good reasons to believe that some perceptual linkages actually serve to focus consumer attention on the important health information that disease awareness communications convey. It is considerably more difficult to develop *successful* consumer-directed promotional communications than many people realize.<sup>27</sup> This is so not merely because of challenges involved in any creative effort to attract favorable attention to a message, but because of the need in today's consumer-oriented society to break through ubiquitous "commercial clutter" to reach the people who can make good use of the information provided.<sup>28</sup> When a certain advertising campaign connects with the public—establishing both recognition and trust among consumers—it makes sense from a communications standpoint to extend the usefulness of the symbols and spokespersons by employing them in the service of

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<sup>26</sup> The constitutional dimensions of FDA's legal burdens in this proceeding are discussed *infra* Section IV.

<sup>27</sup> See Yankelovich Partners, Inc., *2004 Marketing Resistance Survey* (Apr. 15, 2004) (explaining that "Response to all forms of marketing is declining at precipitous rates ... clutter, competition and fragmentation have steadily chipped away at the productivity of marketing. In response, marketers have redoubled their efforts, flooding the marketplace with a deluge of more marketing in the hope that some message somewhere will break through to consumers. This creates a marketing-saturated environment that consumers are resisting with increasing sophistication and skill.").

<sup>28</sup> See *Clutter on Broadcast Rises*, *Television Wk.*, Apr. 12, 2004 (quoting Debbie Solomon, Senior Partner/Group Research Director, MindShare, as stating that "A new survey by MindShare found that for the first time, three of the Big 4 networks broadcast more than 15 minutes of what's called 'nonprogram' material per hour during prime time in 2003 ... Advertisers are alarmed about clutter because it makes viewers tune out both shows and commercials."); *Record Amount of Advertising Clutter in Primetime TV*, *PR Newswire*, Dec. 15, 2003 (quoting Terry Villines, Director of Analysis, PhaseOne Communications, as noting that "Television viewers are inundated with promotional messages during primetime ... Breaking through the clutter and getting a television ad noticed today is harder than ever ... Advertisers need to be increasingly creative to deliver the same results that television advertising has offered in the past.").

help-seeking messages. Thus, for example, use of a celebrity who speaks out on a particular condition in the context of full product ads could, simply by his or her presence in a help-seeking message, alert interested consumers that the topic is once again before them. The format of the help-seeking message then allows the spokesperson to communicate even more information about the disease or condition to an audience that needs and values the data. As a result, the messages further encourage consumers to act on the information provided and manufacturers to support dissemination of the messages.

Not only does the Guidance fail to take account of the potential for this beneficial outcome, it also is internally inconsistent with respect to its own rationales. For example, the Guidance seems to treat a linkage between a help-seeking message and a full product ad as raising the same concerns as a linkage between a help-seeking message and a reminder ad, even though the content of the two types of regulated advertisements are dramatically different. As Pfizer noted in its initial comments in this docket, the logic behind objections to “bookending” help-seeking messages and reminder ads cannot simply be that the communications “are presented in a manner that causes their messages to be linked together by the audience,”<sup>29</sup> but that *neither* part brings risk disclosures or other mandated information to the mix.

In contrast, the Guidance’s rationale should compel the conclusion that if a product ad were linked with a help-seeking ad, the fully compliant risk disclosures of the former are necessarily brought into the combination. Thus, there would seem to be no basis for concern about possible evasion of full product risk disclosure rules in this situation or any resulting misleading of the recipients of the linked messages. Only real consumer testing, however, could

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<sup>29</sup> Help-Seeking Guidance at lines 203-204.

confirm whether consumers actually connect either the product claim or the risk disclosures of a full product ad and a help-seeking message.

Even if some linkage did exist between a disease awareness message and either a product or reminder ad, it would not establish that the linkage automatically harms the recipients of the communications. At the present time FDA has no research data that could help it determine what consumers or practitioners might “take away” from perceptually similar or proximate messages. FDA simply expresses its own view that such messages convey product efficacy claims that the agency concludes must be balanced by appropriate warnings. But do they create claims that require warnings and, if so, in what detail?

Discerning the consumer take away from allegedly implied claims is no easy matter. As Pfizer’s comments in the Consumer-Directed Promotions docket noted, the European Commission discovered that its recent effort to improve drug risk warnings had the decidedly unintended effect of frightening consumers away from treatments that could help them.<sup>30</sup> Here, FDA could well find that the untested premise of the Help-Seeking Guidance would play out in a counterproductive way by discouraging the dissemination of messages that cause no harm and serve an important public health interest.

Finally, the premise underlying the linkage construct takes no account of the sophistication of the typical American consumer in a commercial environment. Even when standing alone, a help-seeking message by its very nature indicates that some sort of drug therapy is available to treat the particular disease or condition. The messages also are accompanied by the name and corporate logo of the manufacturer who sponsored the

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<sup>30</sup> Pfizer Consumer-Directed Promotions Comments at 53 (citing Diane C. Berry, et al., *Patients’ Understanding of Risk Associated with Medication Use: Impact of European Commission Guidelines and Other Risk Scales*, 26 Drug Safety 1-11 (2003)).

communication.<sup>31</sup> While this does not, in Pfizer’s view, mean that help-seeking messages should be categorized legally as commercial speech, it likely does telegraph to most U.S. consumers that the sponsor probably has an interest in at least one treatment option. But the fact that many consumers may make this connection in their minds—on the basis of a single disease awareness communication—does not prove that consumers are misled or otherwise harmed by the linkage. The Help-Seeking Guidance provides no basis for determining that any linkage between two manufacturer-sponsored messages is necessarily more harmful than the implication that arises from one non-product communication sponsored by the same commercial firm, and it fails to consider the possible benefits to consumers that might result from such linkages.

### **III. The Guidance Does Not Attempt to Tailor Disclosures to Address Any Purported Harm Caused by Arguably Linked Messages**

The Guidance’s failure to specify the harm that FDA perceives in some or all combination of linked communications leads, as a natural consequence, to another omission—the Guidance provides no insight as to what type of disclosures might be appropriate where linkage exists. FDA would be better equipped to provide manufacturers clear guidance on any necessary remedies if the agency had some evidence on point.

To be clear, even if audiences were mentally importing product claims into “linked” disease awareness messages, FDA still does not know the degree of specificity involved in that transference and therefore cannot say what type of risk disclosures might be needed to address any consumer misperceptions. It could be, for instance, that the transference involves nothing more than a general awareness that a related product exists. In such a case, what level of warnings would be required? And if FDA wished to distinguish between the importation of

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<sup>31</sup> In the context of broadcast messages, such identifications are mandated by the Federal Communications Commission’s “sponsorship identification” rules. *See* 47 C.F.R. § 73.1212 (2003).

efficacy or safety claims and risk disclosures from product ads to disease awareness messages, what factual evidence would support that distinction?<sup>32</sup>

The few references in the Guidance to remedies now merely reference the existing print and broadcast disclosure requirements. Does FDA mean to suggest that a help-seeking message that could be linked to a product or reminder ad must contain the full panoply of risk warnings—even though the disease awareness communication itself never names the drug to which the warnings attach? Is a consumer’s awareness that a drug may be associated with the treatment of a condition alone sufficiently specific to warrant comprehensive risk disclosures? Does it make a difference if the identified linkage provides no further information about the drug’s dosage or efficacy? Or, as noted above, does FDA mean that the help-seeking message in this instance must explicitly name the drug as well as provide the attendant disclosures? If that is what the agency expects, what would distinguish a help-seeking message from a full product ad?

In posing these questions, Pfizer does not mean to suggest that the government has no power to address a particular combination of manufacturer communications that do pose a demonstrable harm. If the Guidance were limited to targeted and clearly defined enforcement actions—rather than the sweeping approach to linkages that the document currently suggests—FDA’s new policy would better serve the public health. The agency would also be in a position to encourage linkages that might offer demonstrable benefits to the public health.

#### **IV. The Guidance Raises Significant First Amendment Issues**

In addition to the policy considerations here, FDA also must be sensitive to the constitutional issues that would be raised by enforcement—or the threat of enforcement—of an

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<sup>32</sup> As noted above, the Guidance implies that only product claims make this transference. The document does not address the agency’s apparent assumption that linkages could not also import risk disclosure information from product ad into the help-seeking message.

untested linkage theory premised on inchoate claims of harm. Disease awareness messages, as the agency defines them, should enjoy the highest degree of First Amendment protection as scientific speech. Standing alone, they plainly lack the traditional hallmarks of advertising, *e.g.*, mention of a product or proposal of a commercial transaction. Accordingly, government regulators could only sustain restrictions on help-seeking and other disease awareness messages if restrictions served a “compelling” government interest and only if the mandates were the “least restrictive means” of achieving the objective.<sup>33</sup> As Justice Souter recently noted, such “strict scrutiny” review “leaves few survivors.”<sup>34</sup>

It is not at all clear that help-seeking messages can or should lose their full measure of First Amendment protection simply because the government has linked them with product ads in some conceptual sense. To the contrary, a reviewing court might well be alarmed by the prospect that a government-made fusion of two independently articulated messages could dilute the degree of constitutional protection otherwise given to at least one of them—particularly when the government lacked evidence to support the linkage or its claimed effect on consumers.

Even if a help-seeking message were deemed to share the qualities of a product ad, the burden would be on the government to prove that any imposed disclosures were necessary.<sup>35</sup> Under the so-called *Central Hudson* standard for protection of commercial speech, FDA would face significant burdens in justifying enforcement of the linkage theory as it now appears in the draft Guidance. That analysis would require the agency not only to identify a legitimate harm to be addressed but also show that its linkage policy “directly advances” the identified goal and

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<sup>33</sup> See, *e.g.*, *U.S. v. Playboy Entm’t Group*, 529 U.S. 803, 813 (2000).

<sup>34</sup> *City of L.A. v. Alameda Books, Inc.*, 535 U.S. 425, 455 (2002) (Souter, J., dissenting).

<sup>35</sup> See, *e.g.*, *Edenfield v. Fane*, 507 U.S. 761, 770-771 (1993); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002).

does so in a manner “not more extensive than is necessary to serve” that goal.<sup>36</sup> The discussion above illustrates that FDA at this time lacks the evidence necessary to make a successful showing on any of the three prongs of *Central Hudson*. As an initial matter, the agency has yet to demonstrate that the harm it apparently perceives—communication of a product claim to consumers or professionals without accompanying risk disclosures—has a basis in fact. Moreover, until the agency claims some empirical grounding for the distinctions it may make with respect to either perceptual similarity or spatial/temporal proximity, FDA may be hard-pressed to show that a restriction on linkage “will in fact alleviate [the asserted harm] to a material degree.”<sup>37</sup> On the other hand, while a linkage restriction that amounts to a *de facto* ban might satisfy the “direct advancement” hurdle, it surely would fail *Central Hudson*’s final prong: the amorphous but sweeping linkage concept plainly is “more extensive than is necessary to serve [the asserted] interests.”<sup>38</sup> Indeed, as noted above, the vague nature of the linkage prohibition raises distinct First Amendment considerations wholly apart from the commercial speech issues, in that the inability of manufacturers to determine precisely what speech is prohibited might chill disease awareness communications altogether.<sup>39</sup>

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<sup>36</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 434 (1993).

<sup>37</sup> *Edenfield*, 507 U.S. at 771.

<sup>38</sup> *Western States*, 535 U.S. at 371 (citation omitted).

<sup>39</sup> See, e.g., *Reno v. ACLU*, 521 U.S. 844, 871-872 (1997) (stating that “The vagueness of [a content-based] regulation raises special First Amendment concerns because of its obvious chilling effect on free speech.”); *Keyishian v. Bd. of Regents of the Univ. of New York*, 385 U.S. 589, 604 (1967) (noting that “The danger of that chilling effect upon the exercise of vital First Amendment rights must be guarded against by sensitive tools which clearly inform [those subject to the law] what is being proscribed.”); *NAACP v. Button*, 371 U.S. 415, 433 (1963) (explaining that “Because First Amendment freedoms need breathing area to survive, government may regulate in the area only with narrow specificity.”). Cf. *Gentile v. State Bar of Nevada*, 501 U.S. 1030, 1051 (1991) (stating that “The prohibition against vague regulations of speech is based in part on the need to eliminate the impermissible risk of discriminatory enforcement.”).

## CONCLUSION

The Help-Seeking Guidance appears to advance in two opposing directions. It encourages manufacturers to offer greater support for help-seeking messages and thereby benefit the public health, but it then puts manufacturers disseminating effective versions of those communications at amorphous enforcement risk. Pfizer urges FDA to refrain from either enforcing the Help-Seeking Guidance or moving to finalize it until the agency has evidence showing what linkages consumers and professionals may actually draw between disease awareness messages and product ads—and whether those linkages, if any, create problems that call for appropriately tailored agency action.

Respectfully submitted,

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