



National Venture Capital Association

September 13, 2002

**BY HAND DELIVERY**

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

Re: Docket No. 02N-0209: Request for Comment on First Amendment Issues, 67 Fed. Reg. 34942 (May 16, 2002).

The National Venture Capital Association represents more than 435 professional venture capital firms that invest in emerging growth companies in the United States. A significant amount of this investment is made in the medical industry. In fact, in 2000 more than \$6.4 billion was invested by venture capitalists in medical, health-related, and biotechnology companies. Last quarter, life science investing accounted for 27 percent of all venture investing totaling \$1.5 billion. Simply put, it is the long-term commitment of the venture capital industry that has created the biotechnology industry in the United States today.

Given this reality, NVCA is concerned greatly about the laws and regulations that affect life science and medical industry investing. Therefore, we submit the attached comments in response to FDA's request for comment on First Amendment issues.

Additional information on the venture industry and our position on First Amendment issues can be supplied upon request at (703) 524-2549.

Sincerely,



Nancy L. G. Saucier

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**Comments of the National Venture Capital Association in Response to the Food and  
Drug Administration's Request for Comment on First Amendment Issues  
Docket No. 02N-0209**

**I. Introduction**

The National Venture Capital Association ("NVCA") submits these comments in response to FDA's request for comment on whether FDA's regulations are consistent with modern First Amendment jurisprudence.<sup>1</sup> When considered in light of recent Supreme Court decisions, it is clear that many of FDA's regulations and policies are unduly restrictive of speech and inconsistent with the dictates of the United States Constitution.

When FDA's regulations impact the ability of drug and device manufacturers to exercise their right to free speech, they are subject to the restrictions of the First Amendment. Recent decisions from the Supreme Court and lower federal courts make clear that any restriction on speech must be justified by a specific showing that the speech in question is unworthy of constitutional protection. Particularly when FDA attempts to regulate truthful, nonmisleading speech concerning lawful products and activities, it must justify its restrictions by demonstrating that the regulation directly advances a substantial government interest and that a regulation less restrictive of speech would not suffice. FDA cannot rely on its public health mandate categorically to restrict speech or to impose a ban on speech because it has the potential to adversely impact consumers. Many of FDA's regulations have not been scrutinized through this First Amendment lens.

NVCA is a non-profit organization representing most of the country's leading investors in biotechnology and medical devices. Each year, NVCA members devote significant resources to the development and discovery of new medical technology. NVCA members have funded virtually the entire biotechnology industry and many of the revolutionary medical devices developed during the past twenty years. In conjunction with these investments, companies funded by NVCA members disseminate scientific and medical information to physicians, consumers, and other related entities. They advertise and promote their products, distribute literature, and engage in a significant amount of training for physicians, both through dissemination of educational materials and in-the-field training. Therefore, NVCA has a fundamental interest in safeguarding its right to engage in free speech and an interest in ensuring that FDA exercises its regulatory authority in a constitutional manner.

FDA has an obligation to revisit many of its policies and regulations in light of modern First Amendment jurisprudence. FDA's request for comment is a welcome first step in achieving that goal. NVCA's comments, therefore, proceed in two steps: First, a brief overview of relevant First Amendment principles is provided. Second, these principles are applied to eight specific topics:

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<sup>1</sup> 67 Fed. Reg. 34942 (May 16, 2002).

- (1) Dissemination of Enduring Materials and Support for Continuing Medical Education Regarding New/Unapproved Uses
- (2) Training of Physicians on Medical Devices
- (3) Direct-to-Consumer Advertising
- (4) Statements Regarding Medical Appropriateness
- (5) General v. Specific Claims Regarding Approved Uses
- (6) Publication of On-line Bibliographies
- (7) Press Releases
- (8) Other Policies

In each of these areas, current FDA policy should be reexamined in light of First Amendment jurisprudence.

## II. First Amendment Principles

### A. Commercial v. Non-Commercial Speech

A threshold issue in the consideration of any restriction on speech is determining the appropriate level of scrutiny to apply. In the food and drug context, this requires a determination of whether the regulated speech is “commercial speech,” and thus subject to intermediate scrutiny, or non-commercial speech, subject to strict scrutiny.

The cases have made clear that commercial speech is not readily susceptible to a clearly defined category or bright line tests. At its core, commercial speech is “speech which does ‘no more than propose a commercial transaction.’”<sup>2</sup> Importantly, the characterization of speech should not be based on the identity of the speaker. The fact that the speaker is a commercial entity does not render all its communications commercial. Nor is the fact that a particular communication refers to a particular product sufficient to label speech commercial. The Supreme Court has long held that the expression of views on matters of public importance does not lose First Amendment protection merely because a corporation seeks to utter the speech.<sup>3</sup> Instead, the protection afforded to speech depends on the content of the speech, rather than the speaker. In the words of the Court: “If commercial speech is to be distinguished [from non-commercial], it must be distinguished *by its content*.<sup>4</sup>” Thus, when evaluating whether particular speech is commercial, FDA must justify the restriction based on what is said -- not who is saying it.

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<sup>2</sup> *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66 (1983) (quoting *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976)).

<sup>3</sup> *First National Bank of Boston v. Bellotti*, 435 U.S. 765, 784 (1978); see also *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 62 (1998).

<sup>4</sup> *Bates v. State Bar of Arizona*, 433 U.S. 350, 363 (1977) (quoting *Virginia State Bd.*, 425 U.S. at 761).

If the speech in question is not commercial speech, any restriction must be evaluated under “strict scrutiny.” Strict scrutiny is the most exacting standard under the law. To survive review, the government bears the burden of proving that the regulation advances a compelling government interest and is the least restrictive means to achieve that interest. Regulations subject to this exacting standard rarely survive review. As will be discussed below, manufacturers of medical technology frequently engage in speech that should be protected under the strict scrutiny test.

## **B. Regulation of Commercial Speech**

Labeling speech as “commercial” does not strip the speech of all constitutional protection. To the contrary,

[t]he First Amendment . . . protects commercial speech from unwarranted governmental regulation. Commercial expression not only serves the economic interest of the speaker, but also assists consumers and further the societal interest in the fullest possible dissemination of information. In applying the First Amendment to this area, we have rejected the highly paternalistic view that government has complete power to suppress or regulate commercial speech.<sup>5</sup>

Any restriction on commercial speech must be evaluated under the “intermediate scrutiny” test first established by the Supreme Court’s seminal holding in *Central Hudson v. Public Service Commission*.<sup>6</sup> As the Supreme Court explained in a recent case:

Under that test we ask as a threshold matter whether the commercial speech concerns unlawful activity or is misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not misleading, however, we next ask whether the asserted governmental interest is substantial. If it is, then we determine whether the regulation directly advances the governmental interest asserted, and, finally, whether it is not more extensive than is necessary to serve that interest. Each of these latter three inquiries must be answered in the affirmative for the regulation to be found constitutional.<sup>7</sup>

If government seeks to restrict speech on the grounds that it is false or misleading, the case law makes clear that the government bears the burden to put forth concrete proof that the speech is actually or inherently misleading.<sup>8</sup> “FDA may not restrict speech based on its perception that the speech could, may, or might mislead.”<sup>9</sup> As stated by the

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<sup>5</sup> *Central Hudson v. Public Service Commission*, 447 U.S. 557 (1980).

<sup>6</sup> *Id.*

<sup>7</sup> *Thompson v. Western States Medical Center*, 122 S. Ct. 1497, 1504 (2002) (internal quotations and citations omitted).

<sup>8</sup> *Ibanez v. Florida Dep’t of Business & Prof’l Regulation*, 512 U.S. 136, 146 (1994).

<sup>9</sup> *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81, 85 (D.D.C. 1999).

Supreme Court, “we cannot allow rote invocation of the words ‘potentially misleading’ to supplant the [government’s] burden.”<sup>10</sup> Government must also consider the ability of the recipients of the speech to comprehend the information.<sup>11</sup> Therefore, before finding speech misleading, a court will consider the sophistication of the audience and its ability to understand the information.

In regard to speech that concerns unlawful activity, case law makes clear that the greater power to declare certain conduct illegal does not necessarily include the lesser power to regulate speech or restrict the communication of truthful, non-misleading communication. As stated by the Supreme Court, “the power to prohibit or to regulate particular conduct does not necessarily include the power to prohibit or regulate speech about that conduct.”<sup>12</sup>

If government is unable to put forward evidence that the speech is misleading or concerns an unlawful activity, the agency must satisfy each of the remaining three elements of *Central Hudson*. Because the government has an undeniable interest in safeguarding the health and safety of its citizens, the constitutionality of speech restrictions in the FDA context typically turns on the last two prongs of *Central Hudson* - whether the FDA’s interests are advanced by the restriction and whether the agency’s interests could be served in a less restrictive way. The government “bears the burden of showing not merely that its [action] will advance its interest, but also that it will do so to a material degree.”<sup>13</sup> “This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.”<sup>14</sup>

To satisfy the final element of *Central Hudson*, the fit between the agency action that abridges speech and the government’s legitimate goals must be “narrowly tailored.”<sup>15</sup> A restriction is not appropriately tailored if “there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech.”<sup>16</sup> “If the government can achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.”<sup>17</sup>

Finally, a fundamental principle throughout the Court’s commercial speech doctrine is that broad restrictions on speech fail constitutional scrutiny. “Broad prophylactic rules in the area of free expression are suspect. Precision of the regulation

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<sup>10</sup> *Ibanez*, 512 U.S. at 146.

<sup>11</sup> See *Edenfield v. Fane*, 507 U.S. 761, 775-76 (1993) (holding that because recipients of CPA solicitations are “sophisticated and experienced business executives” who were not “susceptible to manipulation,” a broad prophylactic rule banning such speech violated the Constitution).

<sup>12</sup> *Greater New Orleans Broadcasting Ass’n v. United States*, 527 U.S. 173, 193 (1999).

<sup>13</sup> *44 Liquormart*, 517 U.S. at 505 (internal quotation and citation omitted).

<sup>14</sup> *Edenfield*, 507 U.S. at 770-71.

<sup>15</sup> *Board of Trustees of the State University of New York*, 492 U.S. at 480.

<sup>16</sup> *Discovery Network*, 507 U.S. at 417 n.13.

<sup>17</sup> *Thompson v. Western States Med. Ctr.*, 122 S. Ct. 1497, 1506 (2002).

must be the touchstone in an area so closely touching our most precious freedoms.”<sup>18</sup> “If the First Amendment means anything, it means that regulating speech must be a last -- not a first -- resort.”<sup>19</sup>

### III. Specific Comments

When the principles discussed above are applied to FDA regulation of medical technology, it becomes clear that many of the agency’s regulations and policies are inconsistent with the dictates of the First Amendment.

#### A. Dissemination of Enduring Materials and Support for Continuing Medical Education Regarding New/Unapproved Uses

Peer-reviewed medical journals, independent reference texts, and continuing medical education (“CME”) programs are three critical sources of information about unapproved uses for drugs and medical devices. And although both the medical community and FDA have long recognized that drug and device manufacturers play a central role in the dissemination of medical literature and support for CME, FDA has imposed significant restrictions on these activities.<sup>20</sup> FDA’s policies have failed to take sufficient account of applicable First Amendment principles. Particularly in light of the recent *Washington Legal Foundation* (“WLF”) litigation, FDA should revisit these policies.

As a threshold matter, the dissemination of enduring materials and support for CME should be considered non-commercial speech, and thus fully protected by the First Amendment.<sup>21</sup> When manufacturers distribute academic literature or support CME, they are engaging in an important educational activity -- a fact that FDA itself has acknowledged. Nothing within the four corners of a reprint or CME program “propose a commercial transaction,” which is at the core of the Supreme Court’s description of commercial speech. In order to classify this speech as commercial, FDA would have to look past the content of the speech itself and evaluate the motives of the speaker. In other words, because manufacturers have a commercial motive when they distribute literature, information that is non-commercial when spoken by independent researchers becomes

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<sup>18</sup> *Edenfield*, 507 U.S. at 777 (quoting *NAACP v. Button*, 371 U.S. 415 (1963)) (citations omitted).

<sup>19</sup> *Western States*, 122 S. Ct. at 1507.

<sup>20</sup> *See id.* (prepared statement of Bernard Gersh, Chairman of the Council on Clinical Cardiology of the American Heart Association) (“Pharmaceutical and device companies should be permitted to disseminate copies of peer-reviewed scientific articles that report controlled clinical trials for off-label indications for their products.”).

<sup>21</sup> Although the district court in *WLF* concluded that the dissemination of enduring materials and support of CME should be classified as commercial speech, it stated that “this question is not an easy one.” *WLF*, 13 F. Supp. at 62-65.

commercial when spoken by drug or device manufactures. But this is precisely what the Supreme Court has held that the government may not do.<sup>22</sup>

Even classifying this speech as commercial, in order to restrict the dissemination of enduring materials or CME programs, FDA would have to make a specific showing that particular speech is misleading to physicians. Physicians are fully capable of evaluating scientific information, particularly when such data are accompanied by disclaimers making clear that the information deals with uses for a product that has not been approved by FDA. As stated by the court in the *WLF* litigation, FDA “exaggerates its overall place in the universe” when it argues that only scientific information it has scrutinized should reach physicians. A blanket prophylactic policy that restricts speech cannot be justified on the basis that the information *could* mislead.<sup>23</sup> Instead, FDA must bring forward specific evidence that the enduring materials disseminated or the CME programs are in fact misleading.

Second, assuming FDA cannot show particular programs or materials are false or misleading, FDA would have to be able to show that its policies advance an interest in assuring that physicians receive unbiased medical information. However, this interest, which the *WLF* court found not to be substantial, is undermined by the fact that this very same speech can be made by other speakers. A regulatory scheme that makes exceptions that permit the same or equivalent speech by other speakers or in other contexts, suffers from an “overall irrationality.”<sup>24</sup> As stated by the *WLF* court, “the Supreme Court has repeatedly rejected governmental attempts to equate less information with better decision-making, and in light of the fact that the FDA does not question a physician’s evaluative skills when the information comes from a source other than a drug manufacturer, concerns about a physician’s ability to critically evaluate materials presented to him is not a ‘substantial interest.’”

Nor can FDA’s interest in encouraging manufacturers to seek supplemental approvals for new uses support broad restrictions on enduring materials and CME. Independent incentives exist for manufactures to seek supplemental approvals. Frequently FDA approval is an important factor in physician acceptance of a new therapy, and often is an important component in securing reimbursement from insurance companies. These factors provide real incentives to seek FDA approval for off-label uses.

Finally, there are obvious less restrictive alternatives to meet FDA’s interests. The most appropriate course for FDA is to take action against particular materials or programs that are false or misleading. In addition, FDA could require that any materials

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<sup>22</sup> See *Pacific Gas & Electric Co. v. Public Utilities Comm’n*, 475 U.S. 1, 8 (1986) (plurality opinion).

<sup>23</sup> E.g., *44 Liquormart*, 517 U.S. at 503, *Western States*, 122 S. Ct. at 1507.

<sup>24</sup> *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488-89 (1995); see also *Greater New Orleans Broadcasting*, 527 U.S. at 194 (“decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment”).

disseminated by manufacturers be accompanied by a prominent disclaimer that the off-label use has not been approved by FDA. Disclaimers, moreover, would assist a physician in evaluating materials by flagging the fact that the use has not undergone the rigorous scrutiny required for FDA approval and would encourage manufacturers to seek supplemental approvals so that the disclaimers would not be required.<sup>25</sup>

## **B. Training of Physicians on Medical Devices**

One of the most important sources of information for physicians about medical devices is training provided by device manufacturers. Because medical devices are often technically complex, device manufacturers employ specialists who train and assist physicians in the proper use of the device. These training sessions often occur in the context of actual medical procedures. Usually the training focuses exclusively on approved uses for the device. However, occasionally the issue of unapproved uses for a device arises.

Under current FDA policy, any statements, including oral statements, made by industry representatives regarding an unapproved use for a device can be used as evidence of a new intended use for the device.<sup>26</sup> If these statements promote a use that is inconsistent with the device's approved labeling, the product may be misbranded under section 502(f)(1) of the act and adulterated under section 501(f). Therefore, significant penalties can result from any discussion of unapproved uses by industry representatives -- regardless whether the unapproved use is commonly employed by physicians and regardless whether the information provided would be truthful and non-misleading. At minimum, this policy chills speech from manufacturers to physicians about possible beneficial uses for a medical device or to avoid potentially dangerous uses; at worst, it effects an outright ban on such speech. Since a manufacturer is likely to be the single most complete source of all potentially important information about both the benefits and risks of off-label uses of its device, the real world effect of FDA's speech restrictions is to deny physicians access to information critical to safe and effective patient care.

This policy does not adequately take First Amendment principles into account. First, communications made during physician educational programs are not commercial speech at all, and thus should receive full First Amendment protection. When an industry representative conducts in-service training, this communication is primarily intended to assist the physician to use the product safely and effectively. There is, no doubt, a commercial element to such training; but it is clear that such communication also provides important benefits to the public, and therefore does much more than simply

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<sup>25</sup> See *Pearson v. Shalala*, 164 F.3d 650, 658 (D.C. Cir. 1999) (“[W]hen government chooses a policy of suppression over disclosure -- at least where there is no showing that disclosure would not suffice to cure misleadingness -- government disregards a ‘far less restrictive’ means.”).

<sup>26</sup> See 21 C.F.R. § 801.4 (stating that “intended use” may be shown “by labeling claims, advertising matter, or oral or written statements by [device manufacturers] or their representatives.”) However, section 557(a) of the Act makes clear that responding to unsolicited questions from physicians about unapproved uses cannot constitute evidence that the manufacturer is introducing a new device into commerce.

“propose a commercial transaction.” Moreover, given that the communication takes place after the device has already been selected for use, the connection to future commercial transactions is tenuous and speculative at best.

Second, even if this speech is viewed as commercial, FDA cannot categorically prohibit discussions about off-label uses without demonstrating that the information is false or misleading. *Central Hudson* and its progeny place the burden of proof on the government to demonstrate that any speech it seeks to restrict is actually false or misleading. This requires a specific showing by the government. Moreover, when considering whether speech is misleading, it is necessary to consider the recipient of the speech.<sup>27</sup> In the in-service training context, the audience for the speech is, by definition, physicians who specialize in the area of medicine for which the device is intended. Such an audience is fully competent to evaluate the information provided industry representatives, particularly if the information is accompanied by a disclaimer that the use is not approved by FDA.

Assuming that FDA cannot demonstrate that specific statements are false or misleading, restrictions on discussions about off-label uses must satisfy the remaining three elements of the *Central Hudson* test. There is no question that FDA has a substantial interest in ensuring that medical devices are used in a safe and effective way. Physicians, however, are fully capable of evaluating scientific data and deserve the benefit of all available information when making treatment decisions. FDA’s policy takes the misguided view that patients are better off when their physicians are shielded from truthful information relevant to treatment decisions. In addition, the fact that speakers other than manufacturers can engage in the very same speech prohibited by FDA’s regulations significantly undercuts the government’s interest.<sup>28</sup> FDA must also be able to show that FDA’s interest in assuring the safe use of medical devices could not be achieved in a manner less restrictive of speech. Here, FDA could require that industry representatives inform physicians that a use has not been approved by FDA. Before broad prohibitions on speech are imposed, the government must employ such less restrictive measures.

Therefore, FDA should revise its policies regarding discussions about off-label uses in the in-service training context. At minimum, FDA should clarify the following:

- If an industry representative does no more than provide a warning to a physician about off-label uses, this should not constitute evidence that a manufacturer is introducing a new device into commerce. If a device manufacturer is aware that physicians use a device in an off-label context, common sense dictates that the manufacturer should be able to advise a physician about dangers associated with such use in general, or about risks of specific techniques of use in specific cases. Such a policy would further FDA’s interest in assuring the safe and effective use

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<sup>27</sup> See *Edenfield*, 507 U.S. at 775-76.

<sup>28</sup> See *Coors Brewing Co.*, 514 U.S. at 488.

of medical devices in a manner consistent with the First Amendment. And further, such a warning may be required under state tort law.

- In the context of in-service training, industry representatives should be able to discuss unapproved uses for devices so long as they clearly inform the physician that the use has not been approved by FDA and undertake to provide information about the known benefits and risks of the use in that specific context. This will ensure that the physician is aware that the device has not undergone the rigorous scrutiny required by FDA for that particular use and will provide an adequate incentive for the manufacturer to seek approval for the specific use. Moreover, requiring disclosure of both benefits and risks will ensure that the physician is in a position to make an informed medical judgment.

### C. Direct to Consumer Advertising

Direct-to-Consumer (“DTC”) advertising is commercial speech that is protected by the First Amendment. Although FDA has not imposed any special restrictions of DTC advertising to date, FDA has recently been examining the issue,<sup>29</sup> and several proposals to restrict this type of speech have been put forward. Any policy adopted by FDA must conform to the restrictions of the First Amendment.

It is not constitutionally permissible to impose special restrictions on DTC advertising that is truthful and not misleading. FDA cannot justify any such restrictions on the grounds that this information will cause inappropriate utilization of drugs or medical devices. The First Amendment does not permit government to “suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information’s effect upon its disseminators and recipients.”<sup>30</sup> The Supreme Court has rejected this “highly paternalistic approach” and instructed that government entities must “assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and the best means to that end is to open the channels of communication rather than to close them.”<sup>31</sup> Moreover, the fact that consumers could receive information about drugs or devices from other sources (many of whom are altogether unregulated) would significantly undercut the effectiveness of any policy that restricts or prohibits DTC advertising.

As discussed previously, FDA bears a very heavy burden when it seeks to justify categorical rules preventing or restricting speech. Supreme Court precedent directs that FDA instead look to less draconian measures to ensure that the information is truthful and not misleading. For example, FDA could require the use of disclaimers or that any risk information is clearly communicated to consumers. The outright prevention of speech, or singling certain speech out for special burdens based on a speculative concern that consumers will act foolishly, is simply not permitted.

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<sup>29</sup> See <<http://www.fda.gov/cder/ddmac/dtctitle.htm>>.

<sup>30</sup> *Virginia Board of Pharmacy*, 425 U.S. at 772.

<sup>31</sup> See *id.* at 765.

#### **D. Statements Regarding Medical Appropriateness**

FDA has long acknowledged that physicians frequently prescribe drugs and use medical devices for off-label uses.<sup>32</sup> In fact, in many contexts, the off-label use of a drug or medical device constitutes the standard of care. FDA has never attempted to direct the prescribing practices of physicians or stop physicians from using products for off-label uses. Nor would FDA have the statutory authority to do so.<sup>33</sup> Frequently, however, when FDA learns that a substantial number of physicians are prescribing or using a product in an off-label manner, it requires that the producer indicate in approved labeling that the product is not approved for that use. When FDA places such a statement in approved labeling, the implication to physicians is that FDA disapproves of that use. Given the importance of the FDA in the pharmaceutical and device field, this very often will cause physicians to avoid the off-label use -- even if the use provides significant medical benefits to patients.

To mitigate this effect, manufacturers should be permitted to include a statement in approved labeling clarifying that FDA non-approval for a specific use should not be interpreted as an indication that FDA believes the use to be medically inappropriate or contraindicated. In other words, manufacturers should be permitted to indicate that even though FDA has not approved a product for a specific use, this should not prevent physicians from using the product as they deem medically appropriate. To be clear, we do not argue that manufacturers should be permitted to suggest that the product is medically appropriate for an off-label use. But manufacturers should be permitted to make the neutral statement that FDA non-approval should not be interpreted as FDA saying that it believes the use is medically inappropriate or contraindicated.

Any broad prohibition against such statements would violate the First Amendment principles established above. First, once again, statements such as this should not be considered commercial speech. Although there is undoubtedly a commercial element in speech contained in approved labeling, a statement regarding medical appropriateness has an important educational component for physicians. Therefore, the speech does more than "simply propose a commercial transaction" and thus falls outside the commercial speech rubric.

But even assuming that the speech is commercial, FDA bears a burden to come forward with concrete evidence that a particular statement is false, misleading, or otherwise unworthy of constitutional protection. Here, there can be no argument that a statement that FDA remains agnostic regarding an unapproved indication is factually correct. Nor can FDA plausibly argue that such a statement would be inherently misleading to physicians. Assuming then, that a statement clarifying the implications of

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<sup>32</sup> See *WLF*, 13 F. Supp. 2d at 56.

<sup>33</sup> See Statement of Michael Friedman, FDA Deputy Commissioner for Operations, Statement before the 1996 House Hearings (Sept. 12, 1996) ("The history of the [FD&C] Act indicates that Congress did not intend FDA to interfere with the practice of medicine.").

FDA non-approval is not misleading or false, a broad prohibition against such a statement must be shown to materially advance any FDA interest. But given FDA's acknowledgment that physicians can, and frequently should, employ off-label uses for pharmaceuticals and devices, FDA would be unable to demonstrate that a prohibition against such statements advances FDA's interest in ensuring that patients receive safe and effective medical care.

### **E. General versus Specific Indications**

Another area that should be revisited by FDA is its treatment of specific claims made by a manufacturer when a device is approved for use in regard to a general category. If, for example, a device is approved for use generally on soft tissue, manufacturers should be permitted to indicate that the device is safe/effective for use on a particular type of soft tissue without additional approval from FDA. This issue is of vital importance to device manufacturers because frequently it is necessary to inform physicians that a device is safe and effective in regard to a specific indication when the product is only approved for a use in regard to a general indication.

FDA itself has long recognized that it has failed to provide sufficient guidance to industry in regard to this issue. As early as 1994, Susan Alpert, then director of FDA's Office of Device Evaluation, stated that "the issue has been problematic for the device industry. . . . We recognize that that there is an inconsistency."<sup>34</sup> A prominent example of FDA's lack of a coherent policy was the issue of medical lasers for treatment of benign prostatic hyperplasia ("BPH"). During the mid-1990s, manufacturers of medical lasers, whose devices had long been approved for general use in the urologic tract to treat soft tissues, believed that their products could be labeled and marketed for use in the treatment of BPH. In fact, many of these lasers had been specifically cleared through the 510(k) process for prostatectomy. Not only did FDA take the position that the promotion of BPH required separate clearance, but initially also held that any company wishing to label the product for treatment of BPH would have to file a PMA. At the same time, FDA advised urologists that they were free to treat patients off-label for BPH with lasers cleared only for general urologic indications.<sup>35</sup> This example, and many others like it, demonstrate that the FDA has been overly aggressive and inconsistent in regulating specific claims that fall within a general indication.<sup>36</sup>

Recognizing the lack of coherence in this area, Congress mandated in the Food and Drug Administration Modernization Act of 1997 ("FDAMA")<sup>37</sup> that FDA specify "the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such a device

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<sup>34</sup> See FDC Reports "The Gray Sheet" (Sept. 26, 1994) at 20.

<sup>35</sup> See Clinica, Off-label uses of medical devices: the battle escalates (Oct. 24, 1994).

<sup>36</sup> See Jonathan S. Kahan, Medical Device Indications for Use (Nov. 1996) (describing controversy of general/specific indications for CO<sub>2</sub> lasers for treatment of laser-assisted uvulopalatoplasty).

<sup>37</sup> Pub. L. No. 105-115, 111 Stat. 2296 (codified at 21 U.S.C. § 360aaa, *et seq.*).

for purpose of determining substantial equivalence . . .”<sup>38</sup> On November 4, 1998, FDA issued a guidance document.<sup>39</sup> Unfortunately, this document offers little in the way of new guidance to industry on when specific claims will be found to be within a general indication. In fact, FDA conceded within the document itself that it “does not offer a bright line rule to answer these questions.”<sup>40</sup>

In addition to providing clear guidance to industry, FDA policy in this area must conform to the principles of the First Amendment. If a product is approved for a general indication, no prior approval should be required for speech regarding specific claims that fall within the general category. Any more stringent policy runs afoul of the principles discussed throughout these comments. FDA cannot prohibit speech without concrete evidence that the speech is false or misleading. Specific indications that fall within a general category cannot be presumed to be misleading. And once again, FDA’s interests could be well served by requiring that any claims as to specific indications carry prominent disclaimers that disclose the precise language of the FDA approval.

#### **F. Publication of Bibliographies**

FDA is currently developing a policy in regard to the publication of online bibliographies when certain bibliography entries address unapproved uses. Because the depth of research into a product is a key consideration for physicians when selecting a product for use, manufacturers frequently wish to inform physicians and consumers about all research studies that have been conducted regarding their products. The fact that research dealt with off-label uses for a product should not bar the manufacturer from disclosing that such a study was conducted.

In a recent industry newsletter, the agency indicated that it was “debating the extent to which off-label journal articles may be cited in bibliographies on device company websites.”<sup>41</sup> In the same article, Deborah Wolf, Regulatory Counsel for the Promotion and Advertising Staff, CDRH, stated that “[i]f I can know what the off-label use is from reading the title . . . then that may be considered an explicit claim for that use.”

A policy such as this offers no guidance to manufacturers and affords complete and unrestrained discretion to FDA personnel to declare bibliographies illegal. And moreover, it is wholly dismissive of the First Amendment rights of manufacturers. There is certainly nothing false or inherently misleading when a manufacturer discloses the mere existence of a particular research study. And it is clear that less restrictive means, such as the use of disclaimers, could also serve any interest the FDA may have. But

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<sup>38</sup> 21 U.S.C. § 360c(i)(1)(F).

<sup>39</sup> See Guidance for Industry: General/Specific Intended Use (Nov. 4, 1998) accessible at <<http://www.fda.gov/cdrh/modact/genspec.html>>.

<sup>40</sup> *Id.*

<sup>41</sup> See FDC Reports, “The Gray Sheet” (April 23, 2001).

whatever policy is adopted, FDA must be mindful of relevant First Amendment principles and provide clear guidance to manufacturers.

### **G. Press Releases**

FDA treats press releases regarding approved drugs and medical devices as promotional labeling.<sup>42</sup> As such, they must conform to the myriad of requirements that apply to promotional labeling. Moreover, truthful and non-misleading statements about the drug or device which do not conform to the approved label are prohibited. Similarly, FDA prohibits the “promotion” of investigational new drugs or devices.<sup>43</sup> While these regulations are not intended to restrict the free exchange of scientific information regarding investigational products, the agency strictly prohibits broader representations about unapproved uses.<sup>44</sup>

As a threshold matter, FDA’s treatment of press releases as labeling is highly questionable. The FDCA defines labeling as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” Although the Supreme Court has broadly defined “accompanying” as used in the act to include items not physically attached to the product,<sup>45</sup> FDA’s attempt to encompass press releases that inform the public about study findings and developments stretches the term beyond reasonable limits.<sup>46</sup>

But even accepting FDA’s definition of labeling, any regulation of this speech must be consistent with First Amendment principles. Press releases, especially those dealing with scientific advances and developments, should be treated as non-commercial speech and afforded full First Amendment protection. For example, a press release that discusses the results of a phase III study and states that the product represents a promising new therapy cannot fairly be characterized as commercial speech. Indeed, it is clear that if the same information was conveyed by independent researchers, no one would argue that the information was commercial. The fact that the same speech is made by drug or device manufacturers should not transform this communication into commercial speech.

Even if press releases are commercial speech, FDA’s policies fail the *Central Hudson* test because they prohibit truthful, non-misleading speech solely because they relate to unapproved uses. As has already been discussed, a broad prophylactic policy that categorically prohibits speech cannot withstand scrutiny. Instead, the FDA must be able to point to concrete evidence that particular press releases are misleading or present false information. Finally, it is clear that less restrictive alternatives, such as the use of

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<sup>42</sup> 21 C.F.R. § 202.1(k)(1)(2).

<sup>43</sup> 21 C.F.R. §§ 312.7, 812.7.

<sup>44</sup> *See id.*

<sup>45</sup> *See Kordel v. United States*, 335 U.S. 345, 350 (1948).

<sup>46</sup> *See, e.g., Alberty Food Prods. v. United States*, 194 F.2d 463 (9th Cir. 1952) (limiting scope of “accompanying” to cases in which separate literature has same destination as drug).

disclaimers could promote the government's interest. For example, FDA could require that press release include disclaimers that detail the evidentiary support for the statements and reference any negative information along with the positive. These less restrictive approaches are consistent with the opinion of the D.C. Circuit in *Pearson v. Shalala*<sup>47</sup> and the district court in *WLF*.<sup>48</sup> They, moreover, preserve the government's interest in ensuring manufactures have an incentive to seek product approvals. Only by obtaining the approval would a company be permitted to omit the required disclaimers.

## H. Other Policies

Several other FDA policies raise similar concerns to those discussed throughout these comments. These include:

- FDA's regulations require that a product's labeling reveal all material information about the drug, but "does not permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, or cosmetics under the act."<sup>49</sup> This regulation erects an absolute ban on statements presenting differences of opinion or responding to required warnings, without regard to whether the response is constitutionally protected.
- FDA has regulated the use of trademarks that suggest particular uses for a product without having specific evidence that the mark is actually misleading. Before FDA may prohibit the use of a particular mark, it must be able to show that the mark is actually misleading. In addition, it must consider less restrictive means such as the use of disclaimers.<sup>50</sup>
- FDA has aggressively regulated claims made by drug and device manufactures about the cost-effectiveness of their products. Any restrictions on such speech must be consistent with the First Amendment.
- FDA has also taken action against manufacturers for information about off label uses provided at scientific booths at professional meetings. FDA cannot enforce a blanket prohibition on the provision of scientific information through professional exhibit booths solely because the information concerns an unapproved use.

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<sup>47</sup> 164 F.3d 650 (D.C. Cir. 1999).

<sup>48</sup> 13 F. Supp. 2d 51 (D.D.C. 1998).

<sup>49</sup> 21 C.F.R. § 1.21(c).

<sup>50</sup> FDA itself has long recognized that disclaimers could eliminate or reduce the possibility that trademark is misleading. A regulation proposed in 1974 would have required that FDA consider whether the use of disclaimers could eliminate the possibility that a trademark might be misleading before it orders the excision of the mark. *See* 39 Fed. Reg. 11298 (Mar. 27, 1974). Although this regulation was never formally adopted by FDA, *see* 56 FR 67440 (Dec. 30, 1991), the agency never disagreed with the substance of the proposal. *See* 56 FR 42668 (August 28, 1991).

#### **IV. Conclusion**

Throughout these comments two central themes have emerged. First, FDA's current policies frequently erect broad prophylactic rules that prevent manufacturers from engaging in a great deal of constitutionally protected speech. It is clear that FDA has a substantial interest in regulating the information that device manufacturers disseminate to physicians and consumers. But under the First Amendment, this interest cannot justify overbroad rules that categorically restrict speech. Instead, FDA must move to a regulatory scheme in which any restriction on speech is based on specific evidence that the speech is false, misleading or otherwise not worthy of constitutional protection.

Second, particularly in the device context, FDA's policies are often vague, undeveloped and insufficient to give guidance to industry on what is permitted speech. When FDA's policies infringe on the First Amendment rights, it is critically important for the agency to provide clear guidance. Ambiguous or equivocal policies chill protected speech and infringe manufacturers' constitutional rights.

NVCA appreciates FDA's invitation to submit these comments. We look forward to a continued dialogue as FDA evaluates these critical First Amendment issues.