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THE FOOD AND DRUG ADMINISTRATION V. THE FIRST AMENDMENT: A SURVEY OF RECENT FDA ENFORCEMENT

Gerald Masoudi† and Christopher Pruitt‡

INTRODUCTION

Congress has charged the Food and Drug Administration (FDA) with the task of “promot[ing] the public health” through various regulatory functions, one of which is assuring that regulated products are not misbranded.¹ There is little debate about the importance of this task: consumers and medical providers cannot make informed decisions about regulated products without access to truthful, scientifically accurate, and balanced product information. Subject to significant debate, however, is the agency’s performance of the task. While some commentators have accused the agency of adopting anemic enforcement policies,² a number have argued persuasively that many of the agency’s speech-related policies violate the First Amendment.³ A survey of recent developments illustrates that the frequency and magnitude of such actions have grown more pronounced as the agency increases its enforcement activities.

In the drug and medical device context, the FDA has recently been involved in two cases, Allergan v. United States⁴ and United

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² Mr. Pruitt is an associate at Covington & Burling LLP in the food and drug group.
⁴ See, e.g., U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-08-597, FOOD LABELING: FDA NEEDS TO BETTER LEVERAGE RESOURCES, IMPROVE OVERSIGHT, AND EFFECTIVELY USE AVAILABLE DATA TO HELP CONSUMERS SELECT HEALTHY FOODS (2008); Peter Lurie, DTC Advertising Harms Patients and Should be Tightly Regulated, 37 J. L. MED. & ETHICS 444, 444-50 (2009).
States. v. Caronia, involving First Amendment challenges to particularly aggressive—and likely unconstitutional—enforcement positions regarding off-label promotion. The agency has also taken several other actions infringing on First Amendment rights, including a crackdown on internet advertising through sponsored search links. In the food and supplement universe, FDA has taken several unduly restrictive, and likely unconstitutional, positions in both litigation and enforcement letters regarding the use of health claims and nutrient content claims. The agency has also asserted various likely unconstitutional positions in its enforcement of the Family Smoking Prevention and Tobacco Control Act.

The agency’s curtailment of constitutionally protected commercial speech carries serious consequences. These range from the practical results of removing truthful (and useful) product communications from the marketplace, as market players seek to avoid enforcement by over-editing their own speech, to the more fundamental problem of allowing a government bureaucracy to become a gatekeeper of speech.

Compounding this problem is the lack of a meaningful way for manufacturers to protect their constitutional rights. For most, litigation is a not viable option. Manufacturers contesting enforcement actions face heavy risks in the form of billion-dollar fines, Park doctrine (vicarious) liability, and exclusion and debarment from federal programs and contracts. Prospective actions to enforce First Amendment rights are equally challenging, especially when the agency does not fully comply with adverse decisions.

These circumstances demonstrate the need for greater internal review of agency policies for First Amendment compliance. To meet this end, the agency should continue its initiative, begun in 2002, to better conform its regulations and guidance documents to First Amendment requirements. And perhaps more importantly, the agency should immediately put into place a robust review process to screen all speech-related enforcement actions for First Amendment compliance.

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5 No. 09-5006-CR (2d Cir. filed Apr. 22, 2010).
6 See infra Part II.A.iii.-iv.
7 See infra Part II.B.
8 See infra Part II.C.
9 See infra Part III.A.
10 See infra Part III.B.
I. REGULATORY AND CONSTITUTIONAL BACKGROUND

A. FDA’s Regulation of Drug, Device, Food, Supplement, and Tobacco Promotion

FDA regulates a quarter of the United States economy—ranging from frozen pizza, eyeliner, and cigarettes, to animal drugs, cancer medicines, and bandages. These various products are subject to differing levels of regulation and speech restrictions. Summarized below are the regulatory bases for some of the more significant and controversial speech restrictions that have been the subject of recent enforcement action.

1. Drugs

FDA has historically relied on claims made by a manufacturer to determine whether the product at issue is a drug. The very definition of “drug” under the Federal Food, Drug, and Cosmetic Act (FDCA)—an “article intended” to perform various functions including the diagnosis or treatment of disease—is based on the speech of a manufacturer. Indeed, FDA views a claim that positions an article of food as a treatment for a disease as indication that the food should be considered a drug. For example, FDA found olive oil to be an unapproved new drug following manufacturers’ statements regarding the effects of olive oil on heart disease and inflammation.

To be marketed commercially, human drugs must be approved through one of several regulatory channels, meet the specifications of an FDA over-the-counter (OTC) monograph, or fall within one of

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11 Top 10 “Things That Hill Staff Need to Know About FDA”, ALLIANCE FOR A STRONGER FDA (Mar. 6, 2010), http://strengthenfda.org/2010/03/06/top-10-%E2%80%9Cthings-that-hill-staff-need-to-know-about-fda%E2%80%9D/.

12 E.g., 21 C.F.R. § 201.128 (2010) (describing how the agency evaluates the intended use of an article to determine whether it is a drug); Nat’l Nutritional Foods Ass’n v. Mathews, 557 F.2d 325, 334-38 (2d Cir. 1977) (describing the legal standard for evaluation of intended use).


15 The OTC monographs provide a regulatory pathway to market certain specified drugs without filing a new drug application or abbreviated new drug application. See 21 C.F.R. § 330.10 (describing process for establishing monographs).
several grandfather exceptions.\textsuperscript{16} The approval process can take several forms. New drugs (compounds that are not generally recognized as safe and effective) must be the subject of a new drug application (NDA) or a biologics license application (BLA), both of which must be supported by well-controlled clinical investigations demonstrating safety and effectiveness.\textsuperscript{17} New uses of already-approved compounds may be approved through abbreviated means, as can "generic" versions of already-approved drugs.\textsuperscript{18} In approving a drug under an NDA or BLA, FDA will approve a package insert (sometimes known as the "PI" or "FDA-approved labeling"), the language of which is strictly set forth by FDA.\textsuperscript{19}

Perhaps the most well-known—and controversial—aspect of FDA’s speech regulations is the requirement that manufacturers limit product claims to the specific indications FDA has approved and permitted to appear in the product’s FDA-approved labeling, regardless of the drug’s safety and efficacy for other uses. The Federal Food, Drug, and Cosmetic Act (FDCA) does not expressly ban such "off-label promotion"; instead the FDCA and FDA’s implementing regulations prohibit this practice in two ways. First, FDA may classify a previously approved drug that is promoted in labeling for unapproved alternative uses as an unapproved "new drug" within the meaning of section 505(a) of the FDCA.\textsuperscript{20} Because the drug is not approved for the promoted off-label use, shipment of the product in interstate commerce would violate Section 301(d) of the FDCA.\textsuperscript{21}

Second, FDA may consider a drug that is promoted for off-label use to be misbranded under section 502(f) of the FDCA.\textsuperscript{22} Under this provision, a drug is misbranded if its labeling fails to bear "adequate directions for use."\textsuperscript{23} For prescription drug labeling, the manufacturer must provide adequate directions for licensed practitioners to use the drug for all of the purposes for which the drug is "intended," which the regulations define to include all uses for which the drug is "adver-
tised or represented." At the same time, however, the only permitted source of the directions to licensed practitioners for the intended uses is the FDA-approved labeling in the NDA (or ANDA or BLA).

This regulatory construct purports to limit all permissible promotion to the approved indications because the only permitted source for adequate directions is FDA’s approved labeling. Therefore, it is not possible to provide directions for a claim that a drug is safe or effective for an unapproved use. Making the claim for the unapproved indication will establish an intended use without the required corresponding directions, and in doing so will (in FDA’s view) cause the drug to be deemed misbranded under section 502(f)(1) of the FDCA.

Another key aspect of FDA’s regulation of drug product speech is the requirement of fair balance and the proper presentation of risk information. Under the FDCA, “labeling”—a term recognized to include a broad array of communications beyond the package of the drug—may not be “false or misleading in any particular.” Further, the regulations require advertisements for drugs to present a “fair balance” between information relating to side effects and contraindications and information relating to effectiveness of the drug, and they must not fail to reveal material facts.

“Fair balance,” as defined by the regulations, requires drug advertisements to place information in a proper context. Specifically, the advertisement must present a fair balance “between information relating to side effects and contraindications and information relating to effectiveness in that the information relating to effectiveness is presented in greater scope, depth, or detail . . . ” In addition, the regulations require that claims and risk information be given comparable prominence and readability. One important exception to the fair balance requirement, however, is reminder advertising. These types of

24 21 C.F.R. § 201.100(c)(1) (2010); see also id. § 201.100(d)(1).
25 Id. § 201.100(c)(2).
26 See John E. Osborn, Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information, 10 YALE J. HEALTH POL’Y L. & ETHICS 299, 309 (2010) (“A manufacturer’s intended use includes all uses objectively intended by the drug manufacturer based upon statements made in labeling, in advertisements, or in written or oral statements by company representatives, and if the FDA-approved labeling does not cover each “intended use” then a drug is also deemed to be misbranded.”); see also John N. Joseph et al., Enforcement Related to Off-Label Marketing and Use of Drugs and Devices: Where Have We Been and Where Are We Going?, 2 J. HEALTH & LIFE SCI. L. 73, 78-79 (2009).
27 HUtt et al., supra note 16, at 98-106.
30 Id.
31 Id. § 202.1(e)(3)(i); id. § 202.1(e)(7)(vii-viii).
adsvertisements feature the name of a drug without referencing any uses or benefits of the product. Reminder advertisements may not be used for products with boxed warnings, a type of warning that describes a risk FDA has deemed particularly serious.

2. Devices

In relation to drugs, medical devices are subject to a similar but more complex regulatory scheme. Medical devices are categorized into classes based on risk. These risk categorizations largely dictate pre-market requirements, which include a pre-market approval (PMA) application that is similar in depth to an NDA; a more-abbreviated "510k clearance" based on substantial equivalence to a predicate device; and no pre-market notification or approval requirements for certain low-risk devices exempted by regulation.

FDA regulates the labeling of all medical devices and the advertising of certain devices that it classifies by regulation or approval order as "restricted," which subjects the devices to additional requirements. In many respects, the laws and regulations are similar to those governing drug promotion. The same misbranding provisions that apply to drug labeling under the FDCA apply to medical device labeling. Thus, medical devices must not have promotional labeling that is false or misleading in any particular or that lacks adequate directions for use. The rules exempt prescription devices (which may or may not include restricted devices) from the adequate directions for use requirement in a manner largely similar to the exemption for prescription drugs. In addition, FDA considers claims that go beyond a device's cleared or approved indication to adulterate a device under section 501(f)(1)(B) of the FDCA, which requires premarket approval for class III devices. Such claims would also misbrand the device under section 502(o), which considers a device to be misbranded if it is introduced into interstate commerce without being the subject of notification under section 510(k).

32 Id. § 202.1(e)(2)(i).
33 Id.; id. § 201.57(e).
34 HUTT ET AL., supra note 16, at 991-1025.
37 Id. § 352(f).
38 Id. § 352(q).
39 See, e.g., Letter from Timothy A. Ulatowski, Dir., Off. of Compliance, Ctr. For Devices & Radiological Health to Karen Roche, Vice President, Operations and Technology, Spineology, Inc. (Aug. 15, 2007), available at
Neither the FDCA nor FDA regulations set forth specific fair balance requirements for prescription or restricted devices, although the FDCA prohibits device labeling and advertising that is false or misleading. And recently, the agency indicated that its policies regarding fair balance and presentation of risk information apply equally to devices, even though these policies stem in part from the agency's interpretation of the regulations governing drug labeling and advertising.

3. Food and Supplements

Foods and dietary supplements, which are considered foods but receive special treatment under the FDCA, are subject to various affirmative labeling rules regarding ingredients, quantity, and nutritional information. In addition, FDA has promulgated regulations regarding the more contentious issues of nutrient content claims and health claims. Nutrient content claims are claims that characterize the amount of a nutrient in a food (e.g., “low fat”), while health claims are statements that directly or indirectly characterize the relationship of nutrients in food to a disease or health-related condition.

FDA permits health claims for conventional foods after the agency has promulgated a regulation specifying its language and the conditions under which it may be used. Manufacturers may petition for a health claim, and FDA must review and provide a ruling within 540 days. FDA will permit the claim if it determines, on the basis of all available scientific evidence, that there is “significant scientific agreement” supporting the claim.

The agency also allows for “qualified” health claims, as a result of First Amendment case law described below. These claims require pre-market approval through a petition describing how the claim is

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076472.htm

43 Carver, supra note 3, at 153-55.
44 Id. at 159-61 (citing 21 C.F.R. §§ 101.14(a)(1), 101.13(b)).
45 Id. at 159 (citing 21 U.S.C. § 343(r)(2)(A)(i)).
46 Id. (citing 21 C.F.R. §101.70(j)(4)(ii)).
supported by "credible evidence," among other requirements. A disclaimer is required depending on the level of scientific evidence supporting the claim. FDA will permit health claims that are aimed at risk reduction; the agency considers claims about disease mitigation or treatment to be drug claims not authorized for use in foods.

Similar to conventional foods, the agency permits dietary supplement health claims after it has promulgated a regulation authorizing such claims and providing their explicit language, or when the claims are "qualified" according to FDA standards. The rules regarding claims for supplements are regulatory in origin, unlike the statutory basis for such claims for food, but FDA interprets them in a similar manner.

FDA generally prohibits nutrient content claims unless they recite the exact language provided in its regulations. Two forms are allowed: "absolute," and "relative or comparative." The absolute category describes the level of a nutrient in a product, whereas relative claims compare the amount of the nutrient in the product with that amount in a similar product. Some nutrient content claims are prohibited if the amount of another component (e.g., cholesterol) exceeds a certain level, and some claims are subject to additional disclosure requirements if the food contains certain nutrients (e.g., fat, sodium) above a specified level.

4. Tobacco

The regulation of tobacco is the newest of FDA’s regulatory tasks. Although the agency attempted to assert jurisdiction over tobacco products under its authority over medical devices in the 1990s, the United States Supreme Court ruled that the FDCA did not provide the

49 Carver, supra note 3, at 160.
50 Id.
51 Id. at 161-62.
53 Id. § 321(r) (setting forth the process for approval of health claims for foods).
54 See Carver, supra note 3, at 159-62.
55 Id. at 160.
56 Id.
57 Id.
58 Id. at 161; 21 C.F.R. § 101.13(h)(1) (2005).
agency with statutory authority for this function. In 2009, however, Congress enacted the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act), which provided FDA with express statutory authority over tobacco products.

The Tobacco Control Act contains a number of restrictions on the marketing of tobacco products. Under the Act, FDA is authorized to restrict the sale, distribution, advertising, and promotion of tobacco products, as well as access to tobacco products as appropriate to protect the public health (of both users and non-users). The Tobacco Control Act instructs FDA to reissue the 1996 final rule that the Supreme Court struck down, with several specified revisions. Some specific speech limitations in the Act include:

- Prohibitions on billboard and outdoor advertising within 1,000 feet of schools and public playgrounds (subject to modification by FDA in light of the Supreme Court’s opinion in Lorillard Tobacco Co. v. Reilly).

- Prohibitions on tobacco manufacturers from distributing items such as caps, t-shirts, and sporting goods that bear the name or logo of a tobacco brand.

- Prohibitions on the sponsorship of sporting events or teams using the brand name of a tobacco product.

- Restrictions limiting tobacco advertising to black text on white background only, with the exception of advertising in adult-only facilities and predominately adult periodicals.

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62 Id. § 387(d)(1).
63 Id. § 387a-1.
64 Id. § 387a-1(a)(2)(E). FDA has stated that it does not intend to enforce this restriction until it further considers how to modify this restriction. Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act, 75 Fed. Reg. 13,241, 13,241-43 (Mar. 10, 2010).
• Requirements for new, explicit warnings and colored graphics depicting the negative health consequences of smoking, and rotating statements in bold type, occupying at least the top 50 percent of both panels for cigarettes and 30 percent of both panels for smokeless tobacco products.68

• Prohibitions on labeling and advertising on existing products using “light,” “mild,” “low,” or similar descriptors after June 22, 2010 (unless a modified risk claim is approved by FDA).69

FDA has already implemented a number of these restrictions. As instructed, the agency reissued its 1996 rule,70 Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.71 In addition, the agency issued an advance notice of proposed rulemaking asking for comment on potential outdoor advertising restrictions.72 And recently, the agency issued proposed rules that would require the use of a series of graphic images depicting, among other things, a cancer patient, a corpse, damaged lungs, and a sickened neonate.73

B. First Amendment Protection of Commercial Speech

1. The General Framework

“Commercial speech,” as defined by the Supreme Court, is speech that either proposes a commercial transaction or meets a three-part test that analyzes whether the speech is otherwise commercial because it constitutes an advertisement, refers to a specific product, or is made

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72 Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act, supra note 64.
73 See Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,524-65 (Nov. 12, 2010).
with an economic motivation.\textsuperscript{74} Speech fulfilling all three of these factors will almost surely be considered commercial, but it is unsettled whether speech meeting only one or two of these factors will be considered commercial in nature.\textsuperscript{75}

The Supreme Court has held that commercial speech enjoys First Amendment protection, and the government may restrict such speech only under certain conditions. In \textit{Central Hudson Gas \\& Electric Co. v. Public Service Commission of New York},\textsuperscript{76} it set forth the following four-part test to evaluate the validity of a commercial speech restriction, still used today:

For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.\textsuperscript{77}

A government agency seeking to impose the restriction bears the burden of justifying it under this four-part test.\textsuperscript{78}

Under the first prong, the government may ban commercial speech concerning an activity that itself is illegal (e.g., prostitution).\textsuperscript{79} It also may ban “misleading” speech, which the Supreme Court has stated comes in two categories: potentially misleading speech and inherently misleading speech.\textsuperscript{80} While inherently misleading speech may be banned outright,\textsuperscript{81} potentially misleading speech may be banned only when the government shows that the speech is in fact misleading. This burden generally requires the government to make a

\begin{footnotes}
\footnote{Carver, supra note 3, at 170 (citing Bolger, 463 U.S. at 67 n.13, 68 n.14).}
\footnote{447 U.S. 557 (1980).}
\footnote{Id. at 566.}
\footnote{See id. at 570.}
\footnote{Id. at 570.}
\footnote{In re R.M.J., 455 U.S. 191, 203 (1982).}
\footnote{Id.}
\end{footnotes}
substantial evidentiary showing, and it must also demonstrate that disclaimers would not cure the problem.

The second prong—a requirement that the government assert a substantial interest—typically requires a showing that speech in question poses a real (and not hypothetical) harm. The government typically satisfies this prong, as the Supreme Court has found a variety of harms to justify a substantial government interest.

The third and fourth prongs of the Central Hudson test often pose a greater challenge for the government. To satisfy the third prong, the government must produce evidence showing that the regulation directly and consistently advances its goals. The speech restriction must "alleviate [the cited harm] to material degree," and the connection cannot consist of "mere speculation or conjecture." Further, the speech restriction must be consistent and rational. The Supreme Court has struck down speech restrictions where "overall irrationality" prevents them from achieving the government’s supporting interest.

To satisfy the fourth prong, the government must demonstrate that its restriction is narrowly tailored—that is, the same result could not be achieved by avoiding a speech restriction or by restricting less speech. Put differently, "regulating speech must be a last—not first—resort." The government may also fail this prong if it singles out commercial speech for a selective ban while permitting other types of speech.

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82 Carver, supra note 3, at 172-73 (citing Friedman v. Rogers, 440 U.S. 1, 12-17 (1979)).
84 Carver, supra note 3, at 173.
85 Id. at 174.
87 Carver, supra note 3, at 174.
88 Rubin v. Coors Brewing Co., 514 U.S. 476, 488-89 (1995) (finding law banning alcohol percentage in advertisements was irrational because it permitted alcohol content on labels); see also Greater New Orleans Broad. Ass’n, Inc. v. United States, 527 U.S. 173, 190 (1990) (finding that a ban on casino advertising contained so many exceptions and inconsistencies that it could not advance its stated purpose).
89 Thompson v. W. States Med. Ctr., 535 U.S. 357, 371 (2002) ("[I]f the Government could achieve its interest in a manner that does not restrict speech, or that restricts less speech, the Government must do so." (emphasis added)).
90 Id.at 373.
91 Carver, supra note 3, at 176 (citing City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 418 n.13 (1993)).
2. Commercial Speech in the Food and Drug Context

a. Thompson v. Western States Medical Center

These concepts have been applied a number of times in the food and drug context. In Thompson v. Western States Medical Center, the Supreme Court struck down a provision of the Food and Drug Administration Modernization Act (FDAMA) that exempted compounding pharmacies from the new drug, adulteration, and misbranding provisions of the FDCA, provided the pharmacies did not advertise or promote their products. The parties did not dispute that the speech was commercial and non-misleading. Further, the court found that prong two of the test was satisfied because the government had a substantial interest in preserving the NDA approval process. On the third prong, the Court agreed—with some hesitation—that a speech ban could serve as a means to further useful small-scale pharmacy compounding while discouraging large-scale manufacturing. The Court found, however, that the fourth prong could not be satisfied. Importantly, the government failed to pursue other non-speech restrictions, such as banning equipment for large-scale manufacturing, forbidding wholesale of compounded drugs, limiting compounded drug sales, and relying on existing restrictions on compounding sales and revenues.

b. Cases Considering Off-Label Speech

In Washington Legal Foundation v. Friedman and Washington Legal Foundation v. Henney, the District Court for the District of Columbia considered the constitutional validity of FDA’s guidance on industry-supported scientific and education activities (which restricted manufacturers’ ability to discuss off-label uses with the medical profession). The court found that prong two of the test was satisfied because the government had a substantial interest in preserving the NDA approval process. On the third prong, the Court agreed—with some hesitation—that a speech ban could serve as a means to further useful small-scale pharmacy compounding while discouraging large-scale manufacturing. The Court found, however, that the fourth prong could not be satisfied. Importantly, the government failed to pursue other non-speech restrictions, such as banning equipment for large-scale manufacturing, forbidding wholesale of compounded drugs, limiting compounded drug sales, and relying on existing restrictions on compounding sales and revenues.

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Footnotes:
94 Thompson, 533 U.S. at 360.
95 Id. at 368.
96 Id. at 369.
97 Id. at 371 (“Assuming it is true that drugs cannot be marketed on a large scale without advertising, the FDAMA’s prohibition on advertising compounded drugs might indeed ‘directly advance[e]’ the Government’s interests” (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n, 447 U.S. 557, 566 (1980)).
98 Id. at 373 (“The Government has not offered any reason why these possibilities, alone or in combination, would be insufficient to prevent compounding from occurring on such a scale as to undermine the new drug approval process.”).
community) and FDAMA’s off-label provision. In the first decision, the court found that the agency’s policy, as articulated in the guidance document, violated the First Amendment. At the outset, the court rejected the agency’s argument that off-label speech was actually conduct, and that the speech itself was illegal or inherently misleading.\textsuperscript{101} The speech was not inherently misleading because restrictions short of a total ban could remedy the misleading aspects.\textsuperscript{102}

The court found that the second and third prongs were satisfied because the ban furthered a substantial interest in protecting the NDA approval scheme.\textsuperscript{103} The court rejected, however, the agency’s argument that the government had a substantial interest in ensuring that physicians received accurate information, reasoning that doctors—a sophisticated audience—were capable of evaluating promotional materials.\textsuperscript{104} The policy failed the fourth prong because disclaimers constituted a less-restrictive alternative to a total ban.\textsuperscript{105} In the \textit{Friedman} case, the district court later invalidated FDAMA’s section 401—which permitted dissemination of information about unapproved uses provided that the manufacturer file a supplemental NDA and meet other requirements\textsuperscript{106}—on very similar reasoning.\textsuperscript{107} The district court’s decisions in these cases were later vacated by the D.C. Circuit when FDA mooted the controversy by claiming, for the first time on appeal, that its position was simply a “safe harbor” outside of which FDA would not necessarily take enforcement action.\textsuperscript{108} The D.C. Circuit observed, however, that it did not reach the merits of the controversy, and it was “not criticiz[ing] the reasoning or conclusions of the district court.”\textsuperscript{109}

More recently, in \textit{United States v. Caputo}, the Northern District of Illinois considered the validity of FDA’s off-label speech ban in a criminal case brought against executives of a medical device company who had promoted a modified version of a previously cleared device.\textsuperscript{110} The district court found that the defendant’s off-label speech (which it assumed was not misleading, for purposes of the ruling) was

\begin{footnotes}
\item[102] \textit{Id.} at 68-69.
\item[103] \textit{Id.} at 69-71.
\item[104] \textit{Id.}
\item[105] \textit{Id.} at 73-74.
\item[107] Wash. Legal Found. v. Henney, 56 F.Supp.2d 81, 87 (D.D.C. 1999) (reasoning that the requirement acted as a sort of “constitutional blackmail.”).
\item[109] \textit{Id.} at 337 n.7.
\end{footnotes}
not constitutionally protected because the Government had satisfied the four prongs of the Central Hudson test. Specifically, the court reasoned that, unlike the Washington Legal Foundation cases, the defendants’ argument struck “at the very heart of” FDA’s regulatory scheme, and it was “unable to identify a less burdensome alternative that would advance the government’s substantial interest.”

On appeal, the Seventh Circuit affirmed but did not reach the constitutional question. Rather, because the jury found that subject devices could not be marketed legally, there were no lawful uses to promote. In dicta, however, Judge Easterbrook discussed the constitutionality of an off-label speech ban:

And if a given use is lawful, and thus can be written about freely in newspapers or blogs, and discussed among hospitals that already have purchased a Plazlyte, doesn’t it make a good deal of sense to allow speech by the device’s manufacturer, which after all will have the best information? Why privilege speech by the uninformed? The manufacturer has an incentive to slant the speech in its favor and may withhold bad news, but many listeners (especially professionals such as physicians) understand this and can discount appropriately. That, at any rate, is the anti-paternalist view of Virginia Citizens Consumer Council and the cases that followed in its wake.

At the same time, however, he noted that dismantling the off-label construct could motivate FDA to withhold approvals of drugs and devices with additional, questionable uses, injuring consumers who use them for both on and off-label uses. Easterbrook concluded, that “[d]oubtless the first amendment differs from Bentham’s felicific calculus”—in other words, one need not demonstrate a net societal positive to invoke its protections—“but a court should hesitate before extending an a [sic] historical reading of the Constitution in a way that injures the very audience that is supposed to benefit from free speech.”

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111 Id. at 921-22.
112 Id. at 922.
113 United States v. Caputo, 517 F.3d 935, 940 (7th Cir. 2008).
114 Id.
115 Id. at 939.
116 See id. at 940. It is questionable whether FDA could really do this as a practical matter. In the device context, for example, the agency must look only to the proposed labeling when determining the intended use of a device seeking 510(k) clearance. 21 U.S.C. § 360c(i)(1)(E) (2006).
117 Caputo, 517 F.3d at 940.
c. Cases Considering Health Claims for Foods and Supplements

A series of cases have also considered the validity of FDA’s approach to approving and rejecting health claims for dietary supplements. In *Pearson v. Shalala*, the D.C. Circuit found the FDA had acted unconstitutionally when it rejected proposed health claims by dietary supplement makers. The manufacturers had asserted a connection between antioxidants, fiber, and omega 3 acids and the risk of several diseases, and claimed that folic acid in supplement form provided greater protection against neural tube defects than lower amounts in conventional foods. Applying prong one of the *Central Hudson* test, the court rejected as paternalistic the agency’s claim that the proposed claims were inherently misleading, reasoning that consumers are capable of exercising some judgment at the point of sale. The court characterized FDA’s argument as “almost frivolous,” because it essentially viewed consumers as being “asked to buy something while hypnotized.”

The government also argued that the claims were potentially misleading and, thus, it did not need to consider a disclaimer policy for them. The court reasoned that the government’s argument required it to consider the remaining three prongs of the *Central Hudson* analysis. The court found that the government had satisfied the second prong because it had substantial interests in protecting public health and guarding against deceptive marketing practices. However, it found that the government fulfilled the third prong with respect to the latter of these interests only. On the first point, the government contended that “common sense” supported its position but did not come forward with any evidence, leading to its rejection. On the second point, the court reasoned that some health claims would invariably mislead the public, and a high standard requiring FDA approval would reduce the amount of fraud.

Despite satisfying the first three prongs of the *Central Hudson* test, the government’s insistence that it need not permit disclaimers ultimately doomed its case. The fourth prong cannot be satisfied.

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118 164 F.3d 650, 651-52 (D.C. Cir. 1999).
119 Id. at 655.
120 Id.
121 Id.
122 Id. at 656 (“Under *Central Hudson*, we are obliged to evaluate a government scheme to regulate potentially misleading commercial speech by applying a three-part test.”).
123 Id.
124 Id.
125 Id.
"when the government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness . . .". The court remanded the claim for FDA to consider proper disclaimers.\textsuperscript{127}

FDA then published a notice requesting submission of scientific data concerning the four health claims at issue in that case and issued a guidance setting forth the standard that the agency planned to use to evaluate qualified health claims.\textsuperscript{128} After reviewing the scientific information submitted in support of the folic acid claim, the agency rejected the proposed claim, finding that it would be inherently misleading.\textsuperscript{129}

The district court rejected FDA’s position, finding that the agency “failed to comply with the constitutional guidelines outlined in [the D.C. Circuit’s opinion].”\textsuperscript{130} Although the court deferred to the agency’s “method of dissecting” and reading the folic acid claim under the Administrative Procedure Act, it disagreed with FDA’s weighing of the scientific data and found as a matter of law that the folic acid claim was not inherently misleading.\textsuperscript{131} The court concluded that “[t]he mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence ‘against’ it.”\textsuperscript{132} Moreover, the court held that the “question which must be answered under [the D.C. Circuit’s opinion] is whether there is any ‘credible evidence’” in support of the claim.\textsuperscript{133} If such evidence exists, the claim may not be prohibited unless that evidence is “outweighed by evidence against the claim” or is “qualitatively weaker” than evidence against the claim.\textsuperscript{134}

In two other cases, however, the agency survived First Amendment challenges. In \textit{Nutritional Health Alliance v. Shalala}, the Second Circuit determined that the 540-day deadline for an agency determination on a health claim was reasonable under \textit{Central Hudson}.\textsuperscript{135} In \textit{Whitaker v. Thompson}, the D.C. Circuit considered whether classify-

\textsuperscript{126} Id. at 657-58.
\textsuperscript{127} Id. at 661.
\textsuperscript{129} Id. at 111.
\textsuperscript{130} Id. at 112.
\textsuperscript{131} Id. at 114 n.24.
\textsuperscript{132} Id. at 115.
\textsuperscript{133} Id. at 118.
\textsuperscript{134} Id. at 114-15. The agency was again reversed in \textit{Whitaker v. Thompson}, when it refused to permit the claims based on the antioxidant-cancer relationship at issue in the D.C. Circuit’s \textit{Pearson} opinion. 248 F. Supp. 2d 1, 16-17 (D.D.C. 2002). Citing the Supreme Court’s decision in \textit{Western States}, the court reasoned that FDA must regulate speech in the “least restrictive means of achieving its goals.” \textit{Id.} at 9.
\textsuperscript{135} 144 F.3d 220, 228 (2d Cir. 1998).
ing products bearing unapproved health claims as drugs violated the
First Amendment. The court found that the statute simply used manu-
ufacturer speech as evidence of intent to market a drug, and Supreme
Court case law permitted “the evidentiary use of speech to establish
the elements of a crime or to prove motive or intent.” Thus, the
court essentially found that Central Hudson permitted FDA to look to
a manufacturer’s intent (as illustrated by its speech) to classify prod-
ucts under the FDCA.

II. RECENT ENFORCEMENT

FDA’s enforcement actions have clashed with the First Amend-
ment over the past several decades. But the frequency and signifi-
cance of these conflicts have increased in the wake of a recent and
more aggressive enforcement posture with respect to speech-related
conduct.

A. Drugs & Devices

FDA has recently participated in two cases—Allergan v. United
States and United States v. Coronia—that involve challenges to par-
ticularly aggressive positions regarding off-label promotion, and
which may have implications for regulatory schemes governing drugs
and devices. Outside the courts, FDA has taken other aggressive en-
forcement positions, including a crack-down on the use of sponsored
search links.

1. Allergan v. United States

Allergan, a California-based manufacturer of drugs and devices,
sued FDA in October of 2009 for declaratory and injunctive relief
regarding its ability to communicate with physicians about off-label
uses of its drug, Botox. Beyond its cosmetic uses, Botox can be
used for therapeutic indications, several of which are off-label and
used for diseases with small populations—in other words, uses for
which there may be little or no financial incentive to seek approval. In
April of 2009, FDA mandated that Allergan implement safety label
changes to Botox and complete a Risk Evaluation and Mitigation


\[136\] 353 F.3d 947, 953 (D.C. Cir. 2004) (quoting Wisconsin v. Mitchell, 508
U.S. 476, 489 (1993)).
\[137\] Id.
\[138\] Id. ¶ 1, 10, Allergan v. United States, No. 1:09-cv-01879, (D.D.C.
filed Oct. 1, 2009) [hereinafter Allergan Complaint].
\[139\] Id. ¶¶ 55-63.
Strategy (REMS) to include a Medication Guide to patients.\textsuperscript{140} In July of 2009, FDA approved Allergan’s REMS, a black-box warning for Botox, a “Dear Health Care Provider” letter, and a medication guide, all of which used the agency’s proposed content. The black-box warning included information about adverse events in off-label uses, particularly instances of the spread of toxins from the injection site when used to treat children with cerebral palsy.\textsuperscript{141} In its lawsuit, Allergan contended that it will continue to provide general warnings through the REMS program, but it believed that FDA regulations concerning dissemination of off-label communications do not permit it to provide physicians with enough specific and detailed information such as dosages, proper injection technique, and patient selection for the off-label uses.\textsuperscript{142}

Allergan’s suit challenged several FDA regulations, both facially and applied to Allergan’s desire to distribute information about Botox’s off-label uses. Specifically, Allergan’s complaint contended that the agency’s intended use regulations, 21 C.F.R. §§ 201.100 and 201.128, in combination with the requirement that a manufacturer provide adequate directions for use (which must include directions for any intended use), form a prior restraint that limits communications to on-label information.\textsuperscript{143}

The Allergan suit appeared to be a near-perfect opportunity to test the constitutionality of FDA’s off-label speech restrictions as applied to truthful and non-misleading speech. It is difficult to conceive how FDA could justify the restriction of Allergan’s proposed communications, which are not really promotional—at least in the normal sense of the word—and are designed to minimize adverse events for a medically accepted use of the product.\textsuperscript{144} The primary issue in this case would likely have been \textit{Central Hudson} step four, specifically whether the prohibition is narrowly tailored to further the government’s interests in protecting the NDA process and removing misleading speech from the marketplace. On the first point, as Allergan noted in

\textsuperscript{140} \textit{Id.} \textsuperscript{¶} 71-72.
\textsuperscript{141} \textit{Id.} \textsuperscript{¶} 73-74.
\textsuperscript{142} \textit{Id.} \textsuperscript{¶} 76-89.
\textsuperscript{143} \textit{Id.} \textsuperscript{¶} 89-95. In count V, Allergan argued that FDA’s ban of speech about a use for which Allergan was seeking a supplemental approval was unconstitutional. This part of Allergan’s suit is now moot, however, as FDA approved Allergan’s supplemental BLA for this use. Def.’s Reply in Support of Mot. to Dismiss or for Summ. J. and Res. to Cross-Mot. for Summ. J. at 19, Allergan v. United States, No. 1:09-cv-01879 (D.D.C. filed Mar. 29, 2010).
\textsuperscript{144} The uses about which Allergan wishes to speak are recognized in compendia and receive reimbursement from government insurance programs. Allergan Complaint, at \textsuperscript{¶} 61-63.
its summary judgment papers, numerous other alternatives exist, including the sensible enforcement of regulations and laws already on the books and the adoption of incentives to encourage the filing of NDAs (e.g., heavier taxes for revenues from off-label uses).\textsuperscript{145} And, of course, the agency would need to demonstrate that requiring manufacturers to use a disclaimer that the use about which they speak is off-label would be insufficient to encourage them from seeking NDA approval in cases where the incentive would otherwise exist.\textsuperscript{146} Also damaging to FDA’s case is that the intended use regulations act as a speaker-specific speech restriction, allowing anyone other than manufacturers, distributors, and packers to speak about off-label uses.\textsuperscript{147}

In September of 2010, however, Allergan dropped the suit as part of a settlement of criminal and civil claims regarding its promotion of Botox.\textsuperscript{148} In a press release regarding the settlement, the Justice Department alleged that Allergan was marketing Botox for the treatment of headache, pain, spasticity, and juvenile cerebral palsy, which were off-label uses during the timeframe alleged.\textsuperscript{149}

Had the case not settled, there is a good possibility that the court would have ruled for Allergan on the most narrow issue presented: whether manufacturers have a right to disseminate instructions for safe off-label use for the purpose of accompanying the warnings FDA has already required. The case also offered an opportunity to provide some guidance on the larger issue of whether and under what conditions companies can communicate, in ways that would typically be considered promotion, about unapproved indications. This larger issue is important: the Department of Justice has lead a lucrative campaign against drug manufacturers, garnering settlements in the billions.\textsuperscript{150}


\textsuperscript{147} Greater New Orleans Broad. Ass’n, Inc. v. United States, 527 U.S. 173, 194 (1999) (“[D]ecisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment.”).


The conduct in these cases varies considerably, but their conceptual underpinnings are generally the same: that off-label promotion is categorically unlawful and may be restricted by the government, regardless of scientific validity.\textsuperscript{151} The industry, the public, and physicians sorely need a declaration on the extent of First Amendment protection for promotional and non-promotional communications regarding off-label use, as the current regime excessively chills both activities.

2. United States v. Caronia

United States v. Caronia is a criminal appeal pending in the United States Court of Appeals for the Second Circuit. The case is a rare government prosecution of a pharmaceutical sales representative for off-label promotion. Even more exceptional, however, are the facts of the case.

Alfred Caronia was employed by Orphan Medical (since acquired by Jazz Pharmaceuticals) to sell Xyrem, a drug approved at the time for cataplexy in narcolepsy patients.\textsuperscript{152} Xyrem also had various off-label uses, one of which was for excessive daytime sleepiness.\textsuperscript{153} At some point, Caronia attended a meeting with Dr. Steven Charno, a government informant. Dr. Charno asked a number of questions about off-label uses of Xyrem, to which Caronia provided answers.\textsuperscript{154} Towards the end of the meeting, Caronia arranged for a follow-up meeting with Dr. Charno and Dr. Peter Gleason, a doctor who spoke on behalf of Orphan Medical on uses of Xyrem.\textsuperscript{155} During the follow-up meeting, Gleason (who pled guilty to misbranding)\textsuperscript{156} spoke to Char-
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no about off-label uses of Xyrem to treat excessive sleepiness. Caronia did not discuss these uses, but he did discuss reimbursement issues. Shortly thereafter, FDA approved Xyrem for excessive daytime sleepiness. The jury found these facts sufficient to convict Caronia of conspiracy to misbrand.

Before the trial, the district court rejected Caronia’s First Amendment argument, finding that FDA’s restriction of off-label speech was sufficiently narrowly tailored under Central Hudson step four. The opinion follows the reasoning of United States v. Caputo, summarized above, in which a district court rejected a constitutional challenge to the off-label construct, reasoning that it would topple FDA’s drug approval regulatory scheme.

The case is legally significant for several reasons. Perhaps most importantly, it presents a challenge to FDA’s practice of avoiding constitutional challenges by recharacterizing its speech ban as a ban on conduct. In other words, FDA attempts to circumvent the constitutional implications of banning speech by arguing that it is simply using off-label speech as evidence to establish intended use. In this case, the only evidence of Caronia’s crime was his and Gleason’s off-label speech, meaning that he was convicted solely based on speech. And more significantly, that speech concerned a use of the product that FDA approved just days after the alleged criminal conduct. To prevail on the constitutional issue, the government must demonstrate that criminal punishment is necessary to advance the interests it has presented.

The district court, however, tersely concluded that Washington Legal Foundation v. Friedman and Western States were distinguishable, because Caronia’s challenge struck at the “heart” of the regulatory scheme, and the court was otherwise “unable to identify non-speech restrictions that would likely constrain in any effective way manufacturers from circumventing that approval process.” In a

158 Id. at A-48 to A-54.
159 Id. at 40.
161 Id. at 401 (“This Court, however, finds more compelling the conclusion reached by the district court in Caputo that a First Amendment challenge by a drug or de-vice-maker or its agents in such circumstances ‘strikes at the heart of the FDA’s ability to proscribe manufacturer promotion of off-label use.’” (quoting United States v. Caputo, 288 F. Supp. 2d 912, 922 (N.D. Ill. 2002))).
163 Caronia, 576 F. Supp. 2d at 401.
footnote, the court noted that several non-regulatory options have been suggested by commentators, but “[n]o one, including Caronia, has pointed to any regulatory proposal FDA could adopt to plug the loophole in the new approval process . . . .” That statement is troubling in two respects: (1) it is unclear why other options would need to be “regulatory” in nature; and (2) more importantly, it was the government’s burden to demonstrate the need for the speech ban, not the defendant’s burden to show that other options would work equally well. Given that the government carries the burden to justify its speech ban, the presumption in step four should be that the speech ban is too restrictive, unless the government discharges its burden to show that it is an appropriate fit.

Like Allergan’s lawsuit, however, the case could be resolved on very narrow grounds. Because Xyrem was approved for daytime sleepiness immediately after the alleged off-label speech relating to that use, the Second Circuit can hold that the First Amendment protects the exact speech at issue—that is, speech relating to an off-label use under consideration and subsequently approved by FDA.

3. The End of the “One-Click Rule”

Pharmaceutical companies had previously taken the approach that sponsored links—a short advertisement appearing above search engine results—could feature the drug’s brand name and a short description without featuring the established name, risk information, and FDA-approved indication, provided such information could be accessed by clicking on the link. On April 2, 2009, however, FDA sent fourteen untitled letters alleging that these links made representa-

164 Id. at 402 n.12.
167 The government is also litigating a case against a former drug executive, Scott Harkonen of InterMune, based on a press release he authored describing a phase III study for an unapproved use of a drug. The district court in that case refused to grant a motion to dismiss the indictment on First Amendment grounds, finding that the government’s allegation that the release was false removed it from First Amendment protection. United States v. Harkonen, No. 08-00164 MHP, 2009 WL 1578712, at *8 (N.D. Cal. June 4, 2009).
tions about the efficacy of a product without providing sufficient risk information.\textsuperscript{169}

The industry interpreted the FDA's regulations to permit the practice of sponsored links. This interpretation was reasonable—indeed much more so than a contrary reading. After all, a link is just that—a link to more information. Given FDA's prior treatment of print advertising, which had generally permitted a summary of risk information to appear on a different page of an advertising spread, a link would seem appropriate because clicking it is analogous to turning a page.\textsuperscript{170}

As opposed to a banner advertisement, which is more often meant to stand alone as an advertising piece, the sponsored link is one part of an advertising piece that is fully integrated only after one follows the link.

The constitutionality of the agency's position in these letters is questionable. To begin, links with a short summary of truthful efficacy information do not mislead by their failure to include safety information on the same screen. The sponsored link does not give the impression that it contains all relevant information about the product, especially in cases where the teaser instructs readers to "learn more facts" by following the link.\textsuperscript{171} Rather it gives the opposite impression: the user must click the link to learn about the product. Thus, the sponsored link does not falsely imply that the advertised product is without a safety risk.

Assuming the agency could satisfy the first three prongs of the Central Hudson test, it would have to show that its policy is narrowly tailored to further the asserted rationale for the rule—ensuring consumers have truthful and non-misleading information about drug. But it is unclear how such a policy could be considered narrowly tailored. Because of space constraints in sponsored search advertising, FDA's insistence that the industry "cease the dissemination of violative" materials\textsuperscript{172} amounts to an outright ban on even mentioning the drug's use in these advertisements. Current practice appears to be a hyperlink

\begin{footnotesize}
\begin{enumerate}
\item[169] Id.
\item[172] Id.
\end{enumerate}
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with the drug’s brand name featured above a sentence stating the site is “official,” contains “answers” about the drug, or a similar variant. FDA’s policy has also discouraged industry members from using Twitter or other space-constrained media platforms, especially for black-box drugs that are not permitted to be the subject of reminder advertisements and labeling.\textsuperscript{173} Interestingly, FDA’s own use of space-constrained social media would violate this policy, if FDA were subject to the speech restriction. For example, on November 5, 2010, FDA tweeted: “FDA clears Cymbalta to treat chronic musculoskeletal pain.”\textsuperscript{174} This, of course, belies an argument that space-constrained messages about drugs are inherently misleading or dangerous.

Certainly, less restrictive alternatives could achieve the same goal of permitting consumers to obtain truthful and non-misleading information about products. But the agency never considered these possibilities, choosing to send out a blitz of letters rather than open a dialogue with the industry. Perhaps realizing its mistake, FDA called for comments several months later regarding the use of the Internet and social media to promote regulated products.\textsuperscript{175} The comments filed in response illustrate the many alternatives the agency should have considered. For instance, PhRMA suggested that the agency permit an abbreviated discussion of efficacy and risk accompanied with a “universal symbol” that marks a direct link to FDA-regulated information.\textsuperscript{176} Consumers would know to follow this link to obtain safety and other relevant information about a product.

\textsuperscript{173} FDA’s Division of Drug Marketing, Advertising, and Communications sent an untitled letter in July of 2010 regarding Tasinga, a Novartis drug. Letter from Karen R. Rulli, Acting Group Leader, Div. of Drug Mktg., Adver., and Comm’ns, to Lisa Drucker, Dir., Regulatory Affairs - Oncology, Novartis Pharm. Corp. (July 29, 2010), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM1325.pdf. The letter cited the manufacturer’s use of the “Facebook Share” widget, which allows users to share a link to the website on their “Facebook Wall.” FDA’s objection to the practice was that the link appearing on a user’s wall featured a short description of the shared site that lacked safety information. \textit{See id.}

\textsuperscript{174} U.S. Food & Drug Admin., \textit{FDA Drug Information, Twitter} (Nov. 5, 2010, 8:17 AM), http://twitter.com/fda_drug_info (last visited November 9, 2010). Similar to its policies regarding off-label promotion, FDA’s position in this context again serves as a speaker-specific restriction.

\textsuperscript{175} Public Hearing: Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, 74 Fed. Reg. 48,083 (Sept. 21, 2009).

\textsuperscript{176} Jeffrey K. Francer, Asst. General Counsel, Pharm. Research and Mfrs. of Am., Statement at FDA Public Meeting on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools (Nov. 12-13, 2009), available at: http://www.phrma.org/issues/fda_issues.
Even beyond constitutional issues, the crackdown is unwise in terms of its effect. By dissuading manufacturers from sponsoring links to legitimate and regulated content regarding brand-name drugs, FDA widens the gap for the illegitimate (off-shore) internet “pharmacies” that sell drugs (sometimes counterfeit) to United States consumers without prescriptions, as well as “natural” remedies that FDA has never evaluated.177

B. Foods and Supplements

FDA has continued its policy of speech suppression in the food and supplement industries through its exceedingly narrow construction of the standard for permitting qualified health claims and a blitz of warning letters in March of 2010 addressing nutrient content claims, health claims, and various other labeling matters.

1. Alliance for Natural Health US v. Sebelius

Similar to the Pearson cases, various plaintiffs have sued FDA over its denial of qualified health claim petitions for dietary supplements containing selenium.178 The plaintiffs had sought approval for ten qualified health claims regarding selenium’s effects on cancer, and provided over 150 scientific articles supporting the claims.179 In response, the agency permitted qualified versions of three claims and rejected seven other claims outright.180 The plaintiffs filed suit, arguing that the denial of four of the claims was unlawful and the disclaimer put on a fifth claim was unduly restrictive.181 The court found for the plaintiffs, reasoning that FDA’s disclaimer of the approved claim essentially “replaced” the plaintiffs’ claim and, further, that FDA erred by disqualifying various studies the plaintiffs had offered in support of their rejected claims.182

The case is illustrative in several respects. First, it emphasizes the need for FDA to consider requiring a disclaimer in lieu of an outright ban on the proposed speech. In the underlying administrative action,

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177 Mark Senak, FDA Issues Warning Letter on Cheerios—Priorities Askew, EYE ON FDA (May 13, 2009), http://www.eyeonfda.com/eye_on_fda/2009/05/fda-issues-warning-letter-on-cheerios-priorities-askew.html (“That means now, if you search on a term like “diabetes treatments” as I did this morning, and you may see an ad that suggests that you can cure your diabetes naturally without drugs.”).
179 Id. at 57.
180 Id. at 58.
181 Id.
182 Id. at 71–72.
FDA ruled that the plaintiffs’ proposed claims stating selenium reduced the risk of “certain cancers” and had “anticarcinogenic effects” were inherently misleading because only a few types of cancer were implicated. The court soundly rejected this rationale, finding that “the explanation FDA offers to demonstrate that plaintiffs’ claims are misleading—that the claims leave out pertinent information—is not support for banning the claims entirely, but rather favors the approach of remedying any potential misleadingness by the disclosure of additional information.”

Secondly, the case illustrates FDA’s recalcitrance in complying with First Amendment case law regarding qualified health claims. The court had previously instructed FDA to consider approving a “short, succinct, and accurate disclaimer” to accompany a proposed health claim. Based on its concern about the use of the word “convincing,” and supposedly applying this standard, FDA transformed the proposed:

Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive.

into:

Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer.

The court found that this qualification “eviscerated” the plaintiff’s claim without explaining why a less restrictive approach would not be effective. For instance, FDA could have simply used language that characterized the strength of the studies the plaintiffs cited (since that was FDA’s asserted problem with the language). Further, the court rejected the disclaimer as inaccurate, finding that FDA had misconstrued study results.

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183 Id. at 58.
184 Id. at 63.
185 Id. at 71 (quoting Pearson v. Shalala, 130 F. Supp. 2d 105, 120 (D.D.C. 2001)).
186 Id. at 57 n.16, 58 n.19.
187 Id. at 71.
188 Id.
2. The March 2010 CFSAN Warning Letters

FDA issued a blitz of warning letters in February 2010 to seventeen food manufacturers, alleging violations of various labeling rules. While some speculated that letters sent throughout the previous year were intended to send a message to the food industry, this time FDA was explicit: accompanying the letters were a press release, a letter to the industry, and a webpage describing FDA’s expectation that food manufacturers will reevaluate their practices in light of the agency’s actions.

Several of these letters raised serious constitutional issues. A number cited manufacturers for using a nutrient content claim relating to antioxidants that allegedly did not comply with FDA’s regulations exactly. Specifically, the agency contended that under 21 CFR 101.54(g), a nutrient content claim that characterizes the level of antioxidant nutrients present in a food may be used on a label or in the labeling of that food only when, among other requirements, a reference daily intake (RDI) has been established for each of the nutrients. This would be the case even if the substance in question is indisputably an antioxidant, and the manufacturer’s characterization (e.g., “high levels”) is indisputably correct.

Several constitutional problems exist with this policy. A nutrient content claim for an antioxidant without an RDI could be misleading if the claim itself is inaccurate—for example, if the substance in question is not an antioxidant, or the level present in the food is not as the manufacturer characterizes it. But FDA’s policy assumes that all antioxidant nutrient content claims are inaccurate unless they are tied to an RDI nutrient. Unfortunately, FDA’s nutritional labeling requirements can be a crude and outdated measure of scientific validity. For example, the Institute of Medicine recently questioned whether sodium’s Daily Value of 2,300 mg is an appropriate daily intake lev-

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189 CFSAN is the acronym for the Center for Food Safety and Applied Nutrition.
193 Id.
el. Like many of FDA’s speech suppression policies, the nutrient content claim regulation suppresses all speech that does not receive the agency’s blessing. Under the Central Hudson test, the agency would have to show that this broad stroke approach is necessary to further the goal of promoting accurate labeling. It almost certainly could not meet this burden. Just one of several less restrictive alternatives would be to require nutrient content claims for antioxidants without RDIs to contain disclaimers stating that no FDA-recognized daily intake for the nutrient is recognized.

The letters also continue FDA’s prohibition on the citation of scientific studies by food manufacturers—even on manufacturer websites. FDA achieves this method of speech suppression by considering the citation of a study espousing a health benefit to be evidence that the manufacturer is promoting the food product as a new drug. This is similar to the approach the agency takes with respect to off-label promotion of drugs and devices.

Finally, the most disturbing aspect of the warning letters can be found in a letter to a green tea manufacturer. In a website section entitled “Green Tea and the FDA: Who’s Right?” the manufacturer criticized FDA for rejecting a health claim on the benefit of green tea on heart disease. FDA took this discussion in the article, particularly the argument in the article that studies support such a link, to be an “unauthorized health claim.” What makes this worse than other examples of FDA’s speech suppression is the nature of the speech involved: political. FDA’s view appears to be that manufacturers cannot criticize the agency’s denial of their health claims on websites that

194 Institute of Medicine, Strategies to Reduce Sodium Intake in the United States 225-28 (Jane E. Henney, Christine L Taylor & Caitlin S. Boon eds. 2010).


197 See id.


200 Id.

201 Id.
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contain product information because such sites are subject to labeling rules, and therefore any mention of the health claim is tantamount to promoting the health claim. This type of speech restriction would be subject to even greater constitutional scrutiny because it falls outside of the commercial speech rules, meaning it would be almost certainly unconstitutional. 202

C. Tobacco

The Tobacco Control Act contains a number of statutorily mandated speech restrictions and charges FDA with the task of enforcing them. Although the FDA did not impose the Act’s speech restrictions, most of the controversial provisions were adopted from FDA’s 1996 rule governing tobacco that the Supreme Court invalidated for lack of statutory authority.

Some of these provisions have already been overturned in federal court. In Commonwealth Brands v. United States, several major tobacco manufacturers brought an action against the United States claiming, among other things, that a number of the Act’s speech restrictions are unconstitutional under the First Amendment. 203 Specifically, the suit challenged color restrictions on labeling and advertising, restrictions on sponsorship of events, merchandise restrictions, the additional warning requirements, the modified risk tobacco products provision, the prohibition on claims implying FDA approval, and the ban on outdoor advertising. 204

Regarding the color restriction, the Act directed the FDA to reissue regulations requiring labels and advertisements for tobacco products to include only black text on a white background with no graphics. 205 The ban would not apply to magazine advertising if the publication has only a small under-eighteen readership (which must be demonstrated by the advertiser). 206 In addition, the Act exempts advertising in certain adult-only facilities. 207 The district court found that this restriction could not be justified under Central Hudson because “images of packages of their products, simple brand symbols, and some uses of color communicate important commercial information about their products, i.e., what the product is and who makes

203 678 F. Supp. 2d 512, 521 (W.D. Ky. 2010).
204 Id. at 522-36.
Because Congress could have exempted large categories of innocuous images and colors—e.g., images that communicate brand identity without creating a special appeal to children—the ban was too broad and failed Central Hudson step four.

The court also invalidated a ban on claims implying FDA approval. The Tobacco Control Act prohibits “any express or implied statement or representation directed to consumers with respect to a tobacco product” conveying that: “(1) the product is approved by [FDA]; (2) [FDA] deems the product to be safe for use by consumers; (3) the product is endorsed by [FDA] for use by consumers; or (4) the product is safe or less harmful by virtue of . . . its regulation or inspection by [FDA] . . . or . . . its compliance with regulatory requirements set by [FDA].” The court reasoned that this prohibition was facially unconstitutional because it brought within its scope statements by journalists, doctors, scientists, politicians, and others—in other words, it banned much more than commercial speech.

The court passed on evaluating the Act’s ban on outdoor advertising, finding that the matter would not be ripe until FDA promulgated regulations, and it upheld the other challenged sections of the Act. The court found that each of the remaining regulations were narrowly tailored to further the interest in reducing smoking. For instance, the court upheld the warning mandates—requiring 50 percent of the front and rear panels of the packaging to include updated warnings—because the government supported the enhanced size requirements with evidence showing that young and poorly educated consumers were less likely to apprehend the smaller, text-based warnings currently in use.

Both sides have appealed the decision. While it does not provide a terribly useful window into the FDA’s current view on First Amendment issues, especially given that the restrictions are statutory in nature, the case does perhaps demonstrate the importance of buttressing speech restrictions with facts supporting their need. This is in sharp contrast to FDA’s method of litigating cases involving off-label speech and health claims speech restrictions, discussed earlier in this

208 Commonwealth Brands, 678 F. Supp. 2d at 525.
209 Id.
211 Commonwealth Brands, 678 F. Supp. 2d at 535.
212 Id. at 535-36.
213 Id. at 530-32.
214 See Discount Tobacco City & Lottery, Inc. v. United States, Nos. 10-5234, 10-5235 (6th Cir. 2009).
essay, which the agency often attempts to support through conjecture regarding the prohibited speech’s effect on its regulatory scheme.

III. HOLDING THE AGENCY ACCOUNTABLE

Constitutional liberties are meaningless if they cannot be enforced. But that is exactly the situation FDA-regulated industries face due to a myriad of practical and legal consequences discouraging the exercise of constitutional rights. This reality, considered with the executive branch’s responsibility to adhere to constitutional limitations on its authority, provides reason for FDA to reexamine its speech-related policies.

A. Pyrrhic Victories and Enormous Risk

Significant obstacles prevent regulated industries from effectively contesting FDA speech restrictions. To begin, affirmative challenges to FDA policies require substantial resources in terms of time and money, and victories may not always justify the effort. Part of this expense is due to the nature of high-stakes litigation, but much is also due to the time it takes to litigate against FDA. The Pearson disputes, for example, lasted from 1995 to 2002, during which time the agency suffered at least four legal defeats.215 And even fifteen years later, in Alliance for Natural Health US v. Sebelius, it appears that FDA is still running afoul of court mandates regarding health claims.216 Another notable example is the Washington Legal Foundation cases, in which, after losing at the district court level, FDA mooted the case on appeal by claiming that its position was simply a “safe harbor” outside of which FDA would not necessarily take enforcement action.217 Even after successful legal challenges, there is no guarantee that expended litigation resources will actually result in the relief sought.

Further reasons are related to the risks that come with defending an enforcement action brought by FDA and the Department of Justice. First, there is the possibility of an enormous fine. Since 2004, for example, the Justice Department has obtained $7 billion in fines from criminal pleas and civil settlements from just seven pharmaceutical companies.218

216 Id. at 72.
218 David Evans, When Drug Maker’s Profits Outweigh Penalties: Deceptive Drug Marketing Put Patients at Risk, WASH. POST, Mar. 21, 2010, at G1, available at
Second, employees and executives of targeted companies face potential criminal charges. In addition to cases like *United States v. Caronia*, in which the government targets company employees for their own conduct, the government can seek misbranding charges against executives through a vicarious-liability theory called the *Park doctrine*.\(^{219}\) Under this standard, the Government does not have to provide proof of an individual defendant's intent to commit a violation to impose criminal liability on the individual. Rather, the Government must prove beyond a reasonable doubt only that the individual had a responsible relationship to, or a responsible share in, the furtherance of the transaction that caused the violation.\(^{220}\) An FDA official recently indicated that the agency intends to rely increasingly on *Park doctrine* liability as an enforcement option in misbranding cases.\(^{221}\)

Third, pharmaceutical companies that are criminally convicted face potential exclusion\(^{222}\) and debarment\(^{223}\) from participating in federal programs, described as a "virtual death sentence."\(^{224}\) These firms derive an estimated 30 to 40 percent of their revenue from sales to the federal government (either directly to federal agencies or through Medicare and Medicaid), and the loss of this revenue could bankrupt even the strongest companies.\(^{225}\) Counterbalancing this factor, however, is the practical consideration that the government, too, cannot al-

http://www.washingtonpost.com/wp-dyn/content/article/2010/03/19/AR2010031905578.html.

\(^{219}\) *United States v. Park*, 421 U.S. 658, 673-74 (1975) ("[T]he Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."); see also John R. Fleder, *The Park Criminal Liability Doctrine: Is it Dead or is it Awakened?*, FDLI UPDATE, Sept.-Oct. 2009, at 48, 48-50 (2009), available at http://www.hpm.com/pdf/FLEDERPARK.PDF (describing the use of the Park doctrine against executives of Purdue pharmaceuticals for misbranding of OxyContin).

\(^{220}\) *Park*, 421 U.S. at 673-74.


\(^{225}\) Id.
ways afford to exclude these companies. In cases where a company produces the only available therapy for a condition, exclusion and debarment would deprive government beneficiaries of a needed drug. An interesting twist to this dynamic is that the Office of Inspector General of the Department of Health and Human Services, which administers the exclusion provisions, recently required a parent corporation to divest itself of a subsidiary that pled guilty to a felony conviction.226

B. Encouraging Greater Compliance with the First Amendment

The trends described in this essay suggest that FDA gives insufficient consideration to First Amendment issues when engaging in enforcement activities. In fact, the new administration reduced the amount of legal review given to enforcement letters, reserving review by the Office of Chief Counsel for letters raising “significant legal issues.”227 Some untitled letters challenging the content of advertising are not subject to any legal review by FDA’s attorneys. This practice allows FDA employees without legal training to impose significant speech restrictions through informal and indiscriminate means.

Even where legal review is certain, such as in litigation or rule-making, FDA’s recent practices suggest that the agency’s view of the First Amendment is very different from the view of the courts. As a creature of the Constitution, the executive branch has a responsibility to ensure that actions are consistent with constitutional limitations; it should not rely on the courts to tell it when it has gone too far. Although FDA justifiably seeks for all product claims to be supported by sound science, the agency knows that the First Amendment does not always require one to produce adequate and well controlled clinical studies as a condition of speaking.

The agency could take two important steps. First, starting as soon as practicable, the agency should publicly state that the Office of Chief Counsel will review all enforcement letters—both untitled and warning—that involve promotional or advertising issues for First Amendment compliance. This robust legal review should also include administrative proceedings that touch upon First Amendment issues.

227 Margaret Hamburg, Comm’r of Food and Drugs, Remarks on “Effective Enforcement and Benefits to Public Health” at Food and Drug Law Institute (Aug. 6, 2009), available at http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm; see also Masoudi & Whittingham, supra note 170.
such as denials of health claims. Serious thought about First Amendment issues will not only help protect the industry’s constitutional rights, but it will also make the agency’s positions in court more tenable when challenges are filed.

Second, to aid in the above task, the agency should thoroughly assess the impact of its regulations and policies on First Amendment liberties. The groundwork for this process has already been laid. In 2002, FDA opened a public docket for comment on how the agency could “ensure that its regulations, guidances, policies, and practices . . . comply with the governing First Amendment case law.” Specifically, the agency asked: (1) whether it should apply different levels of restriction toward different products (e.g., drugs versus foods); (2) whether its positions on direct-to-consumer communications were empirically and legally sound; (3) whether claims for foods should be distinguished from dietary supplements; (4) whether disclaimers should be required to share equal prominence with claims; (5) how warnings can be made most effective; (6) whether claims made in advertising should be treated differently from claims on labels, and whether the agency has more latitude to specify label content; (7) the extent of the agency’s ability to regulate off-label speech, and whether such speech would affect the drug approval regulatory scheme; (8) whether the agency’s speech restrictions enhance public safety; and (9) whether the agency should reconsider existing policies in light of First Amendment rights. Eight years later, these questions are not only still relevant, but in fact offer a fairly comprehensive summary of the constitutional defects in the agency’s current policies. The agency should reopen this docket, permit submitters to update their comments, and seriously address the proposals it receives.

The result of this constitutional audit ideally would include at least three tangible improvements. To begin, the agency should create guidance for its employees regarding First Amendment limitations on its enforcement powers, and it should carve out areas of enforcement discretion that are necessary to bring its policies into immediate constitutional compliance. Second, the agency should begin the process of revising its current and proposed regulations and guidance documents to be in better compliance with the First Amendment. And finally, FDA should work with the Justice Department to produce a joint policy statement that adopts a consistent and coherent interpretation of the laws and regulations governing drug and device promotion.

229 Id. at 34,943-44.
In performing these tasks, the agency should consider several overarching First Amendment themes, all of which are highlighted by the agency's recent enforcement discussed above:

- **The agency should permit the use of disclaimers to remedy potentially misleading speech, unless the disclaimer would be ineffective.** Despite courts' instructions, the agency maintains a number of outright speech bans with goals that could be furthered by utilizing disclaimers instead. For example, FDA's ban on nutrient content claims related to antioxidants for which there is no daily value could be furthered by requiring marketers to feature a disclaimer that the antioxidant to which the claim refers does not have an established RDI.

- **Concerns that speech is inherently misleading, or that disclaimers would be ineffective, should be supported by actual evidence of harm and not speculation.** FDA expects that consumers will understand and digest the relatively thick and technical "brief summary" offered in drug advertising, yet at the same time argued in *Alliance for Natural Health US v. Sebelius* that the phrase "anticarcinogenic effects" would be inherently misleading (and thus incurable by disclaimer) because the products were shown to have an effect on some, but not all cancers. Not surprisingly, FDA takes a pessimistic view of consumers when justifying its speech bans. The reality is that different messages will have different effects on different audiences, and courts have been emphatic of the need to provide evidence that a particular example of speech will mislead. Simply put, when FDA seeks to ban speech as misleading, it must meet its burden to show that the speech will in fact mislead.

- **FDA should not attempt to avoid constitutional issues by re-characterizing bans on speech as bans on conduct.** For example, the agency justifies its prohibition against the use of studies regarding disease-reduction benefits in food promotion by taking the position that it has the authority to regulate drugs, and food marketers choose to position their products as drugs by citing clinical studies. But subjecting such studies to the evidentiary standard for approval of a drug operates as an outright ban on their use in the food context. Typically, these studies do not meet the evidentiary standard for approval of a drug. And further, if they did, approval as a drug would mean that the article in question would no longer be regulated as food when using the claim.
• FDA should issue guidance on Internet communication that recognizes unique benefits and constraints of such communication. Manufacturers of FDA-regulated products cannot take full advantage of the power of the Internet without meaningful guidance that respects First Amendment rights. For example, FDA could permit risk information in space-constrained sponsored links to be accessible through a mouse-click.

CONCLUSION

FDA’s conflicts with the First Amendment continue to grow in frequency and magnitude. FDA has taken unduly aggressive positions in various enforcement actions aimed at drugs, food, and tobacco. While the agency is rightfully attempting to protect the public from misleading claims about these products, it has in some cases gone beyond constitutional limits, chilling protected activities. The substantial barriers to private enforcement of constitutional limitations—including massive fines, vicarious liability, and exclusion from federal programs—place the responsibility on FDA to regulate its own conduct. FDA should begin by reviewing all of its enforcement actions for First Amendment compliance and, later, undertake a thorough review of its regulations, guidance documents, and policies.