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ATTACHMENT

AdvaMed
Advanced Medical Technology Association

August 10, 2004

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

Re: Docket Number 2004D-0042: Draft Guidances for Industry on Improving Information about Medical Products and Health Conditions

Dear Sir or Madam:

These comments are submitted on behalf of the Advanced Medical Technology Association (AdvaMed). AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,200 members and subsidiaries manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than $30 million in sales annually.

On April 2, 2004, AdvaMed requested an extension of the comment period. On June 1, 2004, FDA granted an extension until August 10, 2004. (69 Fed. Reg. 30945)

As noted below, AdvaMed has both general comments on DTC advertising as well as specific comments on two of the three draft guidance documents.

GENERAL COMMENTS ON DIRECT-TO-CONSUMER ADVERTISING

The February 10, 2004 *Federal Register Notice* indicated that these draft guidance documents on DTC advertising were, in part, based on discussions and presentations at a September 3, 2003 open public meeting on consumer-directed advertising. The focus of that meeting was consumer-directed drug advertising. Device manufacturers did not provide input. As a result, the guidance documents have a decidedly consumer-directed drug advertising approach and do not consider that consumer-directed device advertising may require a slightly different approach.

The Act's requirements for drug and restricted device advertising are distinct. The guidance on DTC advertising for restricted devices is predicated on the incorrect assumption that FDA's drug misbranding authority under Section 502(n) [21 USC §352(n)] of the Federal Food, Drug, and Cosmetic Act (the "Act") is the same as the agency's authority under Section 502(r) [21 USC §352(r)] for restricted devices. This assumption is contrary to the plain language of the Act and results in inappropriate regulatory guidance for DTC advertising for manufacturers of restricted devices.

For prescription drugs, Section 502(n)(3) of the Act requires that advertisements include "information in *brief summary* relating to side effects, contraindications, and *effectiveness* as shall be required *in regulations*." [21 USC §352(n)(3) (emphasis added).] For restricted devices, Section 502(r) requires manufacturers to include "in all advertisements and other descriptive printed matter . . . *a brief statement of the intended uses of the device* and *relevant* warnings, precautions, side effects, and contraindications . . ." [21 USC §352(r) (emphasis added).]

The highlighted statutory language presents legally significant differences between the requirements for prescription drugs and restricted devices. Specifically, prescription drug advertisements must briefly *summarize* effectiveness and safety information. In contrast, restricted devices need only briefly state a restricted device's intended use and *relevant* risk information, a significantly lesser burden than summarizing all the effectiveness and specified risk information regarding a prescription drug. Further, in enacting the brief summary requirement for prescription drugs, Congress imposed upon FDA the duty to explain and implement a regulatory scheme for drug advertising through notice and comment rulemaking. By comparison, Congress chose to require a straightforward brief statement in restricted device advertising that did not require implementation by regulation. In other words, Congress intended a brief summary of effectiveness and risk-related information for prescription drug advertising to be part of a comprehensive and detailed regulatory scheme and had no such plan for restricted device advertising, which was to be subject only to a brief statement of intended use and relevant warnings, precautions, side-effects and contraindications.

Indeed, FDA's prescription drug regulations are considerably more detailed than the legal requirements imposed by the statute on restricted devices. In its prescription drug advertising regulations, the agency defines the brief summary requirement to require disclosure of the product's major risks in either the audio or audio and visual parts of broadcast advertisements; this is known as the "major statement." Broadcast advertisements for prescription drugs are also required to make "adequate provision ... for dissemination of the approved or permitted package labeling in connection with the broadcast presentation." (21 CFR 202.1(e)(1)). According to CDER guidance, the major statement and the adequate provision of labeling information requirements satisfy the brief summary requirement for broadcast ads. *See Guidance for Industry: Consumer-Directed Broadcast Advertisements* (CDER, CBER, and CVM, August 1999). Although Section 502(n) provides FDA with authority to impose these regulatory requirements on prescription drug advertising, there is no reasonable interpretation of Section 502(r) that would require a major statement and adequate provision of labeling information to satisfy the brief statement requirement for

restricted devices. The plain meaning of the Section 502(r) requirement for a brief statement of relevant information on warnings, precautions, side-effects, contraindications and intended use does not encompass a requirement for a major statement and an adequate provision of labeling information.

In addition, Section 502(r) does not require restricted device advertisements to provide effectiveness information.[1] As a result, Section 502(r) does not raise the concerns regarding fair balance of information on risks and benefits that advertisements for prescription drugs do under Section 502(n) and FDA's drug advertising regulations. Therefore, only if a device manufacturer voluntarily chooses to include effectiveness information is there a need to balance that information with relevant risk information.

In summary, applying a similar approach for restricted device advertising to that of prescription drug advertising is simply inappropriate. By articulating the disclosure necessary for restricted devices as a brief statement, rather than a brief summary, Congress chose new and different substantive requirements for restricted device advertisements. Further, Congress did so with full knowledge of the requirements for prescription drug advertisements in Section 502(n). Had Congress intended the restricted device advertising requirements to be the same as those for prescription drugs, it could just have simplified things and added restricted devices to Section 502(n). As a result, applying prescription drug laws and regulations to DTC device advertising is not in accordance with the Act and violates the Administrative Procedure Act. *See* 5 USC 706(2)(A) (agency action not in accordance with law must be set aside).[2] To be lawful, agency guidance in this area must recognize and reasonably accommodate the differences between the statutory requirements for prescription drug and restricted device advertising.

Because of the need to address restricted device advertising under applicable statutory authority, and because of the need to recognize differences in the way devices and drugs are advertised, AdvaMed requests that FDA convene an open public meeting on device advertising, particularly on consumer directed communications, before finalizing the guidance documents concerning "Consumer-Directed Broadcast Advertising of Restricted Devices" and "'Help-Seeking' and Other Disease Awareness Communications by or on behalf of Drug and Device Firms - Draft Guidance for Industry." At the hearing, unique issues for devices can be presented. After that input, the restricted device advertising

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[1] While we agree FDA may require effectiveness information for individual or types of restricted devices as a condition of approval under Section 520 or a PMA order under Section 515 (21 USC §360e) of the Act, Section 502(r) contains no requirement that effectiveness information be presented in advertisements for restricted devices. FDA does not have the legal authority under Section 502(r) to require effectiveness information to be presented in an advertisement for restricted devices.

[2] Importantly, as discussed above, Section 502(n) requires FDA to implement regulations to effect its advertising requirements, whereas Section 502(r) does not. Therefore, the attempt to apply drug regulations to devices through guidance is unlawful under the APA because FDA is attempting to impose substantive requirements without notice and comment rulemaking. *See* 5 USC § 553. Because guidance can be final agency action upon which a lawsuit can be brought, *Cf. Washington Legal Foundation v. Friedman ("WLF I")*, 13 F. Supp.2d 51, 66-67 (D.D.C. 1998) (challenging agency guidance documents under the First Amendment), the agency's unlawful guidance, if made final, may be subject to court challenge.

guidance document and the disease awareness guidance document can be rewritten to contain provisions that are specifically relevant to devices, rather than merely applying drug laws and regulations to devices.

SPECIFIC COMMENTS ON DRAFT GUIDANCE DOCUMENTS

DRAFT GUIDANCE FOR INDUSTRY AND FDA ON CONSUMER-DIRECTED BROADCAST ADVERTISING OF RESTRICTED DEVICES

Introduction Section

In footnote 1, a description of "restricted devices" is provided. It would be a helpful clarification to include in this footnote the language from footnote 1 of the draft guidance document on disease awareness communications which recognizes that "The agency's authority over device advertising only extends to restricted devices. Other device advertising is regulated by the Federal Trade Commission (FTC)." It would also be important for this language to include a statement that not all prescription devices are restricted devices.

In the Introduction, the guidance document should clearly state that the "broadcast" media to which it refers are radio, television, and telephone advertising.

Background Section

In the first bullet point on page 2, the guidance document states that DTC broadcast advertisements for restricted devices, in order to comply with the prohibition against false and misleading advertisements, "would include communicating that the advertised device is restricted to sale, distribution or use only upon authorization of a licensed practitioner or upon other conditions established by FDA in regulations or in an approval order." This is too broad, as there are generally several pages of "conditions of approval" established by FDA in PMA letters of approval, most of which are too technical to be of any value to communicate to consumers in DTC advertising. This sentence in the guidance document should be deleted and then rewritten to state the following: "If the device is a prescription device, then the DTC advertisement needs to communicate to the consumer that the device is only available with a prescription from a licensed practitioner and the patient should consult with a doctor in order to obtain the device. Some examples of this type of statement include, but are not limited to, the following: 'See your doctor' or 'Available by prescription only' or 'Rx only' or 'Caution: Federal law restricts this device to sale by or on the order of a physician.'"

With respect to the "brief statement" requirement from Section 502(r), any guidance on this subject must take into account that the statutory language contains a crucial term -- "relevant." The legal requirement is for **relevant** warnings, precautions, side effects, and contraindications to be included in the DTC advertisement. Accordingly, it is not correct that "all" of the device's most important warnings, precautions, side effects, and contraindications are to be mentioned in advertising. Guidance on this subject should state that "relevant" means the warnings, precautions, side effects, and contraindications that are related to the

indication(s) being advertised. A device may have several different indication(s) for use. The DTC advertisement may discuss only one of these uses. Accordingly, it would be logical for that particular DTC advertisement's "brief statement" to refer only to the warnings, precautions, side effects, and contraindications that relate to the indication(s) discussed in the advertisement. In fact, it would be confusing for a consumer to be exposed at the same time in one DTC broadcast advertisement to all of a device's other possible indications, as well as the warnings, precautions, side effects, and contraindications for those other indications.

In the third bullet point on page 2, the guidance document states that DTC advertisements are to communicate all information relevant to the device's indication (including a brief statement of the intended use(s) of the device and any limitations to use) in consumer-friendly language. Similar to our comments above, the guidance document should delete the use of the term "all." It would never be possible to communicate "all" information about a device's intended uses in a DTC advertisement and "all" exceeds the statutory requirement. Instead, the term "relevant" should be used and the guidance document should make it clear that a DTC broadcast advertisement focused on one (or a subset) of the device's intended uses, only needs to mention the uses that are relevant to the content of that particular advertisement.

Fulfilling the Brief Statement Requirement

On page 3 of the guidance document, FDA states that the "brief statement" statutory requirement for restricted device advertising may be met by a disclosure of risk information as well as dissemination of device labeling.

Risk Information

With respect to the disclosure of risk information, it is unclear whether there is a distinction in the risk information that may be provided for restricted devices that are used by the patient (e.g. hearing aids) compared to those used by a physician (e.g. stent). Warnings and precautions for the latter types of restricted devices are generally aimed at the procedure/technique and would not be applicable to a consumer. The guidance document should specifically recognize this distinction. The guidance document should specify that any risk information communicated in DTC advertising for restricted devices used only by a physician can be tailored to the needs of a consumer by omitting technical warnings and precautions that are intended for the physician to be aware of in order to perform a procedure with the device. And the guidance document should state that for restricted devices used only by a physician, a general statement about risks, such as the following, can be sufficient in a broadcast advertisement: "As with any surgical procedure, the (name of procedure or device) may present risks. Patients should consult with their doctors for more information."

In some PMA approval letters, while noting the device's restricted status, FDA may have outlined the type of "brief statement" that would, in the agency's view, be acceptable for communication in advertising. The guidance document should recognize this type of situation and instruct that a manufacturer can follow the instructions in the letter, rather than the provisions in the guidance document.

Dissemination of Device Labeling

As noted above, nowhere in the Act or the regulations is legal authority provided for FDA to require dissemination of device labeling in connection with the "brief statement" for restricted device advertising. There are significant legal differences between the laws and regulations for drugs and devices. Dissemination of device labeling is not a necessary legal requirement for a manufacturer to meet its "brief statement" requirement. The guidance document should acknowledge that a "brief statement" by itself is sufficient for a manufacturer to meet its legal requirement for DTC advertising of restricted devices. The guidance document should note that a manufacturer is not obligated to, but may choose to, disseminate a device's labeling in connection with a DTC advertising campaign.

Voluntary Mechanisms to Disseminate Device Labeling

Device manufacturers convey information about their products in a fundamentally different manner than pharmaceutical manufacturers (e.g., most device purchasing decisions are made by physicians without significant input from patients). Because the pharmaceutical industry utilizes pharmacies and pharmacists in the distribution of drugs, there is a preexisting mechanism in place for distributing related product information. The device industry does not have a comparable compendia of patient information from which patient information could be accessed.

The guidance document on pages 3 and 4 outlines "one acceptable approach" for dissemination of device labeling including "the following components" identified in a list of four items (A through D). Assuming that a manufacturer chooses to disseminate its device labeling as part of an advertising campaign, the guidance document should make it clear that any one of the components listed, by itself, is an available option.

The diversity of device types marketed in the U.S. suggests that one mechanism of disseminating labeling would not fit all manufacturers. Therefore, the guidance document should also note that a manufacturer may choose to use a variety of dissemination methods, whichever in the manufacturer's judgment will best suit the purpose of getting the labeling information to the consumer.

Component A

Under Component A, consumers may be read the labeling over the phone, however, the guidance does not specify what labeling to use. For device companies to read the entire user's manual over the phone would be lengthy and overly cumbersome (even given the limitations provided by footnote 3). Further, because the labeling is often only an operator's manual, it is unlikely that a patient's question would be answered. We suggest that the phone option be eliminated. Alternatively we suggest the guidance state that a manufacturer may choose to provide the device's brief statement (including intended uses of the device and relevant warnings, precautions, side effects, and contraindications) in consumer-friendly language over the telephone.

The first bullet in Component A on page 3 specifies: "[h]aving the labeling mailed to [the consumer] in a timely manner (e.g. within 2 business days for receipt generally within 4-6 days)." Mailing within 2 business days after a consumer's call is an overly ambitious time

frame. Instead, the guidance document should specify that a manufacturer may choose to mail labeling within five (5) business days.

Component B

There are two aspects to Component B. First, the discussion of disseminating a print advertisement along with the broadcast advertisement and second, the suggested mechanism of providing brochures in a variety of publicly accessible sites.

With respect to disseminating a print advertisement, the guidance document states that "print advertisements associated with broadly disseminated broadcast advertisements should be comparably broadly disseminated in terms of the targeted audiences." The term "comparably broadly disseminated" is not defined. It should be defined with some examples that give manufacturers a variety of possible locations to choose from in placing a print advertisement. Examples include, but are not limited to, a magazine or a newspaper with national circulation or a consumer-directed publication intended for distribution to physicians' offices.

The suggested mechanism of providing brochures in a variety of publicly accessible sites – such as grocery stores, pharmacies, and libraries – should be eliminated. Such a mechanism intrudes on a person's privacy, is impractical, overly burdensome, and would most likely confuse consumers rather than assist them. In addition, company experience has demonstrated that retail stores do not typically agree to display such third party materials in their locations as a simple matter of course. Retailers generally consider their floor space to be a prime advertising location. Accordingly, they charge for the use of any display space and it may take many months for a company to negotiate access to the space.

Instead, a more appropriate option would be to make brochures available to consumers in various healthcare settings. Many restricted devices are intended for use by physicians in a controlled healthcare setting (i.e. doctor's office, ambulatory surgical center, outpatient hospital facility). Therefore, placing brochures in these settings is more likely to achieve the goal of reaching consumers with information pertaining to a medical device that may be used in their diagnosis or treatment.

Telephone Advertisements

On pages 4-5 of the guidance document, there is a paragraph discussing "telephone advertisements" which are described as "… when there is a telephone communication between an individual and a device's sponsor where both a device name and a representation or suggestion relating to a device (e.g. its indication) are disclosed by the sponsor." FDA asserts that the "brief statement" requirement of Section 502(r) applies to these telephone advertisements, but could be met by simply having the device labeling mailed to the caller or by having the labeling read to them over the phone.

This section requires clarification. Consumers call medical device manufacturers for many reasons, and a call may involve disclosure of a device name and its indications, but should not on that basis alone be considered a "telephone advertisement." For example, a consumer may call a medical device manufacturer to report a complaint involving a device, and this type of call certainly would discuss the name of the product and its indications. This type of

call should not be considered a "telephone advertisement." The guidance document should state that a "telephone advertisement" means a telephone contact that has been initiated by the company to the consumer in order to promote a medical device product, such as a pre-recorded telephone message designed to promote a product directly to consumers.

Similarly, if a company has provided a toll-free telephone number, sponsored by the company (either in a DTC advertisement or in another vehicle), for consumers to contact for additional information about a product, the conversation between a customer who calls that number and the company representative should not be considered a "telephone advertisement." A "brief statement" should not need to be provided in the telephone call since the consumer has already seen or heard the "brief statement" in the broadcast advertisement. The guidance document should specifically point this out.

In addition, the option to mail device labeling to the consumer after a telephone advertisement to satisfy the "brief statement" requirement should be lengthened from two business days to five business days.

Foreign Language Broadcast Advertisements

On page 5 of the guidance document it states that "when a broadcast advertisement is presented in a foreign language, the information sources that are part of the advertisement's brief statement ... should be in the language of the broadcast ad."
A clarification should be provided in the guidance document that this section is intended to refer only to advertisements broadcast in the United States and its territories in a language other than English, as FDA's legal jurisdiction does not extend to advertisements that are broadcast outside the United States and its territories.

DRAFT GUIDANCE FOR INDUSTRY ON "HELP-SEEKING" AND OTHER DISEASE AWARENESS COMMUNICATIONS BY OR ON BEHALF OF DRUG AND DEVICE FIRMS

On page 1 of the guidance document, the statement is made that disease awareness communications are not subject to the requirements of the FDCA and FDA regulations. Nevertheless, the thrust of the guidance document attempts to justify FDA's reaching out to regulate those communications by hypothesizing some ways in which a disease awareness communication could be linked to product promotion. By doing this, FDA is overreaching -- going well beyond its statutory authority to regulate labeling and prescription drug/restricted device advertising. This guidance document is ill-considered and should be rewritten.

The guidance document states that if a disease awareness communication contains a representation or suggestion about a particular drug or device, then the communication is considered to be labeling or advertising that is regulated by FDA. Such a representation is presumed to occur, for example, if the communication relates to a drug or device that is the first of a kind in its category or is the only product that a company manufactures. Further, in either of these examples, even the mere mention of the company's name could bring the advertising or labeling requirements into play. In reality, this purported linkage between specific product advertising/labeling and disease awareness communication is simply a

punishment for small companies with only one product as well as a disincentive to innovative companies with a first-to-market product. These companies should be encouraged to provide broadcast advertising that reaches consumers to make people aware of new ways in which to diagnose or treat disease. If simply a company name is mentioned during this advertisement, it is not necessary (and would actually be confusing) for the advertisement to contain a litany of product-specific information.

On pages 5-7 of the guidance document, it says that a disease awareness communication will be considered to be labeling or advertising regulated by FDA if it is presented "... in combination with reminder promotion or product claim promotion in a way that causes the audience to perceive the two pieces as one advertisement or promotional piece." The test for such 'togetherness' is articulated as "perceptually similar reminder advertisements" which supposedly include proximity in time or space of a disease awareness communication with a product promotion or with similar presentation elements (such as story lines, colors, logos, tag lines, or graphics). AdvaMed believes that this is a completely speculative discussion by the agency based on sparse and outdated references (footnotes 6 through 9). If FDA were going to pursue this theory of linkage (which we believe is misplaced), then FDA should rely on empirical evidence to define 'perceptually similar' for application in the context of drug and device advertising. The agency is again trying to find any pretext to reach out and regulate disease awareness communications as if they were product-specific advertisements.

<u>The Agency's Guidance Violates the First Amendment</u>

In the proposed guidance, the agency acknowledges that disease awareness and help seeking communications ("disease awareness communications") can provide important information to consumers and health care practitioners. As noted above, FDA also acknowledges that it does not have jurisdiction to regulate them. Nonetheless, the guidance goes on to define disease awareness communications by limiting who can sponsor them, their content, and their placement. Further, the guidance does so in ways that are vague and therefore likely to chill the very speech the agency has identified as important to the public health.

The agency fails to articulate clearly (1) the circumstances under which a disease awareness communication relating to a breakthrough product or a small company's only product becomes advertising or labeling, and (2) what establishes the linkage between a disease awareness communication and reminder advertising (or promotional labeling), thus converting a disease awareness communication into a promotional piece. Instead, on page 4 of the guidance document, FDA states that it "*may* treat the communication as labeling or advertising" when it "determines that a supposed disease awareness communication impliedly identifies a particular product 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." (Emphasis added). In footnote 4, FDA adds that whether or not the labeling or advertising requirements are triggered depends upon "the overall meaning and context of the communication." Similarly, on page 7 of the guidance document, the agency states that it considers two factors in determining whether a help seeking advertisement and reminder ad taken together constitute promotional labeling or advertising, i.e., (1) whether the pieces are "perceptually

distinct in use of graphic, visual, thematic, or other presentation elements" and (2) whether the pieces are presented in "close physical or temporal proximity." The first factor is stated to be more determinative of the two, while the agency acknowledges that the second factor is difficult to define. However, the agency fails to appreciate that perceptional distinctness is no more comprehensible than the second factor. The agency's guidance is more confounding than clarifying of when a disease awareness or health seeking communication stumbles across the line and becomes a promotional claim.

To the extent disease awareness help seeking communications are not false and misleading, FDA should not undertake to regulate them, especially pursuant to vague guidance standards. Certainly, two truthful messages in some undefined proximity should not together create deception or even, necessarily, a claim. It is not enough that speech is potentially misleading; it must be inherently misleading before the agency can regulate it without regard to First Amendment limitations on regulation of commercial speech. *See Washington Legal Foundation v. Friedman ("WLF I")*, 13 F. Supp.2d 51, 66-67 (D.D.C. 1998); *see also Washington Legal Foundation v. Henney* ("*WLF II*"), 56 F. Supp.2d 81, 85 (D.D.C. 1999) ("The FDA may not restrict speech based on its perception that the speech could, or might mislead. Rather for the protections of the First Amendment to fall away, the government must demonstrate that the restricted speech, by nature, is more likely to mislead than inform.").

In spite of recent court decisions like the *WLF* cases, the agency's approach to disease awareness communications fails to recognize and accommodate the First Amendment protection for commercial speech, even assuming circumstances in which disease awareness and help seeking claims are commercial. Under *Central Hudson Gas and Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 100 S.Ct. 2343, 2351 (1980), speech that is both lawful and not misleading can only be restricted by a regulation if (1) the governmental interest is substantial, (2) the regulation directly advances the governmental interest asserted, and (3) the regulation is no more extensive than is necessary to serve that interest. As recent cases make clear, FDA-regulated products deserve no less First Amendment protection than other commercially advertised products. The courts have come down firmly on the side of more rather than less speech regarding FDA-regulated products under the *Central Hudson* test. *See Thompson, et al. v. Western States Medical Center Pharmacy*, 122 S.Ct. 1497, 1508 (2002), quoting *Virginia Board of Pharmacy v. Virginia Citizens Council, Inc.* 96 S.Ct. 1817 (1976) ("'people will perceive their own best interests only if they are well enough informed and . . .the best means to that end is to open the channels of communication rather than to close them . . . .'"). Simply put, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Id.* at 1506. *See also WLF I,* 13 F.Supp.2d at 70 ("the Supreme Court has repeatedly rejected attempts to equate less information with better decision-making . . . .").

Under the *Central Hudson* test, even if FDA has jurisdiction over disease awareness or help seeking communications, which it does not, the agency has presented insufficient justification for the restrictions the guidance places on small companies and companies with breakthrough products, and for the "perception" and "proximity" restrictions regarding ad

placement and content.[3] The scant and outdated references relied upon by FDA in the guidance document do not diminish the speculative nature of the agency's concern that consumers or health care practitioners may identify a disease awareness or help seeking advertisement with a company or product that is not mentioned in a broadcast. Without studies to demonstrate that such linkage would likely occur, some harm would likely result, and that FDA's proposed limitations would prevent the linkage or harm, the agency cannot demonstrate it has chosen a means of defining and regulating disease awareness and help seeking claims that directly advances a substantial government interest that is no more restrictive than necessary.

Indeed, even were the agency's concern about linkage empirically based, there is no reason to believe that such linkage would be inherently misleading or harmful. If a consumer or healthcare professional made the connection between a manufacturer and a disease awareness communication, or between a disease awareness communication and a reminder advertisement, the reader would still have to rely upon other sources to learn any useful information about a treatment or product because reminder pieces, by definition, provide no substantive information about a product and disease awareness claims would not provide information about a specific product. To the extent a company website was relied upon for follow-up product information, the information presented would have to include required disclosures and be truthful.

Importantly, the Supreme Court has "rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Western States*, *supra*, 122 S.Ct. at 1507 (concluding that that the government's fear that advertising compounded drugs would engender the interest of people who otherwise would not use such drugs failed to justify the restrictions on free speech); s*ee also WLF II*, 56 F.Supp.2d at 86 (stating that FDA could not "justify a restriction of truthful nonmisleading speech on the paternalistic assumption that such restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information" and finding sections of the Act that limited the circumstances under which manufacturers could distribute materials on off-label uses to doctors and other healthcare professionals in violation of the First Amendment because they were more restrictive than necessary); *WLF I*, 13 F. Supp.2d at 70 (finding the same regarding agency guidances). FDA's efforts should be focused on ensuring that communications over which it has jurisdiction are truthful and not misleading. Even if the agency's concern about linkage and its potential effect on a consumer's beliefs were reasonable rather than speculative, *Western States* prohibits limiting commercial speech for paternalistic reasons, especially where other means are available to affect the agency's interest.

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[3] In addition, while the content of a help-seeking or disease awareness advertisement may include some of the features FDA lists on pages 4-5 of the guidance, because FDA does not have jurisdiction over such advertisements its suggestion of recommended principles and content is inappropriate.

Furthermore, the lack of firm standards creates uncertainty among manufacturers regarding whether certain communications fall within the purview of the agency. Such vagueness will discourage manufacturers from disseminating disease awareness communications for fear they will unwittingly stray into regulated conduct and be subject to FDA enforcement. This cannot be the result the agency desires for speech it acknowledges is in the interest of the public health. Moreover, the vagueness of the agency's delineations between regulated and non-regulated speech in the guidance document compounds the guidance's violation of the First Amendment under the *Central Hudson* standard because vague and overly broad regulation per se cannot constitute the least restrictive means of regulation.

In sum, by placing vague sponsor, content, and proximity limits on disease awareness and help seeking communications and reminder advertisements, the agency would regulate such communications in violation of the First Amendment under the guise of drawing lines to protect them from regulation. In so doing, it creates vague standards that will have the effect of limiting rather than promoting speech that is important to the public health.

This guidance document needs to be rewritten to acknowledge the agency's support for the area of disease awareness and help awareness advertisements, in a context that does not discourage these types of communications. Although we fully appreciate that disease awareness and help seeking communications are free from regulation when they are not product promotion pieces, FDA must take much more care in describing when these communications cross the line into product promotion. To do otherwise reduces the incentive to provide highly valuable information that advances the public health.

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AdvaMed appreciates the opportunity to provide comments as well as the extension of time for submitting comments that FDA provided. AdvaMed looks forward to participating in the open public meeting on device advertising suggested above. AdvaMed believes that the meeting, along with AdvaMed's comments, will provide substantial input to assist the FDA in rewriting these guidance documents for the medical device industry.

Respectfully submitted,

Carolyn D. Jones

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