

Boston Scientific Corporation

FIRST AMENDMENT CONSTRAINTS ON FDA'S REGULATION
OF MEDICAL PRODUCT LABELING AND ADVERTISING

INTRODUCTION

The U.S. Supreme Court's decision in Thompson v. Western States, No. 01-344, Apr. 29, 2002, has provided authoritative new guidance on the application of the First Amendment to the Food and Drug Administration's regulation of labeling and advertising under the Federal Food, Drug, and Cosmetic Act (FDC Act). The Supreme Court's ruling strongly validates the trend in the lower courts requiring FDA to evaluate its policies against a company's rights under the First Amendment to disseminate commercial speech that is neither false nor misleading.

Western States struck down a statutory advertising restriction relating to compounded drugs. However, the Court's reasoning applies more broadly to the full range of labeling and advertising requirements in FDA's regulations, guidances, policies, and practices. The Supreme Court has confirmed that the burden rests on Congress and the FDA to demonstrate that speech is false or misleading and that it cannot be rendered non-misleading with appropriate disclosures. The Supreme Court made clear that if Congress or FDA wishes to ban or restrict truthful commercial speech they carry a very heavy burden to establish the need for such drastic action. As the Supreme Court said, banning or restricting commercial speech "must be a last – not first – resort." *Slip op.* at 15.

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FDA has requested public comments to assist a review of whether its speech restrictions comport with the First Amendment (67 Fed. Reg. 34,942, May 16, 2002). Boston Scientific Corporation (BSC) applauds FDA for this step. BSC believes that the Western States decision presents an opportunity for FDA to generate fresh thinking on this subject. BSC is responding by submitting these comments, which we hope will assist FDA by providing the perspective of a major medical device manufacturer. BSC develops, manufactures, and sells medical devices focused on minimally invasive surgical procedures in a wide variety of interventional specialties, such as cardiology, gynecology, oncology, radiology, urology, peripheral vascular and vascular surgery. BSC expends substantial time, effort, and resources complying with FDA's requirements for labeling and advertising.

BSC believes that the development, manufacture, and sale of safe and effective medical devices is a public health goal of paramount importance. However, in our view, this public health goal is fully compatible with the Supreme Court's insistence that FDA comply with the First Amendment. Indeed, as the Supreme Court indicated in Western States, the free flow of truthful and nonmisleading information about these products is more likely to contribute to the public health than detract from it.

In our view, not all of FDA's labeling and advertising requirements comply with the First Amendment as explicated in Western States. In the discussion below, we briefly summarize the Western States decision. Then, we focus our comments on three areas:

- FDA's restrictions on the dissemination of peer reviewed journal articles and reference texts that discuss unapproved (off-label) uses for medical devices;
- FDA's restrictions on the dissemination of information about clinical experience with investigational devices prior to premarket clearance or approval;
- FDA's restrictions on the dissemination of peer reviewed journal articles and reference texts discussing post-approval clinical experience.

THE WESTERN STATES DECISION

The First Amendment provides in part that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. In 1976, the U.S. Supreme Court held that the First Amendment protects commercial speech (Virginia State Bd. Of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425

U.S. 748). That decision struck down a law prohibiting licensed pharmacists from advertising prescription drug prices. The Court recognized that a market society requires a free flow of commercial information and also rejected paternalism as a justification for restricting information, stating 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.” *Id.* at 770.

In 1980, the Supreme Court announced a balancing test that permits the Government an opportunity to justify restrictions on commercial speech. The test, set forth in Central Hudson Gas & Elec. Co. v. Public Serv. Comm’n of New York, 447 U.S. 557, adopts a four-part standard for commercial speech protection under the First Amendment: (1) it must concern lawful activity and not be misleading; (2) the Government’s interest must be substantial; (3) the regulation must directly advance the Government’s interest; and (4) it must not be more extensive than necessary to serve the interest. *Id.* at 566. On all these issues, the Government bears the “heavy burden” of proof of justifying its speech restriction. 44 Liquormart v. State of Rhode Island, 517 U.S. 484, 516 (1996); Board of Trustees v. Fox, 492 U.S. 469, 480 (1989).

Until Western States, the Supreme Court had never considered the application of the First Amendment to the FDC Act or FDA’s regulatory requirements. The Western States case, however, involved a facial challenge to a

provision of the FDC Act added by § 503A of the Food and Drug Administration Modernization Act of 1997 (FDAMA), pursuant to which a compounded drug was exempted from New Drug Application (NDA) approval (and other requirements) if the pharmacy that compounded the drug met certain requirements, including a requirement not to advertise the specific drug.

The Supreme Court applied the Central Hudson test to this statutory advertising restriction and found it wanting. First, it was undisputed that the suppressed speech did not concern unlawful activity and was not misleading. Second, the Court agreed that the Government had a substantial interest in permitting small-scale compounding without NDA approval while subjecting large-scale drug manufacturing to NDA approval. Third, the Court accepted, although skeptically, the Government's assertion that the advertising prohibition advanced this interest, based on the Government's theory that the ability to advertise is necessary to create a large-scale compounding operation. Finally, the Court held that FDAMA's speech restriction was more extensive than necessary to serve the Government's interest, because there were a number of non-speech related alternatives that might have satisfied the Government's interest and the Government had not shown that forbidding advertising was necessary to achieve its interest, as opposed to being merely convenient. The Court stated: "If the First Amendment means anything, it means that regulating speech must be a last – not

first – resort.” *Slip op.* at 15. Therefore, the Court invalidated the advertising ban as a violation of the First Amendment.

The Supreme Court expressly rejected any justification for the speech restriction based on paternalism. The dissent argued that suppressing the advertisements would prevent pharmacies from inducing patients to convince their doctors to prescribe unnecessary drugs. The Court responded, “[w]e have previously 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.” *Id.* at 16.

The Supreme Court also indicated that a potentially (as opposed to inherently) misleading advertisement can be cured with appropriate disclosure rather than a speech ban. Thus, the dissent argued that the suppressed advertising had the potential to mislead patients about the level of risk. The Court responded by observing that this concern could be “satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown.” *Id.* at 18.

Finally, the Supreme Court gave some examples of useful speech prohibited by the FDAMA prohibition. It stated: “If the Government’s failure to justify its decision were not enough to convince us that the FDAMA’s advertising

provisions were unconstitutional, the amount of beneficial speech prohibited by FDAMA would be.” *Id*

It is worth underscoring that § 503A was an act of Congress that prescribed detailed requirements and not merely an agency regulation or policy. The courts do not lightly overturn acts of Congress on constitutional grounds. The speech restrictions we discuss below were developed by FDA based upon its general approval authority and without a similar detailed statutory mandate. For this reason, these policies would likely receive *less* judicial deference than § 503A.

DISSEMINATION OF THIRD PARTY MATERIALS THAT DISCUSS UNAPPROVED NEW USES

A. FDA’s Speech Restriction

During the past decade, FDA has attempted to restrict firms from providing physicians with copies of peer-reviewed journal articles and reference texts (enduring materials) that discuss unapproved new uses of products the firms already legally market for another use. Originally, FDA issued a guidance document with significant restrictions on such dissemination. A district court found that the guidance document facially violated the First Amendment. Washington Legal Foundation v. Friedman, 13 F. Supp.2d 51 (D. D.C. 1998). Section 401 of the FDAMA amended the FDC Act to permit dissemination of enduring materials

discussing off-label uses, but imposed numerous requirements, including restrictions on the type of materials to be disseminated, FDA's preapproval of the materials to be disseminated, various mandatory disclosures, the firm's agreement to seek a supplement approval covering unapproved uses discussed in the enduring materials, and various reporting and record keeping requirements. *See also* 21 C.F.R. Part 99 (implementing regulations). The same district court held that Section 401 (and the implementing regulations) facially violated the First Amendment. Washington Legal Foundation v. Henney, 56 F. Supp.2d 81 (D. D.C. 1999).

On appeal, FDA did not directly challenge these findings. Instead, FDA argued that there was no constitutional dispute, because section 401 and 21 C.F.R. Part 99 requirements are merely a voluntary "safe harbor" to avoid enforcement action. The appellate court accepted FDA's representation and vacated the district court's injunction as moot, never reaching the merits of the district court's findings. Washington Legal Foundation v. Henney, 202 F.3d 331, 337 & n.7 (D.C. Cir. 2000).

As a result of the litigation, FDA now says it agrees that the dissemination of enduring materials discussing unapproved uses is not an "independent" violation of the FDC Act. FDA reserves the right, however, to cite such dissemination as evidence that the firm has illegally promoted its product for

an unapproved new intended use. In the absence of clearance or approval for the new use, the product would be rendered misbranded and/or adulterated. A firm that complies with the Section 401 “safe harbor” requirements will avoid any possibility that the dissemination will be cited in an enforcement action. *See* Notice, 65 Fed. Reg. 14,286 (Mar. 16, 2000).

FDA indicates, moreover, that the typical enforcement action will be based upon a combination of the dissemination of enduring materials with other violative activity. FDA states:

When FDA brings an action alleging a violation . . . the trier of fact will consider whether or not the manufacturer intended that its product be used for a use not approved by FDA. The manufacturer’s intent will necessarily be determined on a case-by-case basis, looking at the totality of the facts and circumstances. . . . If evidence of distribution . . . forms part of the basis of FDA’s claim, the trier of fact will consider the context of that activity . . . in assessing the manufacturer’s objective intent.

Letter of Jan. 28, 2002, from Margaret M. Dotzel to Daniel J. Popeo, Esq. and Richard A. Samp, Esq. at 6 (Docket No. 01P-0250) (Samp Letter). FDA adds this

limitation: “FDA is unlikely to initiate an enforcement action where the only evidence of an unapproved intended use is the distribution of enduring materials.”

Id.

B. Requested Change in FDA Policy

FDA should announce a revised policy in which it agrees not to cite or rely upon a firm’s dissemination of enduring materials to prove an unapproved new intended use in any enforcement action. If a firm has truly promoted an unapproved new intended use, FDA should bring its enforcement case based upon the violative promotional activities (*e.g.*, advertisements, brochures, oral statements) without adding the dissemination of enduring materials to the indictment. On the other hand, if a firm has done no more than disseminate enduring materials, FDA should renounce the possibility of an enforcement action, regardless of whether the firm has complied with the voluntary requirements in Section 401.

Of course, FDA may continue to require that enduring materials carry appropriate disclosures to render them non-misleading. FDA should provide public guidance to industry indicating that no enforcement action will be brought if the dissemination is accompanied by the disclosures found necessary by the district court in the Washington Legal Foundation litigation. 13 F.Supp.2d at 68-69

(requiring disclosure that off-label uses were not approved by FDA and disclosure of the disseminating firm's financial interest).

C. Supporting Analysis

The purported distinction between an "independent" violation versus "evidence" of a violation is the crux of FDA's current approach to the dissemination of enduring materials. This distinction is merely semantic. As a practical matter, every time a firm disseminates enduring materials, FDA reserves the right to bring an enforcement action alleging that the firm has created an unapproved new intended use. This legal theory has always been the basis for FDA's attempts to restrict the dissemination of enduring materials. FDA's only concession in the Washington Legal Foundation litigation was to agree that it cannot establish a violation merely by proving that a firm has not complied with the requirements of Section 401 of the FDAMA.

As a practical matter, law-abiding firms risk enforcement action unless they completely abandon their right to disseminate truthful, non-misleading enduring materials. Even FDA's statement that it is "unlikely" to bring an action based solely upon such dissemination offers less than meets the eye. The "unlikely" qualifier is not the same thing as saying FDA will never bring such an action. The inherent subjectivity in judging the intent of a firm's other promotional activity (or how FDA may find it combines with the distribution of enduring materials to create

an allegedly illegal intent) will likely lead law-abiding firms to avoid any dissemination of enduring materials. This ambiguous enforcement policy seems crafted to allow FDA to deter protected speech without conceding that it is doing so.

The district court in the Washington Legal Foundation case has already applied the Central Hudson test and found that FDA's restrictions on the dissemination of *bona fide* peer-reviewed enduring materials with off-label information facially violate the First Amendment. The court found that such speech was not misleading when accompanied by a disclosure noting that the off-label uses were not approved by FDA and describing the company's financial interest in the product. 13 F. Supp. at 68-69. It also found that requiring such disclosures was appropriate and that further restrictions violate the First Amendment, because they are more extensive than necessary to achieve FDA's legitimate interest in preserving an incentive for manufacturers to bring new product uses on label. *Id.* at 72-73. The same district court also found that Section 401 of the FDAMA facially violates the First Amendment for similar reasons. 56 F.Supp.2d at 86-87.

FDA did not challenge the district court's Central Hudson holdings on appeal. While the government technically may not be subject to formal collateral estoppel on this issue in a future enforcement action, another district court would surely give great weight to the unchallenged judicial findings from six years of exhaustive litigation in the Washington Legal Foundation case. Indeed, the district

court's holdings were in the context of a *facial* challenge to FDA's guidance and FDAMA Section 401, which is the most difficult type of First Amendment challenge to sustain. United States v. Salerno, 481 U.S. 739, 745 ("A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid").

The Supreme Court's Western States decision provides even more support for the district court's exhaustive analysis. For example, the Supreme Court has affirmed that FDA may not justify speech restrictions on the basis of a paternalistic concern that the audience will misuse the speech. The Court also indicated a strong preference for the use of disclosure (*i.e.*, more speech) as a less restrictive alternative to resolve concerns that speech may be misleading or inimical to the integrity of the approval process. This approach is exactly the one followed by the trial court in the Washington Legal Foundation litigation. It is likely, then, that even another district court hearing an enforcement action would conclude that exposing dissemination of enduring materials to adulteration / misbranding liability impermissibly burdens such speech.

A particularly unwise aspect of FDA's announced policy is its apparent intent to bring enforcement action by combining enduring materials with violative conduct. By combining protected and unprotected speech in this fashion, FDA may

actually jeopardize its entire enforcement case. As stated in Street v. State of New York, 394 U.S. 576, 586 (1969):

[W]hen a single-count indictment or information charges the commission of a crime by virtue of the defendant's having done both a constitutionally protected act and one which may be unprotected, and a guilty verdict ensues without elucidation, there is an unacceptable danger that the trier of fact will have regarded the two acts as 'intertwined' and have rested the conviction on both together.

Given that the dissemination of enduring materials (with appropriate disclosures) has already been determined to be speech enjoying significant First Amendment protection, a general verdict could be fatally tainted if there is any possibility that it was even partly based upon the protected speech. By renouncing any reliance on dissemination of enduring materials, FDA would avoid risking the ultimate success of its enforcement actions against truly violative conduct.

In sum, FDA should renounce its policy of citing dissemination of enduring materials as a basis for an alleged violation, if the proper disclosures are provided to ensure that the dissemination is non-misleading. FDA also should

provide public written guidance on the appropriate disclosures in accordance with those set forth by the Washington Legal Foundation district court.

DISSEMINATION OF INFORMATION ABOUT ONGOING CLINICAL STUDIES
PRIOR TO FDA APPROVAL

A. FDA's Speech Restriction

Under 21 C.F.R. § 812.7(a), a sponsor may not “promote . . . an investigational device, until after FDA has approved the device for commercial distribution.” Under 21 C.F.R. § 812.7(d), the sponsor may not “[r]epresent that an investigational device is safe or effective for the purposes for which it is being investigated.” FDA has stated:

Although the FDA encourages full exchange of scientific information concerning investigational devices, including dissemination of scientific findings through scientific/medical publications or conferences, safety or effectiveness conclusions and statements of a promotional nature are unacceptable. Information concerning investigational devices may be provided only for the purpose of soliciting clinical investigators and study subjects. Enclosed is a guidance document entitled, *Guidance for Industry and FDA*

*Staff, Preparing Notices of Availability of Investigational
Medical Devices and for Recruiting Study Subjects*, to assist
you in this area.

Warning Letter to Presby Corp., p.3 (Jan. 7, 2000) (emphasis supplied). The first sentence recites that FDA is open to exchange of scientific information in specialized publications or conferences (but not in lay media). The underlined sentences, however, contradicts the first sentence by limiting acceptable dissemination of truthful clinical information about an investigational device to the limited purpose of recruiting investigators and study subjects.

In fact, FDA generally objects to the dissemination of truthful, non-misleading information about ongoing or completed studies of investigational devices and even to video footage of investigational procedures, unless for the purpose of recruiting investigators and study subjects. When such dissemination takes place, FDA typically does not allege that the information is false or misleading. Rather, FDA's takes the position that such dissemination is promotional in violation of 21 C.F.R. § 812.7(a) and/or that it represents the device as safe or effective in violation of 21 C.F.R. § 812.7(d).

B. Requested Change in FDA Policy

FDA should amend 21 C.F.R. § 812.7(a) by adding the following:

This provision is not intended to restrict the full exchange of scientific information concerning the device, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the device for a use for which it is under investigation and to preclude commercialization of the device before it is approved for commercial distribution.

The requested amendment to 21 C.F.R. § 812.7(a) would merely conform it to existing language already in the parallel drug/biologic regulation (21 C.F.R. § 312.7(a)).

In addition, FDA should affirm in clear, sensible, and publicly available written guidance that it is acceptable for companies to disseminate truthful, accurate and fairly balanced information about clinical experience with investigational devices not commercially available in the U.S. (or, if commercially available for other uses, requiring modification to be capable of performing the investigational use). Such information might include, for example, preliminary or

final results from a U.S. or foreign study or video footage showing the device in actual clinical use. The information might be disseminated in scientific or lay media.

FDA's guidance should clarify that such information is not inherently promotional or a representation that the investigational device is safe or effective. Rather, FDA should indicate that appropriate disclosure will be required. For example, FDA could require that the information be accompanied by a disclosure indicating that: (i) the device is investigational in the U.S. and not commercially available, (ii) no definitive conclusions can or should be drawn from preliminary clinical experience or individual case studies, (iii) the device must complete an FDA premarket review process, (iv) FDA will be the final arbiter as to whether the product enters commercial distribution in the U.S., and (v) FDA's ultimate clearance or approval may be for a more limited use than originally sought or depicted in the clinical information being disseminated. FDA could also require disclosure of the speaker's financial interest in the product or other relationship with the device sponsor when applicable.

C. Supporting Analysis

The requested amendment to 21 C.F.R. § 812.7(a) should not be objectionable to FDA. The regulations governing investigational drugs and biologics already has such language. Adding it to the device regulation would assure greater

regulatory consistency. It also would clarify the intent of the regulation in a manner that is consistent even with FDA's restrictive interpretation in the Presby Corp. warning letter quoted above. The only distinction between the two is that the requested language permits dissemination of scientific findings "in lay media" while the Presby Corp. warning letter limits dissemination to "scientific/medical publications or conferences." However, FDA has never articulated a basis for allowing dissemination of scientific findings about investigational drugs and biologics in the lay media, but not investigational devices. We believe that 21 C.F.R. § 812.7(a) should be amended to conform to 21 C.F.R. § 312.7(a).

As to the broader guidance we request, a Western States analysis supports our contention that FDA's policy in this area is too restrictive. Under Western States, the threshold inquiry is whether the speech is misleading or concerns unlawful activity. In this case, the speech does not concern unlawful activity, because the clinical use of the device is permitted under an Investigational Device Exemption (IDE) regulation (21 C.F.R. Part 812) in the U.S. or the laws of the foreign country in which the clinical activity takes place.

As FDA has recognized, reports of the clinical experience with an investigational device represent important scientific and educational information. Such information is not inherently misleading if described in an accurate and balanced way. To the extent that FDA believes the information is potentially

misleading, disclosures such as those we have suggested can address that concern. It is also worth noting that in most cases the audience for information about investigational devices is a sophisticated one (*e.g.*, physicians), which should further mitigate concerns that the information is potentially misleading. Under Western States, it is appropriate to use disclosure to cure potentially misleading speech.

Does FDA have a substantial interest in the speech restriction? We are not aware that FDA has fully articulated the interest underlying its restrictive interpretation of 21 C.F.R. § 812.7. We infer that FDA's interest is in preventing sponsors from creating a misimpression among potential customers about the investigational device's capabilities prior to completion of FDA's review. The harm presumably would occur if FDA clears or approves the device with more limited labeling than suggested by the preliminary results. Of course, if FDA finds that the final data do not support clearance or approval, then the dissemination of preliminary clinical information will not cause any harm, because the device will never reach the market.

Does the speech restriction directly advance the interest asserted? By shutting down virtually all truthful, non-misleading information about clinical experience with investigational devices, FDA will likely prevent sponsors from potentially creating the misimpression among prospective customers for the product.

Is the speech restriction more extensive than necessary to serve this asserted interest? Absolutely. The dissemination of truthful, non-misleading information about clinical experience with investigational devices is crucial to the progress of medicine and science. FDA acknowledges this fact in the Presby Corp. warning letter quoted above, which states that “FDA encourages full exchange of scientific information concerning investigational devices.” Yet, FDA’s approach is to clamp down as tightly as possible on this information, thus burdening a significant amount of concededly useful and important speech.

The rationale for all of these restrictions on truthful speech appears to be a concern about the potentially misleading effect of the information may have at some time in the future after clearance or approval has been granted. In Western States, the Supreme Court made it very clear that this concern must be addressed with appropriate disclosure – *i.e.*, that more speech rather than less speech is the appropriate way to cure any potential for speech with recognized value that may still have the capacity to mislead.

This approach is especially appropriate here because the link is attenuated between the potentially misleading speech and the audience action (purchasing the product). In this case, the information about ongoing clinical experience with an investigational device is an evolving discourse that takes place over months and even years before the FDA review process is complete. Even if the

preliminary results are not completely vindicated by the final data, the product labeling that FDA ultimately clears or approves is an intervening influence that will accurately describe the appropriate use of the device and the supporting data. In rare cases when FDA believes egregious conduct has created an indelible misimpression, FDA can require counter-balancing statements in the cleared or approved labeling. All in all, FDA's current restrictions on the flow of interim scientific information are unnecessary.

DISSEMINATION OF THIRD PARTY MATERIALS THAT DISCUSS POST-APPROVAL STUDIES

A. FDA's Speech Restriction

When a PMA device receives approval, FDA approves a summary of the clinical data supporting approval in the Summary of Safety and Effectiveness (SSE). Under current FDA policy, a manufacturer must label and promote the device solely on the basis of the data in the SSE. FDA's position is that when post-approval clinical experience differs from the data in the approved labeling, the manufacturer may not disseminate the new data without approval of a PMA supplement allowing such dissemination. Failure to obtain the required PMA supplement, according to FDA, is a violation of 21 C.F.R. § 814.39, which requires approval of changes to a device's labeling that could effect safety or effectiveness.

Alternatively, in some cases, FDA has not cited 21 C.F.R. § 814.39, but has alleged that dissemination of post-approval clinical data is misleading unless FDA has reviewed and approved it.

B. Requested Change in FDA Policy

FDA should allow manufacturers to disseminate evolving clinical experience with the use of their device. FDA should permit two types of labeling. One type would be the traditional FDA-approved labeling that could not be altered without approval of a PMA supplement. However, FDA should create a second tier of “post-approval clinical experience.” Firms would be permitted to disseminate the new clinical information concerning their PMA approved devices (whether generated by the firms or independent third parties) without an approved PMA supplement, as long as the information is truthful, accurate, and fairly balanced both as to the results and the nature and quality of the study from which the data were generated. To avoid any misleading implication, firms would be required to disclose that FDA has not reviewed or approved the new information. Firms also can be required to disclose any financial involvement with the studies that generate the information.

C. Supporting Analysis

A Western States analysis supports the requested change in FDA's policy. Under Western States, the threshold inquiry is whether the speech is misleading or concerns unlawful activity. In this case, the clinical studies clearly do not concern unlawful activity. On the contrary, they represent legitimate scientific and medical investigation and research. As such, they cannot be characterized as inherently misleading. In particular, they are not inherently misleading merely because FDA has not reviewed them. As the district court observed in the Washington Legal Foundation, "the FDA is not a peer review mechanism for the scientific community." Washington Legal Foundation v. Friedman, 13 F.Supp.2d 51, 67 (D. D.C. 1998) (quotation marks and citation omitted).

To the extent that FDA believes the information is potentially misleading, disclosures such as those we have suggested can address that concern. In most cases the audience for information about investigational devices is a sophisticated one (*e.g.*, physicians), which should further mitigate concerns that the information is potentially misleading. Under Western States, it is appropriate to use disclosure to cure potentially misleading speech.

Does FDA have a substantial interest in the speech restriction? FDA's interest in preserving the integrity of the approval process (as articulated in Western States, slip. op. at 13) is not implicated, because the information relates to

clinical experience with the product for its approved use and not an unapproved new intended use. Most likely, FDA would argue that its interest is in preserving the integrity of the approved labeling by preventing manufacturers from disseminating unapproved additional information as part of the labeling.

Does the speech restriction directly advance the interest asserted? By requiring manufacturers to adhere to the script set forth in the SSE, and proscribing dissemination of information about post-approval clinical experience (absent a PMA supplement), FDA does advance its interest in preserving the integrity of the approved labeling.

Is the speech restriction more extensive than necessary to serve the interest? Yes. FDA's approach limits the efficient dissemination of useful and valuable information to the healthcare community regarding post-approval study and experience with devices. While it is true that a manufacturer may obtain a PMA supplement approval to disseminate the information, this process is time-consuming, cumbersome, and expensive, as the Supreme Court recognized in Western States. Furthermore, some of the information is likely to be helpful to the healthcare community even when it is not of the quality that would make it appropriate to include in the approved labeling.

A more flexible approach would actually do more to disseminate a more nuanced and robust understanding of device performance as it develops from

post-approval use and study. Healthcare professionals frequently make patient care decisions based upon data that do not rise to the level of controlled clinical trials such as are typically described in the approved labeling. They attend CME meetings, symposia, scientific meetings, and Grand Rounds. They read published journal articles, textbooks, and scientific abstracts and engage in discussions with their colleagues. Healthcare professionals are experienced and adept at critically evaluating the varying quality of information that may contribute to their decision-making. See Washington Legal Foundation v. Friedman, 13 F.Supp.2d at 70. By prohibiting manufacturer involvement in the dissemination of this information, FDA forecloses those with the greatest economic incentive to efficiently disseminate this information from participating in the process.

FDA's policy of prohibiting manufacturers from contributing to the dissemination of this information is not based upon any statutory mandate. By hypothesis, the information relates to a use that has already received FDA review and approval pursuant to the statutory requirement. FDA's policy is based instead upon a restrictive interpretation of its regulations requiring a PMA supplement for a significant labeling changes and/or the mistaken presumption that information is inherently misleading if FDA has not reviewed it. FDA clearly has the authority to adopt a new approach.

FDA's interest in preserving the integrity of the approved labeling can be met by recognizing two tiers of labeling. The first tier would be the traditional core labeling that FDA explicitly approves (*i.e.*, the package insert and promotional material incorporating this information). The second tier would be post-approval information accompanied by prominent disclosure that the information was not reviewed by FDA. There would also be disclosure of the extent of the manufacturer's financial involvement in the underlying study. FDA might even wish to create a required format that healthcare professionals would come to recognize as second tier post-approval information disseminated by manufacturers. For example, FDA could require manufacturers to disseminate either unaltered copies of original study reports or an accurate and fairly balanced summary expressly labeled as a "manufacturer white paper." Finally, FDA could require that the information be truthful, accurate, and fairly balanced in a manner that would allow the recipient to make an informed judgment about its value.

It is neither practical nor wise for manufacturers to submit a PMA supplement for every new study. Our proposed approach would allow manufacturers to disseminate post-approval information developed about their devices without automatically undergoing the PMA supplement process. Nonetheless, if a significant body of useful data were developed, manufacturers would likely find it advantageous to update the labeling, if only to enhance the credibility of the data with an FDA approval or address product liability concerns.

Healthcare practitioners could be expected to critically evaluate lesser data, based upon truthful and accurate descriptions of the nature of the study and the results. Manufacturers could also be required to provide the full range of favorable and unfavorable information to avoid a misleading selection. Ultimately, this flexible approach would increase the supply of nonmisleading information in the market (as the Supreme Court requires) without compromising FDA's approved labeling.

CONCLUSIONS

BSC appreciates this opportunity to comment on FDA's labeling, promotion, and advertising requirements. BSC believes it is appropriate for FDA to carefully reconsider its position in light of the Western States decision. Although many of FDA's policies will withstand scrutiny, it is clear that in some areas FDA will need to make significant revisions. Ultimately, BSC believes that this process will result in a better healthcare environment that will benefit the public.

Boston Scientific

September 11, 2002

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**RE: Docket No. 02N-0209
Request for Comment on First Amendment Issues**

Dear Sir/Madam,

Pursuant to FDA's Request for Comment on First Amendment Issues published in the Federal Register of May 16, 2002 (67 FR 34942), Boston Scientific Corporation is submitting, in triplicate, its comments on this very important issue.

Should you have any questions regarding these comments, please do not hesitate to contact me directly by phone at 508-650-8798 or by facsimile at 508-650-8012.

Respectfully,



Anthony L. Blank
Manager, Corporate Regulatory Affairs

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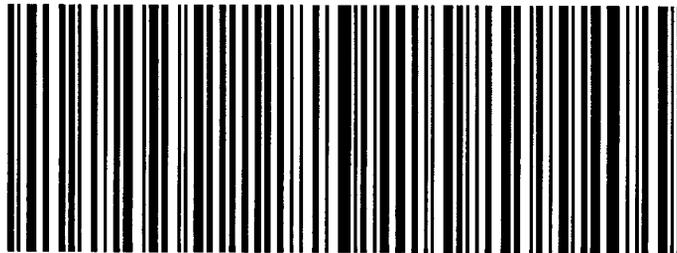
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3. Place label in air waybill pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Shipment Details

To print a copy of the shipment information for your records, please click "Shipment Details".

[Shipment Details](#)

Ship a New Package

[Ship Inside U.S.](#)

[Ship Outside U.S.](#)

[Ship to Same Recipient](#)

Use of this system constitutes your agreement to the service conditions in the current FedEx service Guide, available upon request.

FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.