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Affecting FDA-Regulated Products*

The Food and Drug Administration's Evolving Regulation of Press Releases: Limits and Challenges

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I. INTRODUCTION

For twenty years, the Food and Drug Administration (FDA) asserted that it could regulate press releases and other media statements issued by pharmaceutical and medical device companies concerning their products. During this time, the agency developed an informal framework for regulating press statements it deemed to be false, misleading, or otherwise in violation of certain legal prohibitions. Even though FDA's approaches to drug- and device-related press releases differed in some ways, the agency generally applied a set of common principles to all press materials.

Beginning in 2001, however, FDA became concerned about regulatory actions that could be construed as infringing the constitutional rights of marketers. The agency lost several significant court cases on First Amendment grounds, on the theory that certain regulatory policies were too burdensome on commercial speech.¹ One court reminded the government that the preferred remedy for allegedly false or misleading speech is "more disclosure, rather than less."² FDA began reconsidering its approach to regulatory activities that implicate the First Amendment. The agency's Chief Counsel from 2001 to 2004, Daniel E. Troy, had strong First Amendment views and represented the plaintiff in the *Washington Legal Foundation* suit before joining FDA.³ At FDA, he oversaw several procedural changes that suggested fundamental shifts in policy going forward.

First, the U.S. Department of Health and Human Services (HHS) directed the Office of FDA Chief Counsel to review all proposed Warning or "untitled" letters before dissemination.⁴ Following this directive, but not necessarily because of it, there was a sharp drop in the number of regulatory correspondence issued for alleged promotional violations.⁵ Since 2002, FDA has not issued any Warning or "untitled" letters based on press statements.

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¹ See *Thompson v. Western States*, 535 U.S. 357 (2002); *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

² *Pearson*, 164 F.3d at 657 (citing *Bates v. State Bar of Arizona*, 433 U.S. 350, 376 (1977)).

³ See *Washington Legal Foundation*, 202 F.3d 331, *supra* note 1.

⁴ The agency adopted this policy in late February 2002. Before this policy took effect, FDA's division and district offices issued these letters unilaterally. See Chris Adams, *FDA Cuts Back on Warnings as Critics See Enforcement Easing*, WALL ST. J., (Oct. 1, 2002), at A3.

⁵ *Id.*; Melody Petersen, *Who's Minding the Drugstore?*, N.Y. TIMES, (June 29, 2003), § 3, at 1 (noting that between 1997 and 2000, FDA issued ten warning letters per month in contrast to the four letters per month issued under Troy). See also letter from Rep. Henry A. Waxman to Comm'r. Mark B. McClellan, M.D., Ph.D. (Jan. 29, 2004) (noting reduced enforcement activity and lack of its effectiveness).

Next, FDA requested public comments on the potential conflict between regulation of advertising and promotional claims and the First Amendment.⁶ The comments submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) and several others questioned FDA's policies regarding press releases. Several medical device firms also submitted comments, but none were specific to press releases. A common theme among these comments was that manufacturers should be able to disclose what the product is being studied for and the uses for which approval is being sought, as long as the information is truthful and not misleading.⁷ These comments are likely to color future actions and policies.

Finally, the agency is now being very careful about litigation it brings—or may be brought into—that could result in new defeats on constitutional grounds. Chief Counsel Troy stated that he was concerned that a succession of reversals would undercut FDA's future credibility in the courts.⁸

This article discusses how FDA has regulated press releases in the past and how recent developments may signal new directions in the agency's regulatory approach to press releases and media statements. It also proposes a framework for evaluating whether FDA might assert jurisdiction, and what the "rules" are if jurisdiction is invoked.

This article is organized into six parts. Together, these parts describe how and when FDA might assert jurisdiction over a press release, what requirements the agency may expect the press release to satisfy if subject to FDA jurisdiction, and what actions the agency may take if the press release does not meet these requirements. Part II discusses how FDA asserted jurisdiction over drug- and device-related press releases through its authority over labeling, promotional labeling, and advertising. The authors also discuss how FDA broadened its authority by using the "intended use" doctrine. Part III gives several examples of how FDA has regulated press materials for drugs and devices. It outlines the administrative and judicially-sanctioned actions FDA has taken, and the legal theories upon which these actions relied. Part IV discusses the legal and practical limits to FDA's regulation of press materials. In addition to tailoring its policy to address First Amendment concerns, the agency has had to adjust to resource limitations, which, in part, has led to increasing cooperation with the Securities and Exchange Commission (SEC). Because of these legal and practical limitations, the authors propose a framework for considering FDA's approach to drug- and device-related press releases. Part V outlines the requirements if the press release is subject to FDA jurisdiction. Although a core set of requirements is common to all FDA-regulated press materials, other requirements may apply depending on the product's approval status. Part VI discusses the variety of enforcement tools at the agency's discretion, including statutory sanctions, administrative tools such as warning letters, and most recently, use of its own press releases to counter false or misleading statements in company press materials. Part VII concludes with a brief statement of the implications for manufacturers.

II. FDA'S AUTHORITY OVER PRESS RELEASES

FDA's assertion of authority to regulate press releases regarding medical products derives from its statutory authority over labeling for all such products, and over adver-

⁶ See 67 Fed. Reg. 34,942 (May 16, 2002) (Docket No. 02N-0209).

⁷ See *WLF Answers Democrats in First Amendment Off-Label Promotion Debate*, 28 (44) F-D-C REPORTS, "THE GRAY SHEET" 12 (Nov. 4, 2002).

⁸ *FDA Guidance Practices are Good Model for HHS—General Counsel Azar*, 28 (17) F-D-C REPORTS, "THE GRAY SHEET" 11 (Apr. 29, 2002).

tising of prescription drugs⁹ and restricted medical devices¹⁰ under the Federal Food, Drug, and Cosmetic Act (FDCA). Accordingly, it is appropriate to start with a brief analysis of this underlying authority.

A. *Statutory Authority over "Labeling," "Promotional Labeling," and "Advertising"*

FDA has asserted authority to regulate press releases in part on the theory that press materials constitute "labeling," "promotional labeling," and/or "advertising." How does FDA reach this position? 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."¹¹ Courts have long held that anything that "accompanies" the product as part of the information to influence potential buyers is "labeling," even if it is shipped separately.¹²

The law contains a variety of general and specific requirements relating to labeling of medical products. The two most relevant rules are found in the misbranding provisions of Section 502 of the Act. First, a drug or device is "misbranded" if its labeling is "false or misleading in any particular."¹³ The Act also makes explicit that labeling may be considered misleading if it fails to reveal facts material in light of the representations actually made.¹⁴ Second, a medical product is misbranded if its labeling fails to provide "adequate directions" for the uses recommended or suggested in the labeling.¹⁵ The agency interprets this standard to require directions adequate to a layperson, not just a healthcare professional.¹⁶ Thus, if a company promotes a drug for a medical application not approved by FDA, the official labeling may be deficient because it fails to give directions for the safe and effective use of the product for this purpose.

The FDCA directs the agency to review "official labeling" for products subject to premarket approval. For most prescription drug and biologic products, this requirement translates into preclearance of the package insert (also called "prescribing information" or "physician information") and the container labels. For devices, it involves the "user's instructions" or "operator's manual."

Beginning in 1962, the FDCA also imposed requirements on the advertising of prescription drugs and restricted medical devices, including the requirement that all advertisements must contain the established name of the product, the formula of the product, and a "brief summary" of side effects, contraindications, and effectiveness

⁹ Under the Act, a drug product may be sold only pursuant to a lawful prescription if it has toxicity or harmful effect, if the method of its use or collateral measures necessary to its use mean it is not safe except under supervision of a health care professional, or if it is otherwise required by law to be sold under a prescription. *See* FDCA § 503(b); 21 U.S.C. § 353(b).

¹⁰ Under FDCA § 520(e), FDA is authorized to restrict the sale, distribution, or use of a device if there is not reasonable assurance of the device's safety and effectiveness. A restricted device can only be sold on oral or written authorization by a licensed practitioner, or under conditions specified by regulation. 21 U.S.C. § 320g(e).

¹¹ FDCA § 201(m); 21 U.S.C. § 321(m). "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." FDCA § 201(k); 21 U.S.C. § 321(k).

¹² *See* *Kordel v. United States*, 335 U.S. 345 (1948) (holding that pamphlets and other product literature distributed to consumers yet shipped separately nevertheless "accompanied" the product "when it supplements or explains it"); *United States v. Urbeteit*, 335 U.S. 355 (1948) (holding that descriptive leaflets that did not physically accompany the shipment of devices nevertheless constituted labeling).

¹³ *See* FDCA § 502(a); 21 U.S.C. § 352(a).

¹⁴ *See* FDCA § 201(n); 21 U.S.C. § 321(n).

¹⁵ FDCA § 502(f); 21 U.S.C. § 352(f).

¹⁶ 21 C.F.R. §§ 201.5, 801.5.

information.¹⁷ Violation of these rules misbrands the product. The agency is generally not authorized to require prior approval of advertising.¹⁸

The Act does not define “advertising” or distinguish it from “labeling.” The agency at one time considered that differences in statutory language might provide less legal authority over “advertising” more than “labeling,” and thus wanted promotional materials to be “labeling”—not “advertising”—whenever possible. But FDA also did not want to preclear marketing materials other than “official labeling.” Hence, in 1963, it created a category not set forth in the Act: “promotional labeling.”¹⁹ This category covers everything other than the container label, the package insert, and “advertising.” The regulatory definitions of material that may constitute “advertising” or “promotional labeling” for prescription drugs reads as follows:

- (1) Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television and telephone communication systems.
- (2) Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and *similar pieces of printed, audio, or visual matter descriptive of a drug* and references published (for example, the “Physicians Desk Reference”) for use by medical practitioners, pharmacists, or nurses, *containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor* are hereby determined to be labeling as defined in section 201(m) of the act.²⁰

No analogous rule has been developed for medical devices, but the principles would intuitively be the same. The italicized language (“*similar pieces of printed, audio, or visual matter descriptive of a drug ... containing drug information supplied by the manufacturer ... and which are disseminated by or on behalf of the manufacturer*”) shows how FDA could interpret press materials to constitute “promotional labeling.”

B. The “Intended Use” Doctrine

The agency also exercises jurisdiction over marketers and their products based on press releases and other communications in part under the “intended use” doctrine. The term “intended use” refers to how the persons legally responsible for the labeling of the product objectively intend it to be used.²¹ These persons’ intent can be determined by their expressions or by the circumstances in which they distribute the product. FDA states that objective intent can be shown by promotional labeling, advertising matter, or other statements by these persons or their representatives.²²

If FDA finds that a manufacturer intends a particular use for its product, multiple legal consequences follow. For all medical products, the “official labeling” must provide

¹⁷ FDCA §§ 502(n), (r); 21 U.S.C. §§ 352(n), (r).

¹⁸ *Id.*

¹⁹ The regulations are now codified at 21 C.F.R. § 202.1(l); *see also* 21 C.F.R. § 314.81(b)(3)(i) (using the term “promotional labeling”).

²⁰ 21 C.F.R. § 202.1(l) (emphasis added).

²¹ 21 C.F.R. §§ 201.128, 801.4.

²² 21 C.F.R. §§ 201.128, 801.4.

adequate directions for the intended use.²³ In addition, for drugs, an intended use that differs from that approved by the agency can result in the product being a “new drug” requiring FDA approval of New Drug Application (NDA) for that use. Distributing the product for that use without such an approval violates the Act.²⁴

The legal consequences are similar for medical devices. Distributing products for intended uses that have not been approved by the agency under a Premarket Approval (PMA) application, or cleared under a “510(k) notice,” is prohibited.²⁵ Most medical devices are “cleared” for marketing under section 510(k) of the Act rather than under a PMA. To obtain clearance, a company must show that its product is substantially equivalent to a product marketed prior to 1976 or to a device classified as not requiring a PMA. An important element of this process is ascertaining the “intended use” of the product. If a company obtains 510(k) clearance but then markets it for a different intended use, it must obtain a new 510(k) clearance.²⁶

The 510(k) process, however, has several complicating features. The agency does not usually review the “official labeling” of the product. It looks only at the intended use that is described in the 510(k). Moreover, 510(k) devices are often cleared for a general purpose rather than a particular “intended use.” For example, a medical laser might be cleared for excising certain kinds of tissues, but not for the performance of specific medical procedures. The agency could complain that particularization of procedures that can be performed with the laser creates novel “intended uses” that were not cleared in the 510(k) process.²⁷

The importance of the “intended use” doctrine is that it permits FDA to exercise jurisdiction over products and marketers based on the content of communications, without asserting jurisdiction over the communications themselves. For example, the agency has relied on corporate filings to the Securities and Exchange Commission (SEC) to demonstrate the company intended its product be used for a medical purpose, without claiming that the SEC filing was a document subject to FDA regulation.²⁸

C. *Applicability of FDCA to Oral Communications*

Because press statements are often made orally, it is important to note that FDA has asserted the position that *oral* statements by or on behalf of a manufacturer regarding one of its products are also “promotional labeling,” even though they do not consist of “written, printed, or graphic matter.” Thus, the agency has claimed that it can regulate the oral presentations of sales representatives in physicians’ offices, before formulary boards, or at exhibit booths. To illustrate, FDA wrote an “untitled” letter to Actelion Pharmaceuticals, accusing a company representative of making misleading oral statements to a hospital staff member.²⁹ The oral statements were inconsistent with the approved labeling because they promoted unapproved uses and “failed to present *any*

²³ FDCA § 502(f); 21 U.S.C. § 352(f).

²⁴ FDCA § 505(n); 21 U.S.C. § 355(n).

²⁵ FDCA §§ 501(f)(1), 502(o), 510(k); 21 U.S.C. §§ 351(f)(1), 352(o), 360(k).

²⁶ 21 C.F.R. § 807.81(a)(3)(ii).

²⁷ See, e.g., Warning Letter from FDA to ESC Medical Systems (June 2, 1997).

²⁸ In 1987, FDA sent a Regulatory Letter to Advanced Tobacco Products, Inc., stating that the agency had reviewed several SEC filings, including registration statements, responses to SEC comments, and annual reports, to determine that the company’s smokeless cigarettes were intended as “a nicotine delivery system,” and thus were intended for medical uses. See Regulatory Letter from FDA to Advanced Tobacco Products, Inc. (Feb. 9, 1987); see also Peter Barton Hutt & Richard A. Merrill, *FOOD AND DRUG LAW CASES AND MATERIALS* 386 n.7 (1991).

²⁹ See “Untitled” Letter from FDA to Actelion Pharmaceuticals U.S., Inc. (Oct. 30, 2002), at <http://www.fda.gov/cder/warn/2002/11014.pdf>.

information on the risks associated with the use [of the product]."³⁰ More recently, Gilead Sciences, Inc., received a warning letter asserting that a sales representative at an exhibit booth made statements that allegedly minimized the risk information and broadened the indication for the product.³¹ Therefore, it would not be surprising to see FDA assert jurisdiction over oral press statements on the grounds that such statements constituted "promotional labeling."

D. Extraterritorial Application of FDA Rules

In asserting jurisdiction over press statements, FDA might scrutinize foreign-issued press statements. Many FDCA-regulated companies are international or multi-national. Thus, it is important to note that the agency has taken enforcement actions against conduct occurring outside the geographic United States if it caused the dissemination of false or misleading information, or otherwise misbranded a product, within the United States. In a criminal prosecution against Hoechst AG, FDA argued that the failure of the German corporation to inform its U.S. subsidiary about certain adverse events associated with the drug Merital (nomifensine) resulted in the omission of important warnings from the U.S. labeling. All of the activities occurred outside the United States and Hoechst's U.S. subsidiary was not indicted. Hoechst's German parent pled guilty in 1990.³²

Likewise, many companies issue press statements via the Internet, so it is noteworthy that FDA has also asserted that it can regulate Internet sites accessible in the U.S. even if the server hosting the site is located outside the United States. In 2000, the agency began sending "cyber letters" to foreign-based websites engaging in potentially illegal activities such as offering to sell online prescription drugs.³³ In such cases, electronic documents resembling traditional regulatory letters are sent to the domain holders for sites the agency determines may be engaged in illegal activity.

Thus, taking these two precedents together, it should not be surprising for FDA to assert jurisdiction over foreign-issued press releases posted on the Internet if accessible in the United States.

E. FDA Organization for Policing Advertising and Promotion

Because the agency has asserted that press materials constitute labeling, advertising, and/or promotional materials, regulatory review of press statements is handled by FDA's advertising and promotional arms. The responsibilities and resources for policing the advertising and marketing of drugs, biologics, and medical devices has changed over the years. FDA was first given jurisdiction to regulate prescription drug advertising by the Drug Amendments of 1962. Dating back at least to the early 1970s, the agency has had a special unit for this specific activity, now called the Division of Drug Marketing, Advertising, and Communications (DDMAC) in the Center for Drug Evaluation and Research (CDER). This unit has always been active and has compiled a significant "body of law" through legal actions, regulatory correspondence, guidance, and other policy statements.

³⁰ *Id.* (emphasis added).

³¹ See Warning Letter from FDA to Gilead Sciences, Inc. (Jul. 29, 2003), at http://www.fda.gov/foi/warning_letters/g4180d.pdf.

³² See *Trade and Government Memos*, 52 (51) F-D-C REPORTS, "THE PINK SHEET" 9 (Dec. 17, 1990).

³³ See FDCA § 502(r); 21 U.S.C. § 352(r). FDA's "Cyber Letter" website is at <http://www.fda.gov/cder/warn/cyber/cyber2003.htm>.

Only in the 1990s did FDA's Center for Biologics Evaluation and Research (CBER) create a special unit, now called the Advertising and Promotional Labeling Branch (APLB), to parallel DDMAC. As a result, there has been far less "case law" concerning the promotion of biologics. Because biologics are also drugs, however, DDMAC's precedents are directly relevant. FDA recently transferred review authority over promotion of therapeutic biologics generally to DDMAC.³⁴

Similarly, although FDA was given authority over advertising of restricted devices in 1976, it was not until the 1990s that FDA's Center for Devices and Radiological Health (CDRH) established a unit with formal responsibility over device marketing, the Promotion and Advertising Policy Staff (PAPS). The CDRH "body of law" is both more limited than DDMAC's and more complex due to the differences in the statutory authority and regulatory scheme applicable to devices. Despite these differences, CDRH policies were influenced through the temporary assignment of DDMAC staff to the CDRH group. In 2003, PAPS was dissolved and folded into the Office of Compliance. The function was assigned to the reorganized Divisions of Enforcement A and B, with only two full-time employees to support the function.³⁵ It is difficult to ascertain the significance of this change apart from the lack of resources within the agency.

III. FDA'S PAST REGULATION OF PRESS MATERIALS

A. Enforcement Actions against Press Releases for Drugs and Biologics

1. Administrative Actions

Beginning in 1982, FDA has on numerous occasions taken enforcement action based on the content of press releases or other public relations materials. The first such instance was in 1982 when the agency sent a letter to Pfizer concerning Feldene (piroxicam) stating, "We regard a press kit prepared by or on behalf of the manufacturer and disseminated to the press to be labeling for the product."³⁶ Within weeks, FDA also sent a Regulatory Letter (the predecessor to the warning letter) to Eli Lilly based on the Press Kit for Oraflex (benoxaprofen), a product that competed with Feldene, and asserted that this Kit also was "promotional labeling."³⁷

In the years leading up to 2002,³⁸ FDA became especially vigilant of false and misleading, or otherwise unsubstantiated, claims made in press releases or press kits. In the five years between 1996 and 2001, for example, it issued over 40 warning letters and untitled letters citing company press releases for alleged violations of the statute and regulations. The agency's attention coincided with the practice of companies using their websites to post press releases, making them more accessible to FDA.

As many letters reveal, FDA considers the review of press releases and press kits to be part of its routine monitoring and surveillance program. For instance, in an untitled letter to Wyeth-Ayerst Laboratories, the agency stated, "DDMAC has obtained a copy

³⁴ CDER Ad Division to Create Separate Biologics Review Group, 65 (25) F-D-C REPORTS, "THE PINK SHEET" 23 (June 23, 2003).

³⁵ See CDRH Promotion/Advertising Merging with OC Under Reorganization Plan, 29 (5) F-D-C REPORTS, "THE GRAY SHEET" 17 (Feb. 3, 2003).

³⁶ Letter from FDA to Pfizer, Inc. (July 13, 1982).

³⁷ Letter from FDA to Eli Lilly & Company (July 27, 1982).

³⁸ 2002 is the year when HHS directed the Office of FDA Chief Counsel to review all proposed warning or "untitled" letters before dissemination. See *supra* note 4.

of the press release from the Internet and finds it to be misleading and in violation” of the FDCA.³⁹

FDA’s letters further show that the agency reviews press materials under similar standards to those used when it reviews all other “promotional labeling.” For example, in an untitled letter to Celgene Corporation, the agency wrote under the heading of “Press Releases”:

Promotional materials must provide fair balance. They are in violation of the Act if they fail to present information relating to adverse consequences associated with the use of a drug and fail to include appropriate reference to warnings, precautions, and contraindications. . . . Celgene’s three press releases lack fair balance and are therefore misleading.⁴⁰

Similarly, Vivus, Inc., received an untitled letter stating, “The January 26, 1998, press release announcing the launch of Vivus’ direct-to-consumer advertising campaign is misleading”⁴¹ Even in a press release meant solely to announce an advertising campaign, the agency required Vivus to include “information regarding contraindications, side effects, and other important risk information” regarding the product.

FDA has also criticized press statements made in less promotional contexts, such as the release of results of clinical studies, where such statements include violative promotional language. For example, an untitled letter to Cubist Pharmaceuticals, Inc., FDA argued that Cubist had promoted its drug for several indications prior to approval in numerous press releases, including a release announcing the presentation of positive safety and efficacy data by a physician at a medical conference.⁴² The agency noted that the press release “fail[ed] to disclose important risk information.”

Thus, press releases have been within the realm of activity that triggers administrative enforcement actions. When FDA scrutiny is triggered, the agency has reviewed press materials under similar standards to those used when reviewing “promotional labeling.”

2. *Judicially-Sanctioned Actions*

The agency has gone beyond simply issuing letters. In 1991, it sought (and obtained) an injunction against ICN Pharmaceuticals, Inc., based upon the contents of a press kit that allegedly promoted Virazole (ribavirin) for off-label uses. Virazole was approved for treatment of respiratory syncytial virus in late 1985. Soon thereafter, ICN issued various press materials, including a video news release, discussing research on possible use of Virazole in the treatment of AIDS-related diseases. In March 1986, a Regulatory Letter accused the company of allegedly promoting Virazole for off-label uses through these press materials. The media materials followed

several months of intense communications between Viratek [ICN’s subsidiary], SPI and ICN Pharmaceuticals and [FDA’s] Division of Drug Advertising and Labeling in which your representatives were repeatedly advised against representations and suggestions beyond the limitations of the drug’s labeling

³⁹ Untitled letter from FDA to Wyeth-Ayerst Laboratories (May 19, 1997). FDA does not have a specific policy for communications over the Internet, but has concluded that information on websites can constitute labeling. See Letter to Washington Legal Foundation, Docket No. 01P-0187/PDN1 (Nov. 1, 2001).

⁴⁰ Untitled Letter from FDA to Celgene Corp. (Nov. 9, 1998).

⁴¹ Untitled Letter from FDA to Vivus, Inc. (Feb. 19, 1998).

⁴² Untitled Letter from FDA to Cubist Pharmaceuticals, Inc. (Nov. 9, 1998).

in a broad range of promotional materials. These communications included numerous admonitions [*sic*] against statements suggestive of use of Virazole in conditions other than severe respiratory syncytial virus infections We believe that the Press Kit represents an intentional effort to circumvent the prescriptions noted in our review of the introductory promotional materials.⁴³

After an extended investigation, FDA filed a complaint seeking to enjoin ICN from marketing Virazole for off-label uses in May 1991. The following month, ICN entered into a consent decree under which it paid \$400,000 for its misconduct and \$200,000 to cover the agency's administrative costs. More importantly, for the next three years, FDA required ICN to ask physicians for what indications they intended to use drugs purchased from the company. FDA also required ICN to inform the agency two days prior to any "dissemination within the U.S. of findings or actions of foreign regulatory bodies relating to any new drug," or any other communication necessary for "the full exchange of scientific information," including "the form and substance, and, where feasible, the identify of each person ... to whom the proposed disclosure is to be made."⁴⁴

3. Legal Theories

The foregoing enforcement activities were all based on press releases or press kits. In each instance, FDA asserted unequivocally that the press materials at issue fell under the categories of advertising or promotional labeling listed in 21 C.F.R. § 202.1(l) and thus were directly subject to regulation.

The agency's position was that company press releases are "printed, audio, or visual matter" that "are disseminated by or on behalf of" the manufacturer of a product. If the press release is descriptive of a product made by that manufacturer—that is, if the release refers to a specific product either expressly or by implication—FDA contended that the release is "labeling" subject to regulation.⁴⁵

⁴³ Regulatory Letter from FDA to ICN Pharmaceuticals, Inc. (Mar. 24, 1986).

⁴⁴ See Consent Decree with ICN Pharmaceuticals, Inc. (May 24, 1991); see also *ICN Settles Justice Department Virazole AIDS Promotion Suit with \$600,000 Payment*, 53 (22) F-D-C REPORTS, "THE PINK SHEET" 7 (June 3, 1991) ICN also entered into a consent decree with the SEC in October 1991 permanently enjoining CEO Milan Panic and director Weldon Jolley from future securities fraud for making false statements to the investing public in press releases, investor mailings, satellite broadcasts, and in SEC filings regarding the results of two clinical trials testing Virazole for the treatment of AIDS in 1987. See *Consent Decree between United States and ICN Pharmaceuticals, Inc.*, FDA ADVERTISING AND PROMOTIONAL MANUAL, Appendix V, 7 (May 1993). The SEC later initiated cease-and-desist proceedings against two ICN executives. See *SEC, In the Matter of David C. Watt*, Exchange Act Release No. 46,899 (Nov. 25, 2002), at <http://www.sec.gov/litigation/admin/34-46899.htm>; *In the Matter of Nils O. Johannesson*, Exchange Act Release No. 46,900 (Nov. 25, 2002), at <http://www.sec.gov/litigation/admin/34-46900.htm>. Finally, the SEC entered into a consent decree with ICN requiring ICN to preclear with FDA any materials related to its drug products for a period of five years. See, *ICN Must Clear News Releases with FDA under SEC Settlement*, 34 (47) WASHINGTON DRUG LETTER (Dec. 2, 2002); *FDA/SEC Regulatory Coordination Talks Await New Securities Chairman*, 64 (48) F-D-C REPORTS "THE PINK SHEET" 12 (Dec. 2, 2002).

⁴⁵ See, e.g., *FDA Looking at Single Company-Sponsored Journals, Investor Contact and Press Releases as "Accompanying Labeling"*, Agency Ad Div. Director Tells PMA Workshop, 48 (37) F-D-C REPORTS "THE PINK SHEET" 8 (Sept. 15, 1986). There also exists a document on press releases entitled "Statement of Position: Working Guidelines," identified as being "Issued in Early 1980's." In Mar. 1997, FDA published a comprehensive list of guidance documents developed by DDMAC (or its predecessor) and asked for comment on whether to rescind or revise them. 62 Fed. Reg. 14,912 (Mar. 28, 1997). The Mar. 28, 1997 Notice stated that the "Statement of Position" document is obsolete and suggested that it would be combined with the July 24, 1991 guidance on video news releases discussed *infra*. The context of the early 1980's document is not disclosed, and FDA notes only that it was "retyped 8/3/95 from original document." Given that the "Statement of Position" document stated that FDA's policy was "still in a stage of formation," and that FDA now states that the document is obsolete, it does not appear to be a document on which one can place any significant reliance.

As discussed above, FDA has also implied that oral statements made to the media would also be “labeling” in the same way that remarks of sales representatives would be.⁴⁶ Here, however, the agency may be on firmer ground from a statutory standpoint, which seems to require “written, printed or graphic matter.” For example, the agency might assert that press stories and security analysts’ reports based on oral statements are disseminated “on behalf of” the manufacturer. That is, by holding a press interview or analysts’ briefing, company officials intend to have the information they present disseminated in print by members of the audience. No warning letter or other enforcement action has ever been based on a statement quoted in such an article, although the authors are aware of some non-public FDA inquiries to drug firms requesting information underlying a press report regarding a company’s product. Therefore, for the remainder of the article, the phrase “press release” will be used to refer both to written releases and oral statements made to the media.

B. FDA Enforcement against Press Releases for Medical Devices

1. Actions

FDA has been explicit in asserting jurisdiction directly over drug-related press releases, but the agency has been much less clear on devices. Nevertheless, CDRH does monitor company press statements. For example, a warning letter to APS Limited advised that the agency had “reviewed promotional materials” for the company’s device, citing the company’s website and press release.⁴⁷ Similarly, CDRH sent a warning letter to Jacobson Resonance Enterprises, Inc., stating, “Press releases may not be used as a promotional tool or as an attempt to commercialize a product prior to approval or clearance.”⁴⁸ The letter asserted that misleading or inaccurate statements pertaining to the company’s device were found in “a brochure, subject recruiting advertisements, and a press release and other information distributed via the Internet.”

CDRH’s press release policies are much less well-developed and detailed than CDER’s policies. While CDER has made several policy statements in the area, CDRH has not expressed its policies in any guidance documents. Nevertheless, CDRH appears to apply drug policies to devices, where appropriate. Thus, where there is no principled reason why drug and device policy should differ, it is safe to assume that FDA would treat drug- and device-related press releases similarly.

Although most of the same regulatory expectations would extend to both drug- and device-related press releases, applying CDER’s policies to CDRH is complicated by the fact that labeling in the medical device context is less systematized and straightforward than in the prescription drug context. Consequently, it may be necessary to consider the content of press releases for medical devices differently depending on the type of labeling available for the devices. For example, the more specific the use-related information that is included in device labeling, the more likely it is that FDA would find problems with a press release that suggests a different intended use.

2. Legal Theories

CDRH often skirts issues of direct legal jurisdiction over medical device press releases by regulating them indirectly. As mentioned above, the agency can regulate

⁴⁶ See Part I.C, *supra*.

⁴⁷ Warning letter from FDA to APS Limited (May 24, 2000).

⁴⁸ Warning letter from FDA to Jacobson Resonance Enterprises, Inc. (Jan. 25, 2001).

press releases under the statute if the material qualifies as “labeling” for any device or as “advertising” for a “restricted” device. More commonly, however, CDRH will regulate a press release indirectly by using its *content* as evidence that the manufacturer’s intended use is inconsistent with the uses specifically approved or cleared by the agency. In other words, the alleged violation usually relates to marketing an unapproved device, not improper promotion of the device. For example, a warning letter to Vysis, Inc., warned that company press releases suggested a diagnostic device could be used as a stand-alone test, despite the fact that it had only been cleared for use in conjunction with other tests.⁴⁹

CDRH also prohibits particularizing the intended use for which a device has been cleared or making novel claims of special efficacy. ESC Medical Systems received a warning letter advising that the agency

will permit manufacturers to announce in an initial press release that a specific device has been cleared/approved by FDA for the stated indications in the labeling. However, manufacturers who receive a general clearance for the use of a device may not narrow the indication(s) (objective intent) to specific medical procedures, disease states or conditions, without first submitting supporting data to the agency and receiving prior clearance.⁵⁰

Similarly, OmniSonics Medical Technologies, Inc., was cited for press releases that allegedly made claims for the use of a device for the treatment of specific conditions and for specific body sites, none of which received approval or clearance.⁵¹ The company was told that a new 510(k) submission would be necessary to make such claims.

Many of CDRH’s letters cite company press releases for stating or implying a major change in the intended use of a device without submitting premarket notification. For example, the agency wrote to Biomatrix, Inc., that the company’s press release misbranded and adulterated a device because it made claims constituting a major modification for which a new 510(k) must be submitted.⁵² Such conduct, it was alleged, broadened the approved intended use of the device without submitting the required prior notification. Likewise, the intended uses approved in PMAs may not be changed without submitting PMA supplements if the change affects the safety and effectiveness of the device.⁵³ On this basis, a warning letter advised Medtronic, Inc., that “after FDA’s approval of a PMA, an applicant shall submit a PMA supplement for review and approval before making a change affecting the safety and effectiveness of the device The intended use and other labeling claims that you have made . . . are not permitted until FDA has approved a PMA supplement.”⁵⁴

IV. UNDERSTANDING FDA’S APPROACH TO PRESS RELEASES

A. *FDA Recognizes That It Cannot Regulate All Press Releases*

Of course, the agency cannot take the position that every press announcement that mentions a specific product is promotional labeling that is subject to its jurisdiction.

⁴⁹ Warning letter from FDA to Vysis, Inc. (Feb. 2, 2000). *See also* Warning Letter from FDA to Scion Cardio-Vascular, Inc. (July 11, 2003).

⁵⁰ Warning letter from FDA to ESC Medical Systems (June 2, 1997).

⁵¹ Warning letter from FDA to OmniSonics Medical Technologies, Inc. (June 22, 2000).

⁵² Warning letter from FDA to Biomatrix, Inc. (May 24, 2000).

⁵³ 21 C.F.R. § 814.39.

⁵⁴ Warning letter from FDA to Medtronic, Inc. (Mar. 23, 2000).

Although FDA has made no concrete statements in this regard, it has given clues. In the early 1990s, FDA issued a letter to the drug industry on video news releases (VNRs) and other public relations materials that advised that “public relations materials that *promote* drug products and that are issued by or on behalf of those who market the drugs are ... subject to the requirements of the Act.”⁵⁵ The letter goes on to describe a press release as promotional labeling if it “provides information that makes any representation or suggestion related to the use of an identifiable drug product (whether or not the drug product or its sponsor is explicitly named).”

The VNR letter thus asserts that any press release that refers to a drug product’s use would be subject to the FDCA.⁵⁶ Conversely, the VNR letter implies that press materials that do *not* refer to the use of a specific product might *not* be subject to the Act.

Furthermore, even if a press release mentions a product and a use, it might not be subject to FDA jurisdiction. A medical product firm may disseminate other types of information that reference products without attempting to influence a potential purchaser. These materials could include, for example, information directed to stockholders and investors about research activities and pipeline products, information directed to political officeholders or voters in support of or opposition to legislative proposals, and information directed to a local community regarding employees or activities at a specific facility. They can take the form of SEC filings, submissions to Congress or state legislatures, political issue advertising, and press releases.

Such materials have occasionally presented regulatory challenges to the agency. There are unpleasant practical consequences for FDA if it were to take the position that all product-specific press releases are labeling. The agency does not have the resources, or the desire, to review press releases that are not promotional in nature. More importantly, FDA does not want to interfere with mandatory disclosures required by the securities laws,⁵⁷ and it certainly wishes to avoid unnecessary conflicts over First Amendment rights.⁵⁸ Finally, these materials generally do not concern the agency as much as press materials directed at broad audiences in which companies discuss their products on more than a superficial level.

B. *Commercial v. Noncommercial Speech*

FDA’s regulation of press releases is, to various extents, limited by the First Amendment.⁵⁹ Theoretically, under First Amendment jurisprudence, press releases by

⁵⁵ *FDA Industry-Wide Letter: VNRs and PR Materials*, (Jul. 24, 1991) [hereinafter VNR Letter] in Wayne L. Pines, *FDA ADVERTISING AND PROMOTION MANUAL*, Appendix II, A-47 (May 1993) (emphasis added). FDA issued a notice in the *Federal Register* on Mar. 28, 1997 indicating that this letter would be revised and republished in a new guidance document referred to as “2.A.5 Print and Video News Releases.” See 62 Fed. Reg. 14,915 (Mar. 28, 1997). To date, no new guidance document has been issued.

⁵⁶ The VNR letter came at the same time that CDRH began to develop its approach to device promotion. Although CDRH has issued no counterpart statement regarding device-related video news releases, there is no principled reason why FDA’s analysis in the VNR letter would not apply to such releases.

⁵⁷ Despite FDA’s efforts at caution, however, the Washington Legal Foundation filed a Citizen Petition in Dec. 1995 (FDA Docket No. 96P-0001) requesting that the agency establish a policy which explicitly permits public companies to disclose results of IND studies in reports filed with the SEC. FDA closed the docket in July 2001, after stating in a letter that “FDA’s regulations at 21 C.F.R. 312.7(a) do not, as the petition asserts, operate as a bar to disclosure of study results relating to investigational new drugs in reports with the SEC and in press releases, and public companies make such disclosures on a routine basis.” FDA letter to Washington Legal Foundation (Mar. 19, 2001).

⁵⁸ See *supra* note 1.

⁵⁹ George W. Evans and Arnold I. Friede, *The Food and Drug Administration’s Regulation of Prescription Drug Manufacturer’s Speech: A First Amendment Analysis*, 58 *FOOD & DRUG L.J.* 365 (2003) (assessing the First Amendment limits to FDA’s jurisdiction of drug manufacturer’s communications and “speech”).

pharmaceutical or medical device manufacturers could be protected as commercial or noncommercial speech, depending on the content of the press release and its intended audience. If a press release qualifies as noncommercial speech, the government has no authority to regulate it at all, and FDA must remain silent, even if the statement is false or misleading.⁶⁰ In contrast, the government has much more leeway to regulate commercial speech.⁶¹ Thus, whether a press release is commercial or non-commercial speech greatly affects the extent to which FDA can impose requirements on the press release.

To our knowledge, courts have yet to opine on any FDA regulatory or enforcement activity regarding a regulated company's press release. Nevertheless, there are several indications that courts would treat FDA actions regarding a press release under the commercial speech standard. First, there appears to be an emerging consensus among the courts that FDA restrictions on manufacturers' speech about their products should be judged under commercial speech standards.⁶² In fact, "every major lawsuit challenging FDA speech restrictions has proceeded under the assumption that the speech in question is commercial in character"⁶³—even when the speech at issue involved medical literature and peer-reviewed journal articles.⁶⁴

Second, the U.S. Supreme Court declined to hear *Nike v. Kasky*,⁶⁵ which could have clarified whether press releases qualify as commercial or noncommercial speech. The Court's refusal to hear the case also may suggest the Court may be reluctant to apply anything other than commercial speech standards to government regulation of manufacturers' speech.⁶⁶ In *Nike v. Kasky*, the California Supreme Court held that statements made by Nike in defending its overseas labor practices were commercial speech, even though the speech addressed an important social question and did not resemble more typical forms of commercial speech. The communications made by Nike included "statements in press releases, in letters to newspapers, in a letter to university presidents and athletic directors, and in other documents distributed for public relations purposes."⁶⁷ The state court viewed these communications as being part of a "modern, sophisticated public relations campaign."⁶⁸

It is important to note that FDA was granted statutory authority over drug labeling and advertising before the constitutional implications on manufacturers' speech had ever been considered.⁶⁹ When the concept of commercial speech was first developed, it was originally defined as speech that does no more than "propose a commercial transac-

⁶⁰ See, e.g., *Consolidated Edison Co. of N.Y., Inc., v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 530 (1980) (holding that a state government's ban on an energy company including inserts with monthly bills that discussed a controversial nuclear energy issue violated the company's First Amendment rights). *Consolidated Edison* was the companion case to *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980). In *Central Hudson*, the Court referred to the *Consolidated Edison* case, stating that, "utilities enjoy the full panoply of First Amendment protections for their direct comments on public issues." See 447 U.S. at 563.

⁶¹ *Central Hudson*, 447 U.S. at 563.

⁶² See, e.g., *Thompson v. Western States*, 535 U.S. 357 (2002); *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); see also Richard A. Samp, *Courts are Arriving at a Consensus on Food and Drug Administration Speech Regulation*, 58 *FOOD & DRUG L.J.* 313 (2003).

⁶³ Samp, *supra* note 62, at 314 (citing *Thompson v. Western States*, 535 U.S. 357 (2002)).

⁶⁴ *Washington Legal Found. v. Friedman*, 13 F.Supp.2d 51, 62-66 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000).

⁶⁵ *Nike v. Kasky*, 45 P.3d 243 (2002), *cert. granted*, 537 U.S. 1099 (2003), *cert. dismissed as improvidently granted*, 539 U.S. 654.

⁶⁶ Samp, *supra* note 62, at 314-315.

⁶⁷ *Nike v. Kasky*, 45 P.3d at 248.

⁶⁸ *Id.* at 257; Jason A. Cade, *If the Shoe Fits: Kasky v. Nike and Whether Corporate Statements about Business Operations Should Be Deemed Commercial Speech*, 70 *BROOK. L. REV.* 247, 274 (2004) (discussing the tests for distinguishing commercial from noncommercial speech).

⁶⁹ Evans and Friede, *supra* note 59 at 366.

tion.”⁷⁰ The Court’s subsequent rulings in *Central Hudson* and other cases broadened that definition to include any “expression related solely to the economic interests of the speaker and its audience.”⁷¹ A few years later, the Court again expanded the analysis into an implied “totality of the circumstances” test, asking whether the speech is an advertisement, whether it refers to a particular product, and whether the speaker has an economic motive.⁷² In more recent cases, the Court’s attempt to categorize speech has become “even more complicated by its increasing recognition that much speech has both commercial and noncommercial elements.”⁷³ In passing on *Nike v. Kasky*, the Supreme Court declined an opportunity to further clarify what distinguishes commercial from noncommercial speech.

Yet, while there are several indications that courts would treat any press release by an FDA-regulated company as commercial speech, there is certainly room within the framework of the Court’s current First Amendment jurisprudence to argue that certain press releases would qualify as noncommercial speech.⁷⁴ For instance, one could imagine a press release addressing scientific issues for a scientific audience, or a press release addressing a hotly-debated public health topic. If these press releases were intended to inform the public rather than advertise or promote a particular product, they would more closely resemble noncommercial rather than commercial speech.

Indeed, other authors have noted that FDA’s treatment of press releases and other media communications as promotional labeling is problematic and should be evaluated on a case-by-case basis.⁷⁵ As a practical matter, it seems that FDA recognizes that there are limits to the agency’s ability to regulate all press releases as promotional labeling, regardless of the audience and content.

C. A Proposed Framework for Considering FDA’s Approach to Press Releases

As a practical matter, FDA seems to recognize that gradations exist between those press releases that should be regulated as promotional labeling and those that should not. The following categories illustrate how different regulatory considerations might apply to different types of press releases, depending on their content. The categories are meant to assess whether FDA might assert jurisdiction, not whether FDA would succeed in this assertion if challenged in court. When FDA claims jurisdiction, it would assess the press release according to the rules regarding promotional labeling, which are discussed in Part V below.

- (1) *Press releases that do not refer to any particular product.* These materials would include announcements about corporate organization, new plants, employment actions, charitable activities, matters of interest to local communities such as personnel promotions and retirements, and general financial statements. FDA would

⁷⁰ Richard A. Samp, *supra* note 62, at 314 (citing *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976)).

⁷¹ *Central Hudson*, 447 U.S. at 561.

⁷² *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-67 (1983); *see also* Evans and Friede, *supra* note 59 at 383; Cade, *supra* note 68, at 253-254.

⁷³ Cade, *supra* note 68, at 254.

⁷⁴ *See, e.g.*, Evans and Friede, *supra* note 59, at 415 (noting that manufacturer communications to the media such as press releases could be noncommercial speech, and that FDA’s regulation of such materials as advertising is problematic); *see also* Cade *supra* note 68, at 252 (“While a corporation’s legal obligations to shareholders ensure that virtually all of its communications are economically motivated, it is nevertheless capable of speaking in noncommercial contexts”).

⁷⁵ Evans and Friede, *supra* note 59, at 415, n.323.

probably not consider such material to be promotional labeling because they do not refer to products or their uses.

- (2) *Product-referencing material that does not suggest the medical uses.* These materials would include pricing announcements and sales figures for named products. Since these materials do not make representations or suggestions relating to the product's uses, FDA would either not regulate them as promotional labeling or treat them as reminder advertising under 21 C.F.R. § 202.1(e)(2)(i). One exception should be noted: If the announcement also identifies the therapeutic category for the product (e.g., cardiovascular disease), FDA might consider the release to refer to a medical use, and treat it as falling under the next category below.
- (3) *Product-referencing materials that identify a medical indication without providing safety or effectiveness information.* These materials clearly identify an intended use of a product, such as listing marketed products and approved therapeutic areas in an annual report, or identifying target indications for pipeline products in an update for securities analysts. In such cases, FDA could theoretically assert jurisdiction. But an evaluation of the context (Could the materials have any realistic probability of influencing use of a product?) would probably lead the agency to ignore the material.
- (4) *Product-referencing materials that discuss specific results from research but do not make general safety or effectiveness claims.* FDA regulations permit manufacturers to disseminate scientific and other information about investigational products so long as the communications do not make promotional claims of safety or effectiveness or otherwise commercialize the product prior to approval.⁷⁶ For a press release that discusses specific research results, FDA would probably review the extent to which the communication makes claims of safety or effectiveness before treating any such communication as promotional labeling.
- (5) *Product-referencing materials that discuss real or potential benefits or risks of a product in context of a newsworthy event.* FDA would almost always consider these releases to be promotional labeling; nevertheless, it might not automatically assert jurisdiction. For example, the agency would probably not view a press release announcing a product recall or new warnings as promotional or encouraging a commercial transaction. On the other hand, a press release that announces approval or launch of a product or a new use for a marketed product would always be the focus of agency attention.
- (6) *Product-referencing materials that discuss real or potential benefits or risks of a product outside the context of a newsworthy event.* If the press announcement is not tied to something perceived by FDA to be newsworthy, the agency would treat it as promotional in virtually every situation and be prepared to assert jurisdiction. For example, an announcement that a company was initiating a new study for an approved product for its approved use would seem to have limited novel information of interest to the general media. Excessive publicity could be construed as seeking new customers, not informing the general public of a significant development.

D. FDA and SEC Disclosure Requirements

One area of significant confusion involves the intersection of FDA's regulation of company statements and corporate disclosure obligations required by the SEC. A press release might be subject to the jurisdiction of both agencies, and the fact that SEC has

⁷⁶ 21 C.F.R. §§ 312.7(a), 812.7(a).

jurisdiction would not preclude action by FDA. Therefore, a press release issued to satisfy SEC requirements does not remove it from potential FDA jurisdiction. In practical terms, FDA most likely would not object to specific information in a press release that SEC requires. However, any embellishment, surplusage, or gratuitous information beyond that which SEC requires would attract FDA's attention.

Liaison with SEC has made FDA more skeptical of SEC-related defenses to what it considers inappropriate promotional activities.⁷⁷ First, only rarely does a company have an unconditional duty to make disclosures.⁷⁸ In most cases, a company may choose either to make a voluntary disclosure of information that is likely to have a material effect on the value of the company's stock, or to withhold that information and suspend all trading in the stock by the company and individual insiders. Second, the content of disclosures can be sufficient for purposes of the securities laws if it identifies the nature of the event and how it may affect the stock. Materiality is judged by what information would be important to a reasonable investor in making an investment decision. Thus, the fact that a clinical trial showed a product was superior to placebo for a medical condition that affects a certain population indicates the chance that it will generate revenues. Expansive details, such as statistical p-values and sub-group analyses, are not necessary.

As a result, FDA is less hospitable than it once was to claims that information had to be released to satisfy securities laws. Agency officials have complained that, while reports of favorable studies or the filing of an application for marketing approval was deemed by companies to be "material" and thus had to be publicized, subsequent failed studies or rejected applications were not equally publicized. FDA perceives that companies manage to meet their SEC disclosure requirements quite discreetly when arguably "material" events are negative.⁷⁹ The agency now expects that if the filing of an NDA or PMA is material, its rejection is also likely to be material. Thus, a lack of symmetry on a company's press policy can be used to establish that a positive release, not followed by a negative release, was a promotional announcement, not dictated by SEC rules.⁸⁰ Even more embarrassing is when a company offers the "SEC defense" but has no publicly-traded securities!⁸¹

For its part, SEC has become concerned that announcements about FDA-related events are being used to manipulate stock prices. In response to congressional inquiries into how FDA handled ImClone's oncologic drug Erbitux (cetuximab), the two agencies undertook an initiative to enhance FDA's ability to support SEC's monitoring and enforcement efforts.⁸² To better address the intersection between SEC and FDA laws, the joint program designates liaisons and contact persons within each agency to share information and refer inquiries. It also eases the administrative and paperwork burdens on

⁷⁷ See Michael D. Petty, *Pre-Approval Promotion of Medical Devices*, 49 FOOD & DRUG L.J. 541, 546 (1994).

⁷⁸ See *Basic v. Levinson*, 479 U.S. 880 (1986); Herbert S. Wander & Katten Muchin Zavis Rosenman, SECURITIES LAW DISCLOSURE AFTER SARBANES-OXLEY, JULY 2004, 31 (Practicing Law Institute ed., Aug. 2004) (there is neither a judicial nor a statutory requirement that issuers must affirmatively disclose material information simply because it exists, with certain exceptions).

⁷⁹ Petty, *supra* note 77, at 546.

⁸⁰ SEC may also be sensitive to failures to disclose such "material events." Failure to disclose "bad news" undermines any claim that previous "good news" releases were not intended to manipulate stock prices.

⁸¹ In the mid-1980s, this became a common defense. Companies began releasing important drug announcements in press releases, recognizing that doctors read the *Wall Street Journal* before the *New England Journal of Medicine*, and the authors are aware that DDMAC met with SEC around 1990-1992 to understand better the disclosure requirements of the securities laws.

⁸² See *FDA and SEC Work to Enhance Public's Protection from False and Misleading Statements*, at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01019.html>; see also *SEC and FDA Take Steps to Enhance Inter-Agency Cooperation*, at <http://www.sec.gov/news/press/2004-13.htm>.

FDA's disclosure of non-public information to SEC. The initiative makes it more likely that FDA will refer to SEC those press statements it believes are false or misleading and that SEC will seek FDA's input on issues relating to stock price fluctuations.⁸³

This trend toward increased FDA-SEC cooperation must be balanced by FDA's recognition that it has limited authority and expertise in this area. Then-FDA Chief Counsel Troy stated that the agency would not become the "health SEC."⁸⁴ In responding to suggestions from Congress for FDA to take a more active role in policing investor-related communications, Troy suggested that the agency lacks the authority and competency to do so. Further, FDA's "own regulations, and more importantly the current criminal laws, prohibit [the agency] from disclosing confidential commercial information."⁸⁵

The initiative by FDA and SEC reflects the renewed interest in press statements made by FDA-regulated companies, and will increase the likelihood that false or misleading press releases will be identified and trigger enforcement actions. FDA may look for certain things in press releases containing SEC-related disclosures. First, does it contain any disclaimer language or other method of tempering the information provided? In press releases publicizing study results of a product under investigation, FDA might expect statements regarding the preliminary nature or other limited significance of the study.⁸⁶ The agency could also look unfavorably upon unnecessary or excessive fanfare in headlines or taglines. Second, is the target audience of the press release consistent with its purported purpose? FDA may be suspicious of press releases supposedly intended for the investment community being distributed directly to physicians or other potential purchasers of the company's product.

Thus, although FDA is unlikely to bring an action based on a specific statement in a press release that is required to be made under the securities laws, FDA would regulate statements that are not strictly required, such as gratuitous discussions of a product's benefits or similar embellishment. If FDA were confronted by an argument that challenged statements were necessitated and justified by the securities laws, the agency would most likely consult with SEC under the agencies' cooperative agreement. Thus, if FDA contacts a company to object to information it disseminated in a press release that includes SEC-related disclosures, it is more likely than not that FDA has already consulted with SEC on the matter.

V. FDA'S EXPECTATIONS FOR PRESS RELEASES

If FDA views a press release as promotional labeling subject to its jurisdiction, what information would the agency expect companies to include in the press release or the accompanying press kit? As a practical matter, if the agency treats product-referencing press releases as promotional labeling, the requirements for promotional labeling would logically apply. Nevertheless, not all product-referencing press releases are treated equally. This section discusses four different categories of standards FDA has applied in the past: A) requirements that have been imposed on product-referencing press releases, whether involving approved or unapproved products; B) expectations unique to products approved or cleared for marketing; C) requirements unique to unapproved or investigational product or products pending approval; and D) special challenges for press releases discussing unapproved or uncleared uses for approved or marketed products.

⁸³ The *Gray Sheet* reports that FDA received 60 SEC requests for input in Jan. 2003 alone, compared with 135 requests for all of 2002. See 29 (21) F-D-C REPORTS, "THE GRAY SHEET" 23 (Mar. 26, 2003).

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Petty, *supra* note 77, at 546.

A. Requirement for All Regulated Press Materials

FDA will expect any press release discussing a specific product to be truthful and non-misleading, maintain fair balance between the risks and benefits described in the press release, and provide full disclosure of the relevant contraindications, warnings, precautions, hazards, and adverse events associated with the product. These principles apply to product-specific press releases, regardless whether the release discusses approved or unapproved uses or approved or unapproved products.

1. Truthful and Non-Misleading

Unsurprisingly, FDA expects press releases to be accurate. The agency admonished Chroma Vision Medical Systems, Inc., in a warning letter for falsely claiming in a press release that the company had established a master validation protocol when in fact it had not.⁸⁷ Material omissions or non-disclosures can also render a product violative.⁸⁸ The agency considers the extent to which accurate information fails to reveal facts that would be material in light of the statements explicitly made about the product or in view of the possible consequences under foreseeable conditions of use of the product.⁸⁹

2. Fair Balance

Fair balance requires that risks of a product be clearly identified and offset any benefits that are touted. Press releases should therefore achieve an equilibrium between information relating to safety and information relating to the effectiveness of the product. Failure to balance the positive with the negative aspects of the product in the press release is a violation.⁹⁰

The fair balance standard applies equally to both the content and format of press releases. FDA generally requires that the presentation of any side effects or contraindications have a prominence and readability reasonably comparable to the presentation of information related to effectiveness.⁹¹ The agency will analyze typography, layout, contrast, headlines, paragraphing, white space, and other formatting techniques for prominence and readability when it considers the fair balance of a press release. To illustrate, placing risk information in the footnotes to, or in small print at the end of, a press release would fail the fair balance standard if information related to effectiveness is included in the main body of the release.

Compliance with the fair balance standard varies depending on the nature of the promotional material. If a product has two distinct uses, with different patient populations and different risks in each population, a press release discussing only one of these

⁸⁷ Warning letter from FDA to Chroma Vision Medical Systems, Inc. (Nov. 28, 2000).

⁸⁸ The term "material" in the FDA context does not necessarily mean the same as "material" to SEC. The latter looks to the effect of the information on the market for a company's stock. FDA is interested in the effect on a decision to prescribe or use a drug or medical device.

⁸⁹ FDCA §§ 201(n), 502(n); 21 U.S.C. §§ 321(n), 352(n).

⁹⁰ Although there is no specific regulation for "fair balance" in device advertising as there is for drugs (see 21 C.F.R. § 202.1(e)), CDRH utilizes the "fair balance" principle as it evaluates whether press releases are false and misleading. In particular, CDRH uses the Act's provisions in §§ 201(n) [failure to include material facts], 502(r) [requiring brief statement of intended uses and relevant warnings, precautions, side effects, and contraindications], and 502(q) [prohibiting false or misleading advertising] to require fair balance in press releases.

⁹¹ 21 C.F.R. § 202.1(e)(7)(viii).

uses could provide “fair balance” by presenting adverse effects and contraindications for only that use discussed.

Finally, “fair balance” means, in FDA’s view, acknowledgement of any limitations or scientific findings. A pilot study in a small number of subjects for a short period of time should not be presented in a way that implies a lifetime cure in all types of patients.

3. *Full Disclosure*

The total package of information should provide “full disclosure” of the relevant contraindications, warnings, precautions, hazards, and adverse effects associated with the product.⁹² “Full disclosure” is distinct from “fair balance.” “Fair balance” requires balancing the messages in the content of the material. “Full disclosure” assures that a certain modicum of information is always available, even if not needed for fair balance. For example, if, as discussed above, a press release discusses only one indication for an approved product, “full disclosure” will require that information must be provided in the press kit regarding all contraindications, warnings, precautions, adverse events, and side effects relevant to *all* uses of the product. In the prescription drug context, this requirement is usually met by providing the approved physician labeling with the press release as part of the kit. “Full disclosure” can be satisfied by materials not contained within the four corners of the press release itself, whereas “fair balance” cannot be satisfied through external material.

B. *Unique Requirements for Press Releases Regarding Approved Products*

FDA has additional expectations regarding press releases discussing products that have been approved for marketing.

1. *Consistency with Approved Labeling*

The agency is sensitive to promotional materials that attempt to expand on approved uses. For example, if a product is indicated only for short-term use, a press release may not suggest long-term uses for that product. This “indication creep” may also occur through discussions of reduction of risk of certain side effects or improvement of quality of life. Most importantly, FDA expects that known effects on surrogate endpoints (e.g., reduction of high lipid levels or blood pressure) not be presented as having clinical outcomes (e.g., fewer strokes or heart attacks), if these outcomes have not been demonstrated for the product.

2. *Mandatory Submissions of Promotional Materials for Biologics and NDA Drugs*

The failure to make any report required under various sections of the Act is a violation.⁹³ FDA issued regulations concerning reporting requirements for drug and biological products subject to NDAs or biological applications, including the following:

- (i) Advertisements and promotional labeling.

⁹² FDCA §§ 502(n), (r).

⁹³ FDCA Section 301(e); 21 U.S.C. § 331(e).

The applicant shall submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product Each submission is required to be accompanied by a completed transmittal Form⁹⁴

FDA expects press materials subject to its jurisdiction to be submitted under a Form 2253 for NDA drugs, or a Form 2567 for biologicals, to satisfy post-marketing requirements. The agency issued the VNR letter discussed above specifically to direct drug companies to submit video news releases with a Form 2253.⁹⁵

We are not aware of any enforcement action taken against a company *solely* for violation of section 314.81(b)(3)(i), although DDMAC has cited violations of the provision in numerous letters that also deal with substantive violations of advertising and promotional labeling rules. For example, FDA asserted in a warning letter to Knoll Pharmaceutical Company that:

21 C.F.R. §314.81(b)(3)(i) requires sponsors to “submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination” None of the Isoptin SR promotional materials discussed in this letter have been submitted to the agency by your firm, and only one non-related piece has been submitted since September 1992. This violation has particularly great significance in light of the number of promotional labeling pieces that contain false and/or misleading themes.⁹⁶

As part of the request for corrective action, FDA instructed Knoll to:

- Submit in writing its explanation for why advertising and promotional materials were not submitted pursuant to 21 C.F.R. § 314.81(b)(3)(i) at the time of their initial publication or dissemination. This explanation should include Knoll’s plans for ensuring the timely submission of these materials in the future.
- Review Knoll’s current promotional materials for all of its products and notify DDMAC of any other materials that have not been submitted.⁹⁷

Some companies worry that the mere submission of a press release on a Form 2253 or 2567 is an admission that the release is promotional labeling subject to FDA jurisdiction, when in fact the release may not be, or the company does not wish to concede any legal position. In such cases the company might put on the face of the Form and in its cover letters a statement such as: “The enclosed submission relates to a press release. The Company does not believe that this press release is subject to agency jurisdiction. Nevertheless, because we have made it available to the general public, we have no objection in submitting a copy to FDA.” Thus, while there may be a dispute as to whether the agency has jurisdiction, the press release has been submitted in order to avoid an inadvertent violation of agency regulations. (A company that does not want FDA to see

⁹⁴ 21 C.F.R. §§ 314.81(b)(3)(i), 601.12(f)(4). There is no counterpart requirement for medical devices or for prescription drugs that are not subject to NDAs. Additional reporting requirements apply to “promotional materials, including promotional labeling as well as advertisements” for products subject to FDA’s accelerated approval procedure. 21 C.F.R. § 314.550.

⁹⁵ See Part III.A, and note 55, *supra*.

⁹⁶ Warning letter from FDA to Knoll Pharmaceutical Co. (Oct. 14, 1993).

⁹⁷ *Id.*

a widely disseminated press announcement, out of fear of the agency's reaction, has more serious problems than inadvertent violations.)

C. Unique Requirements for Press Releases Regarding Unapproved Products

1. Investigational Products

New drugs, as defined in the statute,⁹⁸ must be the subject of an approved NDA in order to be marketed.⁹⁹ New drugs under clinical development are considered investigational products and require submission of an Investigational New Drug (IND) application prior to conducting clinical trials in the United States.¹⁰⁰ Similarly, medical devices, to be marketed, generally require submission and approval of a PMA¹⁰¹ or clearance of a 510(k) notice.¹⁰² Medical devices under development are subject to the provisions of the Investigational Device Exemption (IDE) regulations prior to conducting clinical trials in the United States.¹⁰³

Press statements made about investigational products are subject to some promotional and labeling restrictions that differ from products approved or cleared for marketing.

2. Promotion of Investigational Products

FDA restricts what companies can say about investigational products. It generally forbids any promotion of investigational products not yet approved for marketing. Nevertheless, the agency has no desire to prohibit non-promotional statements that announce or discuss "scientific findings."

For drugs subject to INDs, CDER has created by regulation a specific provision prohibiting the promotion of investigational products and permitting only information dissemination:

Promotion of an investigational new drug. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. *This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media.* Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.¹⁰⁴

For medical devices subject to IDEs, CDRH takes a somewhat different approach than for drugs and has detailed regulations regarding the promotion of investigational

⁹⁸ FDCA § 201(p); 21 U.S.C. § 321(p).

⁹⁹ FDCA § 505(a), 21 U.S.C. § 355(a). If a new drug product is not generally recognized as safe and effective by experts, it is considered a "new drug." See FDCA § 201(p); 21 U.S.C. § 321(p); 21 C.F.R. § 312.7(a).

¹⁰⁰ FDCA § 505(i); 21 U.S.C. § 355(i).

¹⁰¹ FDCA § 515(a); 21 U.S.C. § 360e(a).

¹⁰² FDCA § 510(k); 21 U.S.C. § 360(k).

¹⁰³ FDCA § 520(g); 21 U.S.C. § 360j(g).

¹⁰⁴ 21 C.F.R. § 312.7(a) (emphasis added).

devices. Generally, these regulations parallel CDER's and prohibit a sponsor, investigator, or any person acting on behalf of these parties from promoting investigational devices for commercial distribution prior to approval.¹⁰⁵ They also prohibit explicitly or implicitly claiming that an investigational device is safe or effective for the investigational use.¹⁰⁶

CDRH's regulations, however, allow manufacturers to recoup the costs of investigational devices so long as they do not "commercialize" the device by charging a price larger than necessary to recover costs for manufacturing, research, development, or handling.¹⁰⁷ CDRH also permits sponsors of Class III investigational devices to distribute "Notices of Availability of an Investigational Device" in order to recruit investigators for clinical studies.¹⁰⁸ The content of these "Notices of Availability" are strictly regulated by FDA and must target potential investigators that are qualified to evaluate the particular device. Dissemination to a broader audience—such as a notice posted on a manufacturer's website—can be viewed as "promotional."

3. Press Materials Regarding Investigational Products

Manufacturers may disclose data generated from ongoing or completed studies if put into context and without drawing any larger implications or conclusions about the product's *ultimate* safety or efficacy. For example, a manufacturer might be able to state, "In this study of a disease that is invariably fatal within 48 hours of diagnosis, 10 out of 10 patients studied recovered without complications." However, a manufacturer would not be permitted to say "This product cures the disease with no side effects." A company should also take care to qualify any statements explicitly on remaining variables, such as the completion of further studies or the outcome of FDA regulatory review. Press releases for investigational products should maintain a form of "fair balance," assuring that known or potential side effects and other unanswered scientific issues are identified and not minimized.

Press materials that claim safety or effectiveness for investigational products will draw agency attention. For example, a warning letter to Presby Corp. concerning the company's website states, "Although the FDA encourages full exchange of scientific information concerning investigational devices, including dissemination of scientific findings through scientific/medical publications or conferences, safety and effectiveness conclusions and statements of a promotional nature are unacceptable."¹⁰⁹

In navigating the line between promotional and non-promotional press releases, the justification for making a press statement should be carefully considered. If the intent is to make necessary SEC disclosures, for instance, it need not disclose information, which is not material for securities purposes. In addition, the company should also be fully prepared to follow a positive release about a product with a negative release, in the event subsequent developments prove adverse, such as later studies failing to show benefits or uncovering new risks.

¹⁰⁵ 21 C.F.R. § 812.7.

¹⁰⁶ 21 C.F.R. § 812.5(b).

¹⁰⁷ See 21 C.F.R. § 812.7(b).

¹⁰⁸ See *Guidance for Industry and FDA Staff: Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects* (Mar. 19, 1999).

¹⁰⁹ Warning letter from FDA to Presby Corp. (Jan. 7, 2000).

4. *Press Materials for 510(k) Devices Pending FDA Clearance*

CDRH will closely scrutinize such press releases regarding devices that are pending 510(k) clearance. The Center has developed unique and complex policies regarding these products.¹¹⁰ Manufacturers are permitted to advertise or show uncleared products at trade shows, but such materials must be limited to objective, factual statements regarding the device.¹¹¹ The company may not make comparisons to competitors' devices or make safety or efficacy claims about its own device. Moreover, manufacturers may not offer to take orders that might result in sales of the uncleared device.¹¹² For example, companies may not give out pricing information or generate customer lists for a device while the 510(k) application is pending. Some companies use a disclaimer statement for advertisements or displays for such devices: "Pending 510(k), not available for sale within the United States." This type of notice clarifies the device's legal status and helps demonstrate that the company is not soliciting purchases.

These policies apply only while a 510(k) notification is pending but not before it has been submitted. If a device has been studied under an IDE, companies may follow the rules for displaying IDE devices discussed above.

While companies may *announce* receiving 510(k) clearance in a press release, companies may not *promote* devices as being cleared by FDA after receiving 510(k) clearance. Agency regulations prohibit as misleading any representation that creates an impression of official approval for complying with the 510(k) regulations.¹¹³ (Generally, however, CDRH does not, as an informal policy, object to manufacturers providing information regarding the marketing status or 510(k) number of a device in response to specific inquiries.) Therefore, device manufacturers should not mention "FDA," "510(k) clearance," "premarket notification clearance," or the cleared 510(k) number in any press release that could be construed by FDA as being promotional in nature.¹¹⁴ For example, a warning letter to Electronic Waveform Laboratories, Inc., noted that the company's website contained "promotional materials [that made] reference to the FDA name, registration, 510(k) numbers, and FDA clearance."¹¹⁵ This warning letter concerned promotional materials on a website, not in a press release, but seems equally applicable to releases archived on a website. FDA has not established a time limit for leaving such a press release on the company's website.

¹¹⁰ See Section 300.600, *Commercial Distribution with Regard to Premarket Notification* (§510(k)) (Compliance Policy Guide 7124.19) (Sept. 24, 1987) ("Although a firm may advertise or display a device that is the subject of a pending 510(k)—in the hope that FDA will conclude that the device is substantially equivalent to a pre-amendments device—a firm may not take orders, or be prepared to take orders, that might result in contracts of sale for the device unless limited to research or investigational use.").

¹¹¹ Edward M. Basile, Ellen Armentrout, Kelley N. Reeves, *Medical Device Labeling and Advertising: An Overview*, 54 FOOD & DRUG L.J. 519, 525 (1999).

¹¹² See Section 300.600, Compliance Policy Guide 7124.19, *supra* note 104; see also *id.* at 525.

¹¹³ See 21 C.F.R. § 807.97. In contrast, device manufacturers may state in advertising and promotional materials that a PMA for its device has been approved by FDA. See Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, § 421, 111 Stat. 2296, 2380 (1997) (repealing the restriction in FDCA § 301(l) which prohibited reference to FDA approval in the labeling or advertising of medical devices that have an approved PMA or IDE). (Whether 21 C.F.R. § 807.97 is constitutional under Central Hudson is beyond the scope of this paper.)

¹¹⁴ It is doubtful that FDA would object to a manufacturer stating in a press release that it had received 510(k) clearance for a product, so long as the release was not promotional in nature and did not imply that FDA had officially approved the device. As shown by our proposed framework in section III.C, *supra*, the likelihood that FDA would take enforcement action depends on the content of the press release and the context in which it is issued.

¹¹⁵ Warning letter from FDA to Electronic Waveform Laboratories, Inc. (Sep. 17, 1997).

D. *Special Challenges When Discussing Unapproved Uses for Approved or Cleared Products*

FDA's legal standards are more complex for press releases discussing unapproved uses of an approved product. The agency is particularly concerned about promoting unapproved uses for approved drug products. It is inclined to view press releases regarding new uses of marketed products as an effort to promote the sale of a product for such uses prior to agency approval or clearance. After all, the product is already in the market, so the unapproved use can begin in routine medical practice before FDA has reviewed its safety and efficacy.

To set the context, there are two scenarios in which unapproved uses may arise in a press release, and each scenario creates different agency expectations. If a press release discusses *only* unapproved uses without making reference to uses already approved by FDA, the requirements governing investigational drugs will apply. On the other hand, a press release may discuss *both* approved and unapproved uses for the same product. For example, a company may want to announce the results of a study using Product X for use Y and also state that Product X is already approved for use Z. In this scenario, the requirements governing marketed products will *also* apply. The portions of a press release discussing unapproved uses must follow the requirements for investigational products, while the rest of the release must follow the requirements for marketed products.

Applying these relatively simple rules is not always easy. Therefore, companies might be especially sensitive to the content of press releases discussing unapproved or uncleared uses for products that have been approved or cleared for other indications.

VI. FDA'S ENFORCEMENT TOOLS

A. *Statutory Sanctions*

The FDCA empowers the agency to seek criminal penalties for violations, to obtain injunctive relief to prevent further violations, and to seize products that are violative. These tools have been used for advertising and promotional violations, mostly in the drug context. In 1999, Genentech pleaded guilty and paid a \$50 million penalty for promoting human growth hormone for unapproved uses. In 2005, Eli Lilly pleaded guilty and paid \$36 million in penalties for promoting its osteoporosis drug Evista® (raloxifene) for off-label uses.¹¹⁶ The alleged schemes were not built around press materials, however. In the late 1980s, on the other hand, ICN Pharmaceuticals agreed to a decree of permanent injunction specifically because of press releases touting its ribavirin product for AIDS and other unapproved applications.¹¹⁷ Nevertheless, these statutory enforcement tools are rarely used. FDA has not litigated to judgment a drug promotional matter for at least 30 years.¹¹⁸

The Act also empowers FDA to require a manufacturer to submit its advertising and promotional labeling for preclearance.¹¹⁹ This sanction is onerous for both parties, but the risk of having regulators review all marketing materials in advance is a great deterrent to industry.

¹¹⁶ Department of Justice, Press Release, *Eli Lilly and Company to Pay U.S. \$36 Million Relating to Off-Label Promotion*, (Dec. 21, 2005) at http://www.usdoj.gov/opa/pr/2005/December/05_civ_685.html.

¹¹⁷ See Section III.A.2, *supra*.

¹¹⁸ The government has been using other tools to combat inappropriate drug promotional activities, such as the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, but these cases are not perceived as FDA-initiated enforcement actions.

¹¹⁹ FDCA §§ 502(n), (r); 21 U.S.C. §§ 352(n), (r).

B. *Administrative Tools*

1. *Regulatory Correspondence*

The agency has developed a series of informal tools not specified in the Act to attain compliance with its policies and rules. The most common is the use of publicly-released regulatory letters (either warning letters or “untitled” letters), that notify the marketer that the agency believes that a violation of law has occurred. FDA will usually ask the company for its plan to correct the violation and prevent a recurrence; occasionally, the request will include a specific corrective action, such as a new advertisement identifying and correcting the violation or a letter to health care professionals with the same type of message. Finally, a warning letter will put the company on notice that, if the response is not satisfactory, the agency is prepared to initiate litigation. FDA publicly posts regulatory letters on its website.¹²⁰

This combination of threat of litigation and chastisement by public disclosure is generally adequate to bring about “voluntary” compliance. In addition, most companies recognize that the policing of future promotion will be more intense if they do not quickly make peace with the agency.

2. *Referral to SEC*

FDA has fostered its relationship with SEC regarding how the two agencies support one another in investigations and enforcement actions.¹²¹ This interaction may make it easier and more likely that a matter will be referred to SEC. There appears to be increased SEC scrutiny of press releases regarding FDA-regulated products. Although at least some of this heightened attention may be a result of the initiative, it may also be a consequence of increased awareness of issues in light of well-publicized situations, like that involving ImClone.¹²² For example, on April 1, 2004, SEC temporarily suspended trading for the stock of VasoActive Pharmaceuticals because of questions about the accuracy of assertions by the company, including in press releases, concerning “FDA approval of certain key products” and “the regulatory consequences of the future application of their primary product.”¹²³ One week later, on April 8, 2004, SEC temporarily suspended the stock of Whispering Oaks International, Inc., d/b/a BioCurex, Inc., again because of questions about the accuracy of statements by the company, including in press releases, concerning “a study confirming the effectiveness of its primary product” and “approval of its main product” by FDA.¹²⁴ There has also been scrutiny of Biopure Corp. over its disclosures to investors.¹²⁵ In December 2003, SEC notified Biopure that it was initiating a confidential investigation into the company’s alleged failure to notify investors that FDA had put a “clinical hold” on a planned clinical trial for its Hemopure product.¹²⁶ In September 2005, SEC filed a civil suit against Biopure and three execu-

¹²⁰ On June 23, 2003, FDA announced a pilot program to post companies’ written responses to warning letters on FDA’s website. *See* 68 Fed. Reg. 37,162 (June 23, 2003). The program began on Sept. 22, 2003 and was scheduled to run for six months, unless the agency became unduly burdened by the process or found that companies were submitting responses that would “likely mislead the public concerning the safety and efficacy of a company’s product(s).” Currently, FDA posts both warning letters and responses on its website, at <http://www.fda.gov/foi/warning.htm>.

¹²¹ *See* Section IV.D, *supra*.

¹²² *See supra* note 82.

¹²³ SEC Release No. 34-49513.

¹²⁴ SEC Release No. 34-49546.

¹²⁵ *See FDA Investor Relations: SEC Agreement Close, Complete Response* 66 (1) F-D-C REPORTS, “THE PINK SHEET” 20 (Jan. 5, 2004).

¹²⁶ *Biopure May Face Civil Action from SEC*, BOSTON BUS. J. (Dec. 26, 2003).

tives, including the CEO and general counsel, for securities fraud.¹²⁷ The complaint alleged that Biopure and the three executives raised \$35 million from investors while making statements that it would seek FDA approval to use Hemopure in trauma settings, despite FDA's clinical hold barring Biopure from conducting clinical trials for Hemopure in trauma settings due to safety concerns.¹²⁸ The complaint also alleged that shortly after FDA communicated its concerns to Biopure, the company issued public statements describing the communications as a positive development, which caused the company's stock price to rise by over 20 percent.¹²⁹ As the actual FDA status of Hemopure became public, Biopure's stock price fell by 66 percent.¹³⁰

3. *Modification of Product Labeling*

FDA has an additional tool that can be used for what it considers excessive and inappropriate pre-approval promotion of an investigational drug or device. When the product comes to the agency for NDA or PMA review, the agency may take the position that its labeling or advertising needs special attention. This attitude is not retaliatory, but remedial. On the premise that "first impressions are lasting impressions," FDA believes that pre-approval promotion that was exceedingly glowing about potential uses and benefits, and correspondingly scant on risks, side effects and limitations on use, can and must be corrected through labeling. Thus, the "indications" section may be written more narrowly (e.g., a more restricted patient population or a more conservative statement about potential benefits), or warning and side effect information may be given more prominence (through bold face type, black-boxing, or recommendations for patient monitoring). The more extensive and unbalanced the media attention to the product that was stimulated by the manufacturer, the more likely the agency will be to consider the need for such preemptive labeling steps.

4. *Risk Management Activities*

FDA's new "risk management" initiatives¹³¹ for medical products may offer the agency additional tools to combat false or misleading press releases. Risk management efforts target companies' pre- and post-marketing activities in order to prevent the misuse of products to reduce side effects, prevent errors, and improve efficacy. Risk management controls can include requirements for patient information, physician communications such as "Dear Doctor letters," patient registries, doctor and pharmacy registration and certification, and restricted distribution. These mechanisms could be used to counter and remedy imbalanced or misleading statements made previously in company press releases regarding a product.

C. *Publicity—A New Tool?*

FDA is still trying to find ways to increase its regulatory effectiveness. Tom Abrams, director of DDMAC, has stated he would like to use tools other than the traditional warn-

¹²⁷ SEC, Litigation Release No. 19376, *SEC Charges Massachusetts Biotechnology Company and Executives with Securities Fraud*, (Sept. 14, 2005), at <http://www.sec.gov/litigation/litreleases/lr19376.htm>; see also Complaint, *SEC v. Biopure Corporation, et al.*, (D. Mass.), (Civil Action No. 05-11853-WGY), at <http://www.sec.gov/litigation/complaints/comp19376.pdf>.

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ See *Guidances for Industry on Premarketing Risk Assessment* (Mar. 2005), *Development and Use of Risk Minimization Action Plans* (Mar. 2005), and *Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment* (Mar. 2005).

ing or untitled letter to "stop misleading promotion."¹³² One novel approach identified by Abrams was an FDA "Talk Paper" issued in March 2003 to publicize its objections to a press release disseminated by the pharmaceutical manufacturer SuperGen regarding its cancer drug Mitozytrex (mitomycin).¹³³ The Talk Paper admonished SuperGen for a November 15, 2002 press release in which the company allegedly made exaggerated claims of safety and efficacy and failed to include adequate risk information.¹³⁴ Calling the statements "misleading," "demonstrably false," and "particularly egregious," FDA stated that it was important to correct the record given the product's intended use for life-threatening conditions.¹³⁵ In what may reveal the agency's internal struggle with how to respond to the alleged violation, the Talk Paper was not issued until four months after SuperGen's press release.

This Talk Paper was the first time in more than 17 years that FDA has used its own press release rather than a warning or untitled letter to address an allegedly false or misleading press release. FDA's authority for issuing publicity is grounded in section 705(b) of the FDCA,¹³⁶ which allows the agency to disseminate information to the public to address imminent health dangers or gross deception of consumers. The previous time publicity was used to criticize promotional activities, in February 1986, was in response to unfounded claims made regarding an AIDS treatment.¹³⁷

By issuing its own public statement without undertaking formal regulatory action, FDA apparently hopes to accomplish several goals. First, the agency notifies both the company and the public of the agency's objections. FDA's Talk Paper reached a relatively wide audience very quickly because they are disseminated more aggressively than traditional warning or untitled letters, which merely are made public.¹³⁸ Abrams explained the agency's SuperGen Talk Paper as an effort to correct the record in a manner that would reach the same audience as SuperGen's press release.¹³⁹ This tactic may have significant consequences for companies. Within hours of the Talk Paper's release, SuperGen's stock price lost nearly 25 percent of its value.¹⁴⁰

Second, in using the Talk Paper, the agency did not provide procedural safeguards associated with other, more formal, actions.¹⁴¹ According to press reports, SuperGen was not given prior notice of official concerns about the company's press release. Moreover, FDA issued the Talk Paper without giving the company an administrative hearing or any other procedural remedy. Historically, courts have upheld this practice if the agency is not engaged in formal rulemaking or other regulatory action.¹⁴² But such deference may not be assured. In 1973, Professor Ernest Gellhorn published an article addressing

¹³² See *DDMAC Looking for More "Creative" Enforcement Actions*, FDAWEBVIEW, (June 18, 2003), at www.fdaweb.com.

¹³³ See *FDA Warns Public About Misrepresentations in Marketing Claims About Drug to Treat Cancer*, at <http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01204.html> (Mar. 14, 2003).

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ 21 U.S.C. § 375(b).

¹³⁷ See *FDA Responds in Kind to SuperGen: Talk Paper Answers Press Release*, 65 (11) F-D-C REPORTS, "THE PINK SHEET" 6 (Mar. 17, 2003).

¹³⁸ FDA originally published the "Talk Paper" with the disclaimer distinguishing Talk Papers from press releases. The disclaimer noted that Talk Papers are directed to guide FDA personnel, while press releases are directed to inform the general public. Theoretically, then, a Talk Paper is less forceful than a press release. However, the agency has since removed this disclaimer from the Talk Paper.

¹³⁹ See *DDMAC Looking for More "Creative" Enforcement Actions*, FDAWEBVIEW, (June 18, 2003), at www.fdaweb.com.

¹⁴⁰ *FDA Responds in Kind to SuperGen*, *supra* note 137.

¹⁴¹ Note that warning letters are not considered official agency action by FDA. See Samp, *supra* note 62, at 325 (2003).

¹⁴² See *Hoxsey Cancer Clinic v. Folsom*, 155 F. Supp. 376 (D.D.C. 1957).

the lack of standards for agency publicity and the potentially devastating impact on companies.¹⁴³ In response, FDA proposed regulations for the appropriate use of agency publicity.¹⁴⁴ The agency withdrew these proposed regulations on December 30, 1991.¹⁴⁵ It is unclear today whether FDA would voluntarily provide an affected company an opportunity to be heard before issuing a press release, or whether the agency could be legally required to do so.

Finally, unlike taking formal regulatory action, FDA's issuance of press releases and Talk Papers appears to apply a remedy suggested in the court's opinion in *Pearson v. Shalala* that encourages "more disclosure, rather than less."¹⁴⁶ In *Pearson*, the D.C. Circuit Court of Appeals struck down FDA regulations that required dietary supplement marketers to obtain FDA's authorization before making certain health claims on the products' labels. The court required FDA to go back and consider whether it could achieve the same purpose of preventing potentially misleading health claims by instead requiring disclaimers on the labeling. The court rejected FDA's argument that the commercial speech doctrine does not "embody a preference for disclosure over outright suppression."¹⁴⁷ Thus, FDA issuing its own publicity in response to a problematic press release would appear to meet the spirit of *Pearson*.

Even so, whether FDA's new approach would withstand First Amendment scrutiny in the current environment remains to be seen. For example, it is unclear whether the agency could use the same approach to publicize its position in a scientific disagreement with a company over statements that were not "demonstrably false." *Western States* teaches that companies "have little basis for challenging FDA speech restrictions on the ground that none of their speech is false or misleading,"¹⁴⁸ so it is unclear whether truth is, in fact, a defense against agency actions. As a practical matter, however, "FDA lacks the resources necessary to enforce narrower speech restrictions that require consideration of truth or falsity."¹⁴⁹

Companies should expect the agency to take similar non-traditional measures—such as issuing counter-publicity—in the future.

VII. CONCLUSION

This article describes how, over the past twenty years, FDA has developed a somewhat predictable framework for anticipating when the agency will assert jurisdiction over press releases. Certain press materials are more likely to attract FDA scrutiny, depending on their content, purpose, and intended audience. In this article, we described how FDA has asserted jurisdiction in the past, and how the agency's approach continues to

¹⁴³ Ernest Gellhorn, *Adverse Publicity By Administrative Agencies*, 86 HARV. L. REV. 1380 (1973).

¹⁴⁴ See 42 Fed. Reg. 12,436 (Mar. 4, 1977).

¹⁴⁵ Withdrawal of Certain Pre-1986 Proposed Rules, 56 Fed. Reg. 67, 440 (Dec. 30, 1991) (withdrawing FDA's "Administrative Practices and Procedures; Publicity Policy").

¹⁴⁶ 164 F.3d at 657; see also, Samp, *supra* note 62, at 319 (2003) (noting that government agencies have a wide variety of regulatory tools that are consistent with the First Amendment and do not employ "speech containment" strategies).

¹⁴⁷ 164 F.3d at 657 (citing *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977)).

¹⁴⁸ Samp, *supra* note 62, at 316.

¹⁴⁹ A. Elizabeth Blackwell & James M. Beck, *Drug Manufacturers' First Amendment Right to Advertise and Promote Their Products for Off-Label Use: Avoiding a Pyrrhic Victory*, 58 FOOD & DRUG. L. J. 439, 440, 458 (2003) (noting that because the party seeking to impose a speech restriction must bear the burden of justifying it, any adoption by FDA of a policy to prohibit only false and inherently misleading speech would "reverse completely the burden of proof allocation currently operative under existing FDA policy" which currently "requires drug manufacturers to prove the truth, to FDA's satisfaction, of the safety and efficacy claims they wish to make for their drug products").

evolve, based on a variety of factors. Companies should think carefully about where its press releases fall on the spectrum of materials that are likely to attract FDA attention, as we describe in Part III.C, and whether the materials meet FDA's expectations for press releases, as we describe in Part IV. In choosing whether or not to meet those expectations, companies should also consider FDA's enforcement tools, including new tools the agency has developed, such as issuing counter-publicity.

Even though FDA is currently struggling with how to address press releases, the agency will not tolerate false or misleading statements. Concerns about the First Amendment will not prevent the agency from doing *something* in response to false or misleading press statements. Increasingly, the agency has become more creative in its response to allegedly violative press materials.

For their protection, companies may wish to consider using an internal review process as is done for promotional materials. Generally, press releases concerning drug or device products might undergo the same internal procedures as other "promotional labeling," to provide appropriate review by medical affairs, legal, regulatory affairs, or other groups. FDA does not mandate these procedures, but they serve a useful precautionary purpose.

