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Can Speech by FDA-Regulated Firms Ever be Noncommercial?

Nathan Cortez[†]

I. INTRODUCTION

For over a century, the Food and Drug Administration (FDA or the Agency) and its precursors have regulated what companies say about their products.¹ The FDA itself notes that the regulatory scheme imposed by the Federal Food, Drug, and Cosmetic Act “depends on the use of words” and that its requirements can “explicitly limit speech.”² For seventy years, the FDA had little reason to worry about First Amendment constraints. But since 1976, when the Supreme Court reversed its longstanding position that the First Amendment does not protect commercial speech,³ the Agency has had to confront—perhaps more than any other federal agency—the free speech rights of regulated firms.

But how far do those rights extend, and what room do they leave for regulators like the FDA? The answer largely depends on another question: Is the speech commercial or noncommercial? The distinction is paramount. If speech by a regulated firm is commercial, then the FDA can ensure that it is not false or misleading; the Agency can require or compel certain speech; it can impose prior restraints; and it can even limit truthful speech, all within certain parameters.⁴ But if the speech is noncommercial, the FDA may not do many—if any—of these things. The distinction thus determines the extent to which the government can regulate, if at all.

Unfortunately, after three decades of experience with commercial speech, the doctrinal distinctions between commercial and noncommercial speech remain marbled with points of confusion and contention. The prevailing test from *Bolger v. Youngs Drug Products* asks whether the speech is an

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¹ Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (prohibiting “misbranding”).

² Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942, 34,943 (May 13, 2002).

³ *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976).

⁴ Tom Bennigson, *Nike Revisited: Can Commercial Corporations Engage in Non-Commercial Speech?*, 39 CONN. L. REV. 379, 386-87 (2006) (contrasting cases of commercial and noncommercial speech).

advertisement, whether it refers to a specific product, and whether the speaker has an economic motive,⁵ thus considering the form, content, and motivation for the speech. This test capably distinguishes paradigmatic examples of commercial and noncommercial speech. But it is unsatisfactory when categorizing less traditional or even mixed speech, thereby leaving lower courts, regulators, and regulated parties alike with significant uncertainty as to the permissible bounds of regulation.

A point of lingering uncertainty is under what circumstances speech by corporations might qualify for heightened protection as noncommercial. In 2003, the Supreme Court declined to hear *Nike v. Kasky*, passing on a chance to provide much-anticipated guidance.⁶ Before then, the Court established that direct comments on public issues deserve heightened protection, regardless of who is speaking.⁷ But what about other forms of corporate speech? Can speech by regulated firms ever be noncommercial? If so, when?

These are not minor questions for agencies like the FDA that confront myriad forms of speech that are not easily categorized. Marketers of food, drugs, devices, and dietary supplements often speak in ways that disrupt our conventional understanding of what constitutes advertising or promotion. Not only have these companies pioneered the creative use of press releases, web sites, social media, and other formats, but they also speak through intermediaries and third parties—particularly scientific and medical experts—using speakers bureaus, continuing medical education (CME) seminars, industry and academic conferences, and reprints of scientific studies and academic articles.⁸ Are these forms of speech always commercial? What would it take to qualify for heightened protection?

To better answer these questions, this Article offers a framework that identifies the indicia of commercial speech—the relevant factors courts can use to distinguish commercial from noncommercial speech. Relying on both Supreme Court decisions and a systematic review of cases in which FDA-regulated firms claimed First Amendment protection, I propose a more reductionist, disaggregated approach than the three-part test in *Bolger*. *Bolger* considers the form, content and motivation for the speech. I argue that courts should recognize that they are really considering the *Who*, *What*, *When*, *Where*, *Why*, and *How* of the speech at issue: Who is speaking? What is the content of the speech? When is the speech communicated? Where is the speech directed? Why is the speaker speaking? And how is the speech communicated? These questions provide a more complete, detailed picture of

⁵ *Bolger v. Youngs Drug Prods.*, 463 U.S. 60, 66-67 (1983).

⁶ *See Nike v. Kasky*, 539 U.S. 654 (2003).

⁷ *See, e.g.,* *Consol. Edison Co. of N.Y. v. Pub. Serv. Comm'n*, 447 U.S. 530 (1980); *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765 (1978). As Justice Kennedy recently emphasized in his majority opinion in *Citizens United v. Federal Election Commission*, the First Amendment generally prohibits “restrictions distinguishing among different speakers.” *Citizens United v. Fed. Election Comm'n*, 130 S. Ct. 876, 898 (2010). *But, cf.* 130 S. Ct. at 949 (Stevens, J., dissenting) (noting that the majority “dramatically overstates its critique of identity-based distinctions”).

⁸ Indeed, Bill Vodra, a longtime food and drug lawyer and former attorney in FDA's Office of Chief Counsel, made a similar observation over twenty years ago. William W. Vodra, *How the FDA Regulates Drug Promotion and Medical Education Before Drug Approval*, 23 *DRUG INFO. J.* 585, 586 (1989) (noting that “promotional technologies and strategies for marketing drugs have expanded and evolved with unpredicted speed and diversity over the last 10 years”).

the speech. And courts should acknowledge these factors and understand how they operate.

The Article evaluates how courts have applied these factors and offers a few observations. First, when courts apply the three factors from *Bolger*, the distinction often boils down to *why* the speaker is speaking—whether the speech is economically motivated. Despite claims that the Supreme Court is careful not to rest the distinction on commercial intent, which it considers almost “forbidden territory,”⁹ most of the factors indeed look for evidence of commercial intent. As emphasized below, commercial intent can become evident by carefully examining who is speaking, about what, when, where, why, and how. *Why* the speaker is speaking is the most salient factor, but perhaps the most difficult to reliably ascertain.

Second, courts frequently rely on *who* is speaking as a proxy for determining the speaker’s motivations, notwithstanding the Supreme Court’s repeated declarations that not all speech by corporations is necessarily commercial. My review found that out of twenty-four cases in which FDA-regulated firms claimed First Amendment protection, courts categorized the speech as commercial in all but two, neither of which involved FDA rules or enforcement.¹⁰ The case law suggests that courts have developed more than a healthy dose of skepticism regarding speech by FDA-regulated firms, particularly pharmaceutical and medical device manufacturers.¹¹ I consider several types of distinction-blurring speech by these firms—including statements made via press releases and other forms of publicity, speech associated with charitable programs, and speech about off-label uses for FDA-approved products—and conclude that each of the factors would have to align perfectly for a skeptical court to categorize the speech as noncommercial. Thus, the answer to the question in the title (Can speech by FDA-regulated firms ever be noncommercial?) is yes, but only if the stars align.

II. WHY THE DISTINCTION MATTERS

The government enjoys much more latitude to regulate commercial than noncommercial speech. When the speech is commercial, the government can more easily prohibit false or misleading speech, compel speech, impose prior restraints on it, and even limit truthful speech—all of which are extremely problematic in noncommercial contexts.¹² For the FDA’s purposes, this essentially means the difference between being able to regulate or not.

The disparity largely derives from the different tests courts apply. For laws targeting commercial speech, courts apply intermediate scrutiny under the famous four-part test in *Central Hudson Gas & Electric Corp. v. Public Service*

⁹ Alex Kozinski & Stuart Banner, *Who’s Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 640 (1990).

¹⁰ See *infra* Tbl. 1: Cases in Which FDA-Regulated Firms Claimed First Amendment Protection.

¹¹ And for good reason. Bill Vodra notes that “[t]he FDA would probably agree that the pharmaceutical industry has not acted as though it is severely constrained in its advertising and promotion.” Vodra, *supra* note 8, at 587.

¹² Bennis, *supra* note 4, at 386-87 (contrasting cases between commercial and noncommercial speech).

Commission.¹³ The test asks: (i) whether the speech is inherently false or misleading, and if not, continues on to ask; (ii) whether the government asserts a substantial interest; (iii) whether the restriction directly advances that interest; and (iv) whether there is a reasonable fit between the government's ends and the means it uses.¹⁴

By contrast, laws targeting noncommercial speech receive more stringent scrutiny. When the government wants to regulate noncommercial speech directly, it must demonstrate that it has a compelling interest, and that the restriction directly advances that interest using the least restrictive means available.¹⁵ Even content neutral regulations that indirectly affect noncommercial speech must further an important governmental interest that is unrelated to suppressing free expression, and restrict no more speech than necessary.¹⁶

The first factor in *Central Hudson* is crucial, as it recognizes the government's authority to ask whether the content of commercial speech is false or misleading—a query generally forbidden in noncommercial contexts, where restrictions must be content neutral, regardless of the truth or falsity of the speech.¹⁷ Thus, for example, regulators like the FDA can scrutinize the content of a manufacturer's labeling or advertising to determine whether, in the Agency's opinion, it is false or misleading. Noncommercial speech is largely immune from such content-based objections.

The last factor in both the commercial and noncommercial tests look the same, and both essentially ask whether the speech restriction is more burdensome than necessary.¹⁸ But courts apply this criterion much differently depending on whether the speech is commercial or not, tolerating considerably greater burdens on commercial speech.¹⁹ Thus, the distinction largely determines whether, and to what extent, the government can regulate.

Nevertheless, characterizing the speech as commercial does not necessarily mean that courts will uphold restrictions on it.²⁰ Courts have not hesitated to invalidate such restrictions under *Central Hudson*, and the Supreme Court has chastised the government for “seriously underestimat[ing] the value of commercial speech.”²¹

Even so, as FDA-regulated firms devise more novel and creative ways to promote their products, regulators might be guided by Justice Brennan's warning that “those who seek to convey commercial messages will engage in the most imaginative of exercises to place themselves within the safe haven of noncommercial speech, while at the same time conveying their commercial

¹³ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980).

¹⁴ *Id.*

¹⁵ *See, e.g., Reno v. ACLU*, 521 U.S. 844, 868-70 (1997).

¹⁶ *United States v. O'Brien*, 391 U.S. 367, 377 (1968).

¹⁷ *See* Susan H. Williams, *Content Discrimination and the First Amendment*, 139 U. PA. L. REV. 615 (1994).

¹⁸ The Court characterizes the fourth *Central Hudson* criterion this way. 447 U.S. at 566.

¹⁹ Nat Stern, *In Defense of the Imprecise Definition of Commercial Speech*, 58 MD. L. REV. 55, 65 (1999).

²⁰ *Id.* at 95.

²¹ *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 419 (1993).

message.”²² As I demonstrate in Part IV, courts seem to have adopted this skepticism towards FDA-regulated firms.

III. HOW THE DISTINCTION EVOLVED

The distinction between commercial and noncommercial speech first emerged in 1942, when the Supreme Court rejected a transparent attempt to add political objections to an advertisement and use the First Amendment to shield it from regulation.²³ In a “casual, almost offhand” ruling,²⁴ the Court held that the First Amendment does not cover “purely commercial advertising,”²⁵ without elaborating what this meant. So, as the story goes, “the Supreme Court plucked the commercial speech doctrine out of thin air.”²⁶

Although this holding lingered for over three decades, the Court seemed to recognize much earlier that commercial speech deserved at least some protection.²⁷ And with it sprouted the need to define commercial speech with more granularity. When the Supreme Court finally held that the First Amendment protects commercial speech in the mid 1970s,²⁸ it explained in a footnote that “commonsense differences” could distinguish commercial from noncommercial varieties.²⁹ Initially, this meant speech that “does no more than propose a commercial transaction.”³⁰

But instead of sketching out boundaries for tougher cases, the Court was more comfortable speaking about paradigmatic examples, particularly things that clearly were *not* commercial speech.³¹ For example, in *Virginia State Board of Pharmacy*, the Court explained that pure, noncommercial speech is concerned with the “exposition of ideas” about “truth, science, morality, and arts in general,” including “liberal sentiments on the administration of Government.”³² In doing so, the Court contrasted such speech with price advertising for prescription drugs at issue in the case. Therefore, the early

²² *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 540 (1981) (plurality opinion) (Brennan, J., concurring).

²³ See *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942). In *Valentine*, an entrepreneur tried to evade New York City’s Sanitary Code prohibition on distributing commercial handbills in public by printing on the opposite side of his advertisement a statement opposing the City Dock Department’s decision to deny him a permit. See Kozinski & Banner, *supra* note 9, at 627-28.

²⁴ *Cammarano v. United States*, 358 U.S. 498, 514 (1959) (Douglas, J., concurring).

²⁵ *Valentine*, 316 U.S. at 54.

²⁶ Kozinski & Banner, *supra* note 9, at 627.

²⁷ *Id.* at 629 (reciting concurring and dissenting opinions as early as 1959 questioning the holding in *Chrestensen* in 1942).

²⁸ The Court’s decision in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) formally applied the First Amendment to commercial speech, striking down a state statute prohibiting advertising of prescription drug prices. But the previous term, in *Bigelow v. Virginia*, 421 U.S. 809 (1975), the Court struck down a state statute banning newspaper advertisement for abortion procedures, noting that courts must account for First Amendment interests in reviewing regulation of commercial advertising.

²⁹ *Va. State Bd. of Pharmacy*, 425 U.S. at 761-62, 771-72 n.24.

³⁰ *Id.* at 771-72 n.24 (quoting *Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376, 385 (1973)).

³¹ Kozinski & Banner, *supra* note 9, at 638.

³² *Va. State Bd. of Pharmacy*, 425 U.S. at 762 (quoting *Chaplinsky v. New Hampshire*, 315 U.S. 568, 572 (1942); *Roth v. United States*, 354 U.S. 476, 484 (1957)).

cases intuited distinctions between traditional advertising on one hand and romanticized notions of pure speech on the other. But these cases were not equipped to do much else.

Of course, between these two easily identifiable poles resides a great swath of speech that is neither purely commercial nor noncommercial. And eventually litigants would ask the Supreme Court to categorize speech that did not rest comfortably on either end. Indeed, the Court foreshadowed this problem in *Virginia State Board of Pharmacy*, noting that commercial speech is not “wholly undifferentiable from other forms.”³³ But the Court’s 1980 opinion in *Central Hudson* simply explained that commercial speech is any “expression related solely to the economic interests of the speaker and its audience.”³⁴ This definition also seemed too tautological.

The Court recognized that it would need to formulate a test for the tougher cases. Three years later, in *Bolger v. Youngs Drug Products*, the Court broadened its analysis into an implied totality of the circumstances test, asking whether the speech is an advertisement, whether it refers to a specific product, and whether the speaker has an economic motive.³⁵ Though none of these factors alone could render the speech “commercial,” together they could.³⁶ The Court thus gradually shifted from “commonsense” distinctions that could differentiate only classic cases of paradigmatically commercial or noncommercial speech to a series of factors that could handle more difficult ones.

Yet even the more modern test in *Bolger* is marbled with points of confusion and contention. Summarizing the criticisms, one scholar found that “the *Bolger* test has attracted scant endorsement among commentators” who call it “perplexing,” “unworkable,” and other unflattering things.³⁷ To some, even the basic distinction between commercial and noncommercial speech “makes no sense.”³⁸ Justice Thomas would virtually obliterate it.³⁹ Others argue that it is impossible to categorically distinguish commercial from noncommercial speech in any satisfactory way,⁴⁰ as many cases simply do not reflect “a clean distinction between the market for ideas and the market for goods and services.”⁴¹ Still others maintain that commercial speech should not be protected by the First Amendment at all because it does not further any of the First Amendment’s underlying goals or rationales.⁴² Finally, in the middle, dozens of scholars have argued for altering or refining the distinction in various ways,⁴³ as I do here.

³³ *Va. State Bd. of Pharmacy*, 425 U.S. at 771-72 n.24.

³⁴ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 561 (1980).

³⁵ *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-67 (1983).

³⁶ *Id.* at 67.

³⁷ Stern, *supra* note 19, at 86.

³⁸ Kozinski & Banner, *supra* note 9, at 628.

³⁹ See *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 518, 526-28 (Thomas, J., concurring).

⁴⁰ Stern, *supra* note 19, at 75-77 (summarizing others’ arguments on this point).

⁴¹ Thomas H. Jackson & John Calvin Jeffries, Jr., *Commercial Speech: Economic Due Process and the First Amendment*, 65 VA. L. REV. 1, 2 (1979).

⁴² See, e.g., Bennigson, *supra* note 4, at 397; see generally Stern, *supra* note 19, at 73-75.

⁴³ See Stern, *supra* note 19, at 77-79.

Unfortunately, the Supreme Court recently declined an opportunity to clarify the distinction in *Nike v. Kasky*.⁴⁴ In the late 1990s, Nike defended its overseas labor practices against charges that it was underpaying and mistreating foreign workers by using a public relations campaign that included letters to newspaper editors and university administrators, press releases, and other non-advertising documents.⁴⁵ After a consumer sued Nike under California's unfair competition laws⁴⁶ for making false and misleading statements, the California Supreme Court held that Nike's speech was commercial "[b]ecause the messages in question were directed by a commercial speaker to a commercial audience, and because they made representations of fact about the speaker's own business operations for the purpose of promoting sales of its products."⁴⁷

On appeal, the U.S. Supreme Court denied certiorari after originally granting it,⁴⁸ passing up the opportunity to clarify whether Nike's speech was commercial or not. Justice Breyer's dissent argued that although a commercial speaker was addressing its business practices to a commercial audience, the form, content, and regulatory context were all noncommercial, pointing towards heightened protection.⁴⁹ The dismissal surprised those who predicted that the Court would declare Nike's speech to be noncommercial.⁵⁰ Given the Roberts Court's current composition and its aggressive stance towards First Amendment rights, one could certainly envision a different outcome today.

IV. A SURVEY OF THE DISTINCTION IN FDA-RELATED CASES

How have courts made the distinction between commercial and noncommercial speech in FDA-related cases? My research found twenty-four cases since the 1976 *Virginia State Board of Pharmacy* opinion in which an FDA-regulated firm argued that its speech was protected by the First Amendment.⁵¹ Of these, seven involved FDA-regulated firms but did not

⁴⁴ *Nike, Inc. v. Kasky*, 533 U.S. 654 (2003).

⁴⁵ *Id.* at 672 (Breyer, J., dissenting).

⁴⁶ See generally CAL. BUS. & PROF. CODE §§ 17200-17364, 17500 (West 1997).

⁴⁷ *Kasky v. Nike, Inc.*, 45 P.3d 243, 247 (2002).

⁴⁸ *Nike, Inc. v. Kasky*, 533 U.S. 654 (2003).

⁴⁹ *Id.* at 676-79 (Breyer, J., dissenting); see also Erwin Chemerinsky & Catherine Fisk, *What Is Commercial Speech? The Issue Not Decided in Nike v. Kasky*, 54 CASE W. RES. L. REV. 1143 (2003-04) (persuasively arguing that Nike's speech was noncommercial).

⁵⁰ See, e.g., Eugene Volokh, *Nike and the Free-Speech Knot*, WALL ST. J., June 30, 2003, at A16.

⁵¹ Note that I include recent litigation over state prescription confidentiality laws in Vermont, New Hampshire, and Maine that limit the use and dissemination of prescriber data captured by data mining companies. Although the primary plaintiffs are data mining companies like IMS Health, which themselves are not regulated by the FDA, the Pharmaceutical Research and Manufacturers of America (PhRMA) is also a party to some of the litigation, or filed amicus briefs siding with the data mining companies. Note also that I do not include the much-watched case *Allergan v. FDA*, in which the biotech manufacturer challenged FDA's Good Reprint Practices Guidance, see *infra* note 217, arguing that any restrictions on discussing off-label uses of approved drugs are unconstitutional if the speech is truthful and not misleading, and if such off-label uses are "widely accepted" and are reimbursed by government programs like Medicare. Complaint at 28-35, *Allergan, Inc. v. FDA*, No. 1:09-CV-01879 (D.D.C. Oct. 1, 2009). For a discussion of this case, see Osborn, *infra* note 216, at 338-39. Allergan agreed to drop its suit against the FDA in September 2010 as part of a settlement with the government in which Allergan paid \$600 million in civil and

involve FDA rules or enforcement—three alleging unfair competition under the Lanham Act,⁵² three challenging state prescription confidentiality laws,⁵³ and one involving product liability claims.⁵⁴ I include these cases because they generally involve FDA-regulated firms invoking First Amendment defenses of their speech. The Table below identifies the speech at issue in each case, and whether the court deemed it to be commercial or not. I analyze these cases below.

TABLE: CASES IN WHICH FDA-REGULATED FIRMS CLAIMED FIRST
AMENDMENT PROTECTION

1	Alliance for Natural Health v. Sebelius, 2010 WL 2110071 (D.D.C. May 27, 2010)	Health claims on dietary supplement labeling.
2	Commonwealth Brands v. United States, 2009 WL 3754273 (W.D. Ky. Nov. 5, 2009)	Claims about “modified risk tobacco products” made on the label, in the labeling or advertising, or “directed to consumers through the media or otherwise.”
3	United States v. Harkonen, 2009 WL 1578712 (N.D. Cal. June 4, 2009)	Various types of speech discussing the results of a clinical trial, including a press release sent to thousands of potential prescribers.
4	United States v. Caputo, 517 F.3d 935 (7th Cir. 2008)	Various types of promotion for medical devices.
5	United States v. Caronia, 576 F. Supp. 2d 385 (E.D.N.Y. 2008)	Various marketing materials by a sales representative.
	Wallach v. Crawford, 2005 WL	Package including a

criminal fines for promoting Botox off-label. Dep’t of Justice, *Allergan Agrees to Plead Guilty and Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox*, U.S. DEP’T OF JUSTICE (Sept. 1, 2010), <http://www.justice.gov/opa/pr/2010/September/10-civ-988.html>; Allergan, *Allergan Resolves United States Government Investigation of Past Sales and Marketing Practices Relating to Certain Therapeutic Uses of Botox*, ALLERGAN (Sept. 1, 2010), <http://agn.client.shareholder.com/releasedetail.cfm?ReleaseID=503974>.

⁵² See *Beharry v. Bedessee Imports Inc.*, No. 09-CV-0077, 2010 WL 1223590 (E.D.N.Y. Mar. 23, 2010) (alleging that a newspaper article describing FDA enforcement actions against a food importer and a competitor subsequently emailing the article to potential clients violated the Lanham Act); *Bracco Diagnostics v. Amersham Health*, 627 F. Supp. 2d 384 (D.N.J. 2009) (alleging that peer-reviewed scientific journal articles and various print media and oral communications referring to the articles violated the Lanham Act); *In re Warfarin Sodium Antitrust Litig.*, No. MDL 98-1232-SLR, 1998 WL 883469 (D. Del. Dec. 7, 1998) (alleging that computer software, press release, and more traditional written materials used by DuPont Merck violated the Lanham Act).

⁵³ See *IMS Health Inc. v. Sorrell*, 630 F.3d 263 (2d Cir. 2010) (challenging state statute limiting the use and dissemination of prescriber data captured by data mining companies); *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010) (same); *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008) (same).

⁵⁴ See *In re Orthopedic Bone Screw Products Liab. Litig.*, No. MDL 1014, 1997 WL 186325 (E.D. Pa. Apr. 16, 1997) (examining speeches and presentations in seminars and other venues).

6	6054963 (S.D. Cal. Mar. 29, 2005)	cover letter, a reprint of chapter in <i>Physician's Desk Reference</i> , and a list of products and prices.
7	Whitaker v. Thompson, 239 F. Supp. 2d 43 (D.D.C. 2003)	Health claims made on dietary supplement labeling.
8	Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002)	Advertising and promotion for drugs compounded by pharmacists.
9	Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000); Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998)	Reprints of medical textbooks and peer-reviewed journal articles, and CME seminars.
10	Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999)	Health claims on dietary supplement labeling.
11	Wellife Prods. v. Shalala, 52 F.3d 357 (D.C. Cir. 1995)	Health claims on dietary supplement labeling.
12	Nutritional Health Alliance v. Shalala, 953 F. Supp. 526 (S.D.N.Y. 1997)	Health claims on dietary supplement labeling.
13	Wash. Legal Found. v. Kessler, 880 F. Supp. 26 (D.D.C. 1995)	"Enduring materials" (such as medical journals, articles, and textbooks), and scientific or educational activities and symposia. ⁵⁵
14	Mineral Res. Int'l v. Shalala, 53 F.3d 305 (10th Cir. 1995)	Health claims, nutrient content information, and nutrient labeling for foods and dietary supplements.
15	Nat'l Council for Improved Health v. Shalala, 893 F. Supp. 1512 (D. Utah 1995)	Health claims on dietary supplement labeling.
16	United States v. Gen. Nutrition, 638 F. Supp. 556 (W.D.N.Y. 1986)	Marketing materials for dietary supplement.
17	United States v. Undetermined Quantities of Article of Device, Med. Devices Rep. (CCH) ¶ 15,055 (W.D. Mich. 1982)	Self-hypnosis tape recordings making claims to treat various diseases and ailments.
18	Beharry v. Bedessee Imports, 2010 WL 1223590 (E.D.N.Y. Mar. 23, 2010)	Newspaper article describing FDA enforcement against food manufacturer, and

⁵⁵ Although the court in *Kessler* cited *Virginia Board of Pharmacy* as giving rise to a cognizable First Amendment right for standing purposes, the court did not determine whether the Washington Legal Foundations's physician members right to *receive* information from drug manufacturers deserved heightened protection or not. Wash. Legal Found. V. Kessler, 880 F. Supp. 26, 31 (D.D.C. 1995). The court did not cite either *Bolger* or *Central Hudson*.

		emails from competitor to customers attaching the article and offering to discuss it.
19	<i>Bracco Diagnostics v. Amersham Health</i> , 627 F. Supp. 2d 384 (D.N.J. 2009)	Scientific articles published in peer-reviewed academic journals. Brochures, web sites, presentations, and CME seminars referring to the article.
20	<i>In re Warfarin Sodium Antitrust Litig.</i> , 1998 WL 883469 (D. Del. Dec. 7, 1998)	Press releases, computer software for prescribers, letters, faxes, slide presentations, and other forms.
21	<i>IMS Health v. Sorrell</i> , 2010 WL 4723183 (2d Cir. 2010); 631 F. Supp. 2d 434 (D. Vt. 2009)	Gathering, disseminating, and using prescriber data captured by data mining companies (Vermont law).
22	<i>IMS Health v. Ayotte</i> , 550 F.3d 42 (1st Cir. 2008); 490 F. Supp. 2d 163 (D.N.H. 2007)	Gathering, disseminating, and using prescriber data captured by data mining companies (New Hampshire law).
23	<i>IMS Health v. Mills</i> , 616 F.3d 7 (1st Cir. 2010); <i>IMS Health v. Rowe</i> , 552 F. Supp. 2d 153 (D. Me. 2007)	: Gathering, disseminating, and using prescriber data captured by data mining companies (Maine law).
24	<i>In re Orthopedic Bone Screw Prods. Liab. Litig.</i> , 193 F.3d 781 (3d Cir. 1999); 1997 WL 186325 (E.D. Pa. Apr. 16, 1997)	Seminars for physicians discussing devices, delivered by spinal surgeons and other health care professionals, and by professional associations.

Of these twenty-four cases, only two held that the speech was noncommercial, both of which were Lanham Act cases.⁵⁶ Of the seventeen FDA-related cases, no court found the speech to be noncommercial, supporting the observation that “every major lawsuit challenging FDA speech restrictions has proceeded under the assumption that the speech in question is commercial in character.”⁵⁷ However, of these seventeen cases, three courts did not categorize the speech.⁵⁸

⁵⁶ See *Beharry*, 2010 WL 1223590, at *8; *Bracco Diagnostics*, 627 F. Supp. 2d at 456.

⁵⁷ Richard A. Samp, *Courts Are Arriving at a Consensus on Food and Drug Administration Speech Regulation*, 58 FOOD & DRUG L.J. 313, 314; See, e.g., *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).

⁵⁸ See *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 31 (D.D.C. 1995) (citing *Va. Bd. of Pharmacy*, 425 U.S. 728, but only for the standing question, not on the question of whether the speech is commercial or not); *Mineral Res. Int'l v. U.S. Dep't of Health & Human Servs.*, 53 F.3d 305 (10th Cir. 1995) (holding that court lacked jurisdiction and thus not considering First Amendment claims); *United States v. Undetermined Quantities of Article of Device*,

Of the remaining fourteen FDA-related cases in which the court affirmatively found the speech to be commercial, nine did so without really applying (and sometimes without even citing) the *Bolger* test, for example by jumping straight into *Central Hudson*.⁵⁹ Granted, five of these nine involved statements in the label or labeling of FDA-regulated products, which most parties concede are properly categorized as commercial.⁶⁰ And some clearly involved commercial advertising or marketing, in which case the parties often did not even contend that the speech was noncommercial.⁶¹

Only a handful are what could be considered difficult cases, supporting Nat Stern's observation that most commercial expression is clear-cut.⁶² Perhaps the most well-considered opinion was penned by Judge Lamberth in *WLF v. Friedman*. There, the court considered First Amendment challenges to three FDA guidance documents addressing manufacturer use of article reprints, medical textbooks, and CME seminars that discuss off-label uses of FDA-approved products.⁶³ The court noted that reprints, reference texts, and CME seminars are not "typical" commercial speech because "the speech that manufacturers wish to communicate is the speech of others—the work product of scientists, physicians, and other academics."⁶⁴ But in applying the three-part *Bolger* test, the court found that: (i) "these activities are advertisements" because they "emphasize a desirable quality" about the product "in hopes that the physician will prescribe . . . the drug;" (ii) the speech refers to a specific product; and (iii) manufacturers "clearly have an economic motive" because these activities are shown to increase sales.⁶⁵ Hence, even in an ostensibly difficult case involving mixed, scientific speech, the court had no trouble categorizing it as commercial.

Med. Devices Rep., PETER B. HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD & DRUG LAW: CASES AND MATERIALS 71 (3rd ed. 2007) (W.D. Mich. 1982) (allowing audio recordings to be evidence of an intended therapeutic use, though not considering First Amendment possibilities).

⁵⁹ See *Alliance for Natural Health v. Sebelius*, 714 F. Supp. 2d 48, 60-61, (D.D.C. 2010); *United States v. Caputo*, 517 F.3d 935, 938-39 (7th Cir. 2008); *Wallach v. Crawford*, No. 04-CV-216, 2005 WL 6054963, at *8 (S.D. Cal. Mar. 29, 2005); *Whitaker v. Thompson*, 239 F. Supp. 2d 43, 53 (D.D.C. 2003); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367-68 (2002); *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999); *Nutritional Health Alliance v. Shalala*, 953 F. Supp. 526, 529 (S.D.N.Y. 1997); *Nat'l Council for Improved Health v. Shalala*, 893 F. Supp. 1512, 1517 (D. Utah 1995); *United States v. Gen. Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986).

⁶⁰ *Alliance for Natural Health v. Sebelius*; *Whitaker v. Thompson*; *Pearson v. Shalala*; *Nutritional Health Alliance v. Shalala*; *Nat'l Council for Improved Health v. Shalala*.

⁶¹ See *Caputo*, 517 F.3d at 937 (promotion for AbTox medical device); *United States v. Caronia*, 576 F. Supp. 2d 385, 389, 395-96 (E.D.N.Y. 2008) (pharmaceutical sales representative marketing activities); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366 (2002) ("The parties agree that the advertising and soliciting prohibited by the FDAMA constitute commercial speech.").

⁶² See Stern, *supra* note 19, at 94-100 (noting "the prevalence of easy calls" and arguing that "[t]he great majority of the Court's decisions have involved communication that qualifies as commercial speech by virtually any definition.").

⁶³ Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997); Advertising and Promotion; Guidances, 61 Fed. Reg. 52,800 (Oct. 8, 1996).

⁶⁴ *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 62 (D.D.C. 1998).

⁶⁵ *Id.* at 64.

Only in the Lanham Act cases did courts find speech by FDA-regulated firms to be noncommercial. First, in *Beharry v. Bedessee Imports*, the court held not only that an article published in a local newspaper describing FDA enforcement against a food company was noncommercial speech, but also that a competitor was engaged in noncommercial speech when it emailed copies of the article to potential customers with an offer to discuss it.⁶⁶ The first holding is relatively uncontroversial—newspaper articles are generally noncommercial. Even so, the court noted that “[e]ven if the defendants paid to run the piece with a motivation toward indirectly influencing customers to buy their goods, such a motivation does not transform the piece into commercial speech.”⁶⁷ However, the court also held that emails attaching the article were not commercial speech because reproducing the article with an offer to discuss it “is not a commercial proposition or an advertisement.”⁶⁸ This latter holding seems quite dubious, and would be truly exceptional in cases challenging FDA restrictions on speech.

In the other Lanham Act case, *Bracco Diagnostics v. Amersham Health*, the court found that an article in the *New England Journal of Medicine* was noncommercial because “it is a protected form of speech distributed by an impartial educational journal in the field of medicine” and it “did not advocate that the reader purchase a particular product over another.”⁶⁹ However, contrary to the court’s position in *Beharry v. Bedessee Imports*, the court held that “the secondary dissemination of the article . . . does constitute actionable commercial speech.”⁷⁰ The court recognized that the medical device industry uses scientific studies “as an especially important and prevalent marketing tool.”⁷¹ As in *WLF v. Friedman*, the court emphasized that because of the company’s financial motivations and resources, it was much more likely for positive studies about a product to reach customers than negative ones.⁷²

Thus, the *Bracco* holding seems more consonant with prevailing wisdom than the *Beharry* case—journal articles themselves are protected forms of speech that deserve heightened scrutiny, while secondary dissemination of these articles by companies with clear commercial interests do not. Thus, *Beharry* represents the only opinion in which speech by an FDA-regulated company—as opposed to speech by a third party—received heightened protection.

Moreover, the Lanham Act cases are useful only to the extent they can help predict what would happen in FDA cases. Misrepresentation and false advertising claims under the Lanham Act require that the speech occur in commercial advertising or promotion,⁷³ which narrows the universe of speech that might be commercial in other settings. For example, in *Bracco Diagnostics*, the court cited traditional commercial speech cases, but also

⁶⁶ *Beharry v. Bedessee Imports Inc.*, No. 09-CV-0077, 2010 WL 1223590, at *1 (E.D.N.Y. Mar. 23, 2010).

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Bracco Diagnostics v. Amersham Health*, 627 F. Supp. 2d 384, 457 (D.N.J. 2009).

⁷⁰ *Id.* at 458.

⁷¹ *Id.* (quoting *Wash. Legal Found.*, 13 F. Supp. 2d at 63).

⁷² *Id.* at 458-59.

⁷³ 15 U.S.C. § 1125 (2006).

cited Lanham Act cases that seem to construe commercial speech more narrowly as advertising or promotion.⁷⁴

My review thus confirms that courts have yet to encounter an FDA-related case in which the speech was noncommercial. Nonetheless, this finding does not mean that FDA-regulated firms are categorically incapable of speaking noncommercially.

V. INDICIA OF NONCOMMERCIAL SPEECH?

The Supreme Court has identified three factors for determining whether speech is commercial or not, always careful to note that no one factor alone is dispositive.⁷⁵ The prevailing test from *Bolger* asks whether the speech is an advertisement, whether it refers to a specific product, and whether the speaker has an economic motive.⁷⁶ *Bolger* thus considers the form, content, and motivation for the speech.

But doctrinally, with all the possible permutations speech can take, I contend that an even more disaggregated approach would be useful.⁷⁷ Arguably, the first two factors in *Bolger*—whether the speech is an advertisement, and whether it refers to a particular product—both point to the final factor asking whether the speaker is economically motivated. If this is true, we should consider all the indicia of commercial intent by ascertaining the *Who*, *What*, *When*, *Where*, *Why*, and *How* of the speech at issue:⁷⁸

- A. *Who* is speaking? Is it a commercial entity or not?
- B. *What* does the speech discuss? What is the content? Does it refer to a specific product? Does it propose a commercial transaction?
- C. *When* is the speech communicated? Is the timing relevant?
- D. *Where* is the speech directed? Who is the intended audience? Does the speech concern the economic interests of the audience?
- E. *Why* is the speaker speaking? Is the speaker economically motivated?
- F. And *how* is the speech being communicated? Is it an advertisement or a noncommercial format?

These questions further corrugate the three-part *Bolger* test, but together, they can more clearly identify the discrete “indicia of commercial speech”⁷⁹

⁷⁴ *Bracco*, 627 F. Supp. 2d at 455-56.

⁷⁵ *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-67 (1983).

⁷⁶ *Id.*

⁷⁷ Indeed, others have made this argument. See, e.g., Richard L. Barnes, *A Call for a Value-Based Test of Commercial Speech*, 63 WASH. U. L.Q. 649, 706 (1985). Note also that Bill Vodra identifies six factors that FDA generally uses to distinguish promotional activities that it will regulate from educational activities that it will not: (i) the speech’s content; (ii) its context; (iii) its audience; (iv) the medium used to communicate it; (v) the purported rationale for it; and (vi) the real rationale for it. Vodra, *supra* note 8, at 592. He notes that the distinction between promotional and educational activities “is similar to, but not the same as, the Supreme Court’s division between commercial and noncommercial speech.” *Id.* at 591.

⁷⁸ The modern enunciation of what has become “the Five Ws (and one H)” is most often attributed to Rudyard Kipling, “*The Elephant’s Child*,” in *JUST SO STORIES* 63 (Doubleday Page & Co., 1912). Again, Bill Vodra suggested that FDA uses similar but not identical criteria for distinguishing promotional from educational activities. Vodra, *supra* note 8, at 592-96.

⁷⁹ Ralph F. Hall & Elizabeth S. Sobotka, *Inconsistent Government Policies: Why FDA Off-Label Regulation Cannot Survive First Amendment Review under Greater New Orleans*, 62 FOOD & DRUG L.J. 1, 12 (2007).

that distinguish it from noncommercial speech in the novel and difficult cases presented by FDA-regulated firms.

A. WHO?

Although the Supreme Court has refused to categorize all speech by commercial entities as necessarily commercial, *who* is speaking may have the greatest predictive power in anticipating how courts will categorize speech. Indeed, the purpose of this Article is to explore whether speech by FDA-regulated firms can ever be noncommercial. The short answer of course is *yes*. But what would it take?

In non-FDA contexts, the Supreme Court has held that speech by commercial entities can qualify as fully protected noncommercial speech. In *Consolidated Edison Co. of New York v. Public Service Commission*, the Court found that when a power company inserted a pamphlet in its monthly bill advocating nuclear power, it was engaged in fully protected political speech.⁸⁰ The restriction originated with the Public Service Commission, which tried to prohibit Con Ed from including with future bills any materials advocating the company's "opinions or viewpoints on controversial issues of public policy."⁸¹ The Court struck this prohibition down, holding that companies "enjoy the full panoply of First Amendment protections for their direct comments on public issues."⁸²

In the companion case, *Central Hudson*, the Court refused to apply heightened protection to a utility company's advertisements for energy efficient devices, even though the advertisements invoked public concerns about resource conservation.⁸³ The Court drew the line between directly commenting on public issues (*Consolidated Edison*) and drawing connections between products and public issues in advertisements (*Central Hudson*), which almost any advertiser with a brain can do.

Earlier, in *First National Bank of Boston v. Bellotti*, the Court struck down a state statute that prohibited banks and other corporate forms from spending money to influence votes "on any question submitted to the voters, other than one materially affecting any of the property, business or assets of the corporation."⁸⁴ The bank tried campaigning against an amendment to the state constitution that would have authorized a graduated income tax.⁸⁵ Despite the bank's obvious financial interest, the Court held that the value of speech about government affairs does "not depend upon the identity of its source, whether corporation, association, union, or individual."⁸⁶ The Court said that speech should be classified "by its content rather than its origin."⁸⁷

Revisiting the twenty-four cases surveyed above, the vast majority involve speech by or on behalf of drug, device, or dietary supplement manufacturers.

⁸⁰ 447 U.S. 530 (1980).

⁸¹ *Id.* at 533.

⁸² *Cent. Hudson Gas v. Pub. Serv. Comm'n*, 447 U.S. 557, 563 n.3 (referring to the companion holding in *Consolidated Edison*).

⁸³ *Id.* at 557 (1980).

⁸⁴ *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 768 (1978).

⁸⁵ *Id.* at 769.

⁸⁶ *Id.* at 777.

⁸⁷ Stern, *supra* note 19, at 93.

In the Lanham Act cases that found the speech to be noncommercial, both involved speech by a third party in journals or newspapers, and only the outlier opinion in *Beharry* applied heightened scrutiny to the secondary dissemination of the article.⁸⁸ But other than the blip in *Beharry*, none of the FDA-related cases found the speech to be noncommercial, even if made by physicians.⁸⁹ Physicians speaking as independent medical or scientific experts with no financial interest in the product presumably would receive heightened First Amendment protection; physicians speaking on behalf of drug companies presumably would not, absent unique circumstances. Ralph Hall and Elizabeth Sobotka offer a dramatized scenario:

Two people give an identical speech to an identical audience using the identical publicly available scientific information. In doing so, one person is guilty of a felony violation of the Food, Drug, and Cosmetic Act (FDCA); the other is hailed as a scientific leader.⁹⁰

Who is speaking can thus convert pure speech into commercial if a company appropriates it. Again, the court in *WLF v. Friedman* explained that journal reprints, reference texts, and CME seminars are not “typical” commercial speech because manufacturers are communicating the speech of scientists, physicians, and academics not employed by the company.⁹¹ But the court found the speech to be commercial, placing considerable weight on the fact that “this information is in fact supplied by the manufacturer.”⁹²

My intuition is that federal courts will not find speech by FDA-regulated firms to be noncommercial unless all the other criteria neatly align. Some think this is entirely appropriate. And some would even argue that all speech by corporations should be commercial, regardless of the content or circumstances.⁹³ Though the Supreme Court recently warned against

⁸⁸ *Edward B. Beharry & Co. v. Bedessee Imps. Inc.*, No. 09-CV-0077, 2010 WL 1223590, at *8 (E.D.N.Y. Mar. 23, 2010); *Bracco Diagnostics v. Amersham Health*, 627 F. Supp. 2d 384, 456-58 (D.N.J. 2009).

⁸⁹ *United States v. Harkonen*, No. C 08-00164, 2009 WL 1578712, at *6 (N.D. Cal. June 4, 2009) (noting that “[t]he mere fact that Harkonen is an M.D.” did not render the speech noncommercial); *Whitaker v. Thompson*, 239 F. Supp. 2d 43, 53 (D.D.C. 2003) (spending little time considering whether speech is commercial or not even though plaintiffs included a physician); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, No. MDL 1014, 1997 WL 186325 (E.D. Pa. Apr. 16, 1997) (seminar presentations by physicians speaking on behalf of medical device manufacturers). In *United States v. Caronia*, 576 F. Supp. 2d 385, 395-96 (E.D.N.Y. 2008), a pharmaceutical sales representative adopted First Amendment defenses by a physician defendant, Dr. Gleason. Although Caronia did not argue that his speech was noncommercial, the court noted that Dr. Gleason had made such an argument before pleading guilty to misbranding under the FDCA. *Id.* at 390, 395-96.

⁹⁰ Hall & Sobotka, *supra* note 79.

⁹¹ *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 62 (D.D.C. 1998).

⁹² *Id.* at 65.

⁹³ Richard M. Alderman, *Commercial Entities' Noncommercial Speech: A Contradiction in Terms*, 1982 UTAH L. REV. 731, 744 (1982); see also Tom Bennigson, *Nike Revisited: Can Commercial Corporations Engage in Non-Commercial Speech?*, 39 CONN. L. REV. 379, 393-96 (2006) (arguing that because corporations have a fiduciary duty to shareholders to pursue corporate profits, “all legitimate corporate expenditures . . . must be commercial in a sense, including expenditures to publish speech”).

regulations that render speech to be legal or illegal based on who is speaking,⁹⁴ FDA's regulatory scheme requires precisely this.

B. WHAT?

What does the speech discuss? What is its content? The first two factors in *Bolger*—asking whether the speech is an advertisement, and whether it refers to a particular product⁹⁵—require courts to scrutinize the content of the speech.

The second factor, asking whether the speech refers to a specific product, is relatively straightforward, with one complication in FDA contexts. Firms might try to evade FDA's jurisdiction over "labels" and "labeling" by referring to products not by name, but by mentioning a class of products that includes their own, or by discussing the product's uses or the diseases or conditions that it treats, or by using any number of proxies without naming the product itself. Theoretically, a company might seek heightened protection for speech discussing a medical condition without explicitly mentioning the product that treats it. Nevertheless, FDA is usually able to read between the lines, and the Supreme Court has affirmed FDA's broad jurisdiction over "labeling" to include any materials that "accompany," or "supplement or explain" a product.⁹⁶

But the theoretical limitation remains. The court in *WLF v. Friedman* noted that industry-sponsored CME might qualify as noncommercial speech if manufacturers supported "CME regardless of whether their products would ultimately be addressed."⁹⁷ Indeed, this would seem to satisfy FDA's longstanding recommendation that firms that sponsor "educational" seminars or symposia "have little or no influence" over the venue, speaker, topics, or written materials associated with such events.⁹⁸

Typically, the more difficult consideration is whether the speech is an advertisement under the first criterion in *Bolger*. The decisions that I surveyed above interpreted this factor liberally. In *United States v. Caronia*, the court applied a functional definition of "advertisement" to find that various promotional activities by a pharmaceutical sales representative were commercial speech.⁹⁹ And in *WLF v. Friedman*, the court found that hosting CME seminars and distributing reprints of scientific and medical articles were "advertisements" because they "emphasize a desirable quality" about the product "in hopes that the physician will prescribe" it.¹⁰⁰ Courts recognize that

⁹⁴ See *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 191 (1999). For an argument that FDA's restrictions on off-label promotion violate *Greater New Orleans*, see Hall & Sobotka, *supra* note 79. Note also that the Court's recent decision in *Citizens United v. FEC*, 130 S. Ct. 876 (2010), expressed significant skepticism about "speech restrictions based on the identity of the speaker," *id.* at 899, although the restrictions here were clearly focused on political, noncommercial speech. *Id.* at 886.

⁹⁵ *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 69 (1983).

⁹⁶ *Kordel v. United States*, 335 U.S. 345, 348-52 (1948); *United States v. Urbuteit*, 335 U.S. 355, 357 (1948).

⁹⁷ *Wash. Legal Found.*, 13 F. Supp. 2d at 64.

⁹⁸ *Vodra*, *supra* note 8, at 591 (citing a March 14, 1989 speech by Ken Feather to the Pharmaceutical Manufacturers Association Marketing Section).

⁹⁹ *United States v. Caronia*, 576 F. Supp. 2d 385, 389, 395-96 (E.D.N.Y. 2008).

¹⁰⁰ *Wash. Legal Found.*, 13 F. Supp. 2d at 64.

“advertisement” should be construed broadly, particularly for FDA-regulated firms.

Of course, the content of speech can include both commercial and noncommercial elements—so-called “hybrid” speech. In non-FDA cases, the Court has severed commercial from noncommercial elements,¹⁰¹ suggesting that “severable noncommercial elements of the mixed speech at issue would be fully protected if removed from the setting of commercial solicitation.”¹⁰² Accordingly, political pamphlets included with utility bills can qualify as noncommercial speech, even if the bill itself is plainly commercial.¹⁰³

The trick of course is determining whether the elements of speech are indeed severable. The Court will ask “whether the content of a communication contains an essential, inextricable dimension of fully protected expression.”¹⁰⁴ If the noncommercial elements are essential to the communication,¹⁰⁵ the non-severable commercial elements will also receive heightened protection.

In the FDA cases I surveyed, courts have not been very charitable on this point. For example, in *IMS Health v. Sorrell*, the court found that prescribing data “combines commercial and noncommercial elements” because “[i]t is factual information with a degree of redeeming social importance” that could be used to improve public health, for example, by contributing to health research, educational communications, or safety notices.¹⁰⁶ In *IMS Health v. Ayotte*, the First Circuit said that even if gathering and disseminating prescriber data for marketing purposes was speech rather than conduct, it “is of scant societal value.”¹⁰⁷ Yet, courts in FDA-related cases have not been confronted with fact patterns similar to those in *Consolidated Edison* or *Bellotti*. Thus, for example, FDA-regulated firms might be able to directly comment on public policy issues in pamphlets distributed with physician labeling, although none have found it worthwhile to do so.

Another complication in using the content of speech to categorize it arises when the speech is scientific. Some of the most difficult cases concern companies’ scientific claims about the health and safety of their products.¹⁰⁸ Courts have been careful to note that scientific articles and publications are “a protected form of speech,” warning that it would be “inappropriate to inquire into the validity of scientific theories which are not commercial speech and promulgated in scientific journals.”¹⁰⁹ Yet, courts will look beyond the form of the speech by asking, for example, whether a company sponsored the underlying research or paid the author to write the article, and whether the

¹⁰¹ Stern, *supra* note 19, at 89-92.

¹⁰² *Id.* at 121.

¹⁰³ First Nat’l Bank of Boston v. Bellotti, 435 U.S. 765, 775-86 (1978); see *Consol. Edison Co. of N.Y. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 530, 537-41 (1980).

¹⁰⁴ Stern, *supra* note 19, at 89 (citing *Riley v. Nat’l Fed’n of the Blind of N.C., Inc.*, 487 U.S. 781, 786 (1988)).

¹⁰⁵ Bd. of Trs. of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 474 (1989) (analyzing a university rule that prohibited commercial entities from operating on campus).

¹⁰⁶ *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434, 447 (D. Vt. 2009).

¹⁰⁷ *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 52 (1st Cir. 2008).

¹⁰⁸ Stern, *supra* note 19, at 127.

¹⁰⁹ *Bracco Diagnostics v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 457-58 (D.N.J. 2009) See Bd. of Trs. of Leland Stanford Univ. v. Sullivan, 773 F. Supp. 472, 474 (D.C. Cir. 1991) (“It is equally settled . . . that the First Amendment protects scientific expression and debate just as it protects political and artistic expression.”).

article itself recommended that readers buy one product over another.¹¹⁰ There is a good argument that drug companies that hire “ghostwriters” to publish positive scientific articles about their products are engaged in commercial speech.¹¹¹ Thus, even in ostensibly difficult cases, courts’ categorization of the speech as commercial is easily defensible.¹¹²

Judicial skepticism here might stem from courts’ recognition that scientific and medical publications are “an especially important and prevalent marketing tool” for FDA-regulated industries.¹¹³ Indeed, some courts find that manufacturer dissemination of scientific literature is commercial speech without much analysis.¹¹⁴ Courts also recognize that a company’s resources and motivations make it much more likely for positive studies about products to reach prescribers than negative ones,¹¹⁵ removing some of the noncommercial gloss from these publications.

Thus, although mixed scientific speech would seem to complicate the content analysis in FDA cases, few courts have struggled to categorize speech by FDA-regulated firms as commercial.¹¹⁶

C. WHEN?

Courts and scholars have not paid much attention to *when* speech is communicated, and how such timing might distinguish commercial from noncommercial speech. Nevertheless, the timing of speech might reveal its motivations. For example, when considering whether a press release by DuPont Merck that questioned the safety of a new generic competitor was commercial, the court noted that DuPont had timed the press release to coincide with the generic drug’s release.¹¹⁷ Conversely, if a company makes public statements in a debate about the safety of a product that it has recalled or otherwise no longer markets, this could suggest noncommercial motives.¹¹⁸

¹¹⁰ 627 F. Supp. 2d at 457-58.

¹¹¹ See, e.g., Duff Wilson, *Drug Maker Hired Writing Company for Doctor’s Book, Documents Say*, N.Y. TIMES, (Nov. 29, 2010), <http://www.nytimes.com/2010/11/30/business/30drug.html>.

¹¹² See, e.g., Nat’l Comm’n on Egg Nutrition v. FTC, 570 F.2d 157 (7th Cir. 1977) (upholding FTC order that prohibited trade association from running false ads arguing that “there is no scientific evidence that eating eggs increases the risk of . . . heart [and circulatory] disease . . .”); *In re R.J. Reynolds Tobacco Co.*, 111 F.T.C. 539 (1988) (FTC decision that advertisement titled “Of Cigarettes and Science” qualified as commercial speech under *Bolger* criteria).

¹¹³ Bracco Diagnostics, 627 F. Supp. 2d at 458; Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 63 (D.D.C. 1998).

¹¹⁴ Wallach v. Crawford, No. 04-CV-216, 2005 WL 6054963 (S.D. Cal. Mar. 29, 2005) (involving dietary supplement manufacturers distributing portions of a chapter in the *Physician’s Desk Reference* discussing the therapeutic uses and health effects of magnesium).

¹¹⁵ See Bracco Diagnostics, 627 F. Supp. 2d at 458-59; Wash. Legal Found. v. Friedman, 13 F. Supp. 2d at 65; Margaret A. Hamburg, *Innovation, Regulation, and the FDA*, 363 NEW ENG. J. MED. 2228, 2231 (2010) (discussing studies showing that larger percentages of positive trials are published than negative ones).

¹¹⁶ Moreover, FDA tends to look at the content of speech only after using other criteria to determine if it is promotional or educational. Vodra, *supra* note 8, at 593.

¹¹⁷ *In re Warfarin Sodium Antitrust Litig.*, No. MDL 98-1232-SLR, 1998 U.S. Dist. WL 883469, at *13-14 (D. Del. Dec. 7, 1998).

¹¹⁸ Of course, companies that recall products often do so temporarily and hope to sell them again, in which case the company would have clear commercial motives to defend its product. Pfizer, for example, vigorously defended Vioxx after it was pulled from the market.

D. WHERE?

Where is the speech directed? Is it to potential customers or prescribers? To patients? Investors? The scientific community? Policymakers? The Supreme Court's early jurisprudence identified commercial speech as that relating to the economic interests of the speaker and *its audience*.¹¹⁹ In the *Nike* case, the California Supreme Court noted that the audience targeted by Nike—college administrators and the general public—“is likely to be actual or potential buyers or customers of the speaker's goods or services, or persons acting for actual or potential buyers or customers.”¹²⁰ Nike thus addressed its arguments to customers and potential customers. Of course, examining the target audience is not a foolproof analysis for companies like Nike whose customer base is broad and general, and who might be the intended recipients of both advertisements and public policy arguments.

Similarly, it is not easy to categorize speech by FDA-regulated firms based solely on its audience. Ordinarily, scientific speech directed at the scientific or medical communities might warrant more protection than speech directed at customers. But again, FDA-regulated firms complicate this analysis because these audiences overlap—physicians and other prescribers that properly belong to the medical and scientific community are also potential customers. In fact, courts considering First Amendment defenses to FDA actions have noted that pharmaceutical marketing and promotion is unique in this regard.¹²¹

Nevertheless, FDA policies recognize the importance of the target audience. The prohibition against promoting products for off-label uses carves out exceptions for companies wishing to discuss off-label uses with investors, researchers, and research subjects.¹²² But even these exceptions cause problems for the FDA, which recognizes that physicians and potential prescribers might also be investors and researchers.¹²³ Thus, although the target audience might be a relevant factor in delineating commercial from noncommercial speech, it can provide conflicting evidence as to the speaker's motives.

Further complicating the analysis is the reality that companies may target primary and secondary audiences. For example, in 1987 FDA objected to Sandoz publishing a full-page “notice” in the *New York Times* and *Washington Post* stating that one of its products did not cause a particular side effect.¹²⁴ Though the notice was addressed to physicians, the FDA took the position that Sandoz was trying to promote the product because it could have used more targeted ways to communicate that message to physicians.¹²⁵ Likewise, in the mid-1980s the saga of ICN Pharmaceuticals was notable in part because ICN sent video news segments to shareholders and television stations

¹¹⁹ Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 561 (1980).

¹²⁰ Kasky v. Nike, Inc., 45 P.3d 243, 256 (Cal. 2002).

¹²¹ Wash. Legal Found. v. Friedman, 13 F. Supp. 2d at 64.

¹²² Hall & Sobotka, *supra* note 79, at 9. For example, companies can violate their obligations under federal securities law if they fail to disclose material information about products. See, e.g., SEC v. Biopure Corp., Civil No. 05-11853 WGY (Sept. 14, 2005).

¹²³ Vodra, *supra* note 8, at 592-96; Hall & Sobotka, *supra* note 79, at 9.

¹²⁴ Vodra, *supra* note 8, at 594.

¹²⁵ *Id.*

discussing research supporting new uses for one of its products.¹²⁶ Again, the FDA found that ICN was trying to promote the product because communicating to investors did not require national media.¹²⁷

In both cases, the company tried to camouflage its intent to promote to a secondary audience by ostensibly targeting a more innocent primary audience first. Consequently, courts should read between the lines as the FDA has learned to do.

E. WHY?

Why is the speaker speaking? The speaker's motives are perhaps the most important factor in determining whether the speech is commercial or not. The Supreme Court's early jurisprudence relied heavily on economic motives to identify commercial speech. In *Central Hudson*, the Court said that speech is commercial if it "related solely to the economic interests of the speaker and its audience."¹²⁸ In *Bolger*, the test evolved to include three factors, the third being whether the speech is economically motivated.¹²⁹ Again, it is arguable that the first two factors—whether the speech is an advertisement, and whether it discusses a particular product—also try to illuminate *why* the speaker is speaking.

Yet, as early as *Virginia Board of Pharmacy*, the Court recognized that economic motives do not automatically disqualify speech from heightened protection.¹³⁰ In *Bolger*, the Court reiterated that an economic motive, without more, does not render the speech commercial.¹³¹ For the tougher cases, *Central Hudson* delineated between "direct comments on public issues" that deserve heightened protection and public policy arguments "made only in the context of commercial transactions."¹³² Thus, although the Court clearly considers commercial intent, it is careful not to over-rely on it.

The Court's hesitation may stem from the problem of ascertaining commercial intent, and the reality that even noncommercial speech may be economically motivated. Justice Stevens observed that "even Shakespeare may have been motivated by the prospect of pecuniary reward."¹³³ Indeed, the Court has found speech by commercial entities to be noncommercial in cases in which the entity had a clear financial interest in speaking.¹³⁴ Lower courts have also shown a willingness to painstakingly review the content of speech to determine whether it proposes a commercial transaction or otherwise tries to

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561 (1980).

¹²⁹ *See Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 65-68 (1983) (stating that the fact that pamphlets are advertisements, refer to a specific product, and are economically motivated provides "strong support" that the pamphlets are "properly characterized as commercial speech").

¹³⁰ *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 762 (1976).

¹³¹ *Bolger*, 463 U.S. at 66.

¹³² 447 U.S. at 563 & n.5.

¹³³ *Id.* at 580 (Stevens, J., concurring).

¹³⁴ *See Consol. Edison Co. of N.Y. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 530 (1980) (energy utility company advocating for nuclear power); *Fist Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765 (1978) (bank objecting to proposed amendment to state constitution authorizing personal income tax).

induce sales.¹³⁵ Thus, the Court has always been careful to avoid resting the distinction on commercial intent,¹³⁶ which it considers almost “forbidden territory.”¹³⁷ Nevertheless, most of the factors that courts consider essentially point towards the overarching question of why the speaker is speaking.

It is worth noting that in recent years, litigants and government investigators have uncovered internal documents that reveal motivations far different than those cited by drug and device companies.¹³⁸ In the past decade, aggressive enforcement of federal fraud and abuse laws has pulled the curtain on industry marketing and promotional practices, revealing creative, sophisticated, and far-reaching efforts to generate sales. These nontraditional methods often obscure commercial intent with ostensibly educational or scientific speech.

Mixed or “hybrid” speech complicates the analysis, as noted above, but the Court has held that mixed motives do not, in and of themselves, render otherwise commercial speech noncommercial.¹³⁹ For example, “advertising which links a product to a current public debate is not thereby entitled” to heightened protection.¹⁴⁰ The query is “whether the content of a communication contains an essential, inextricable dimension of fully protected expression.”¹⁴¹ The speech in *Nike v. Kasky* was a unique mix of commercial and noncommercial. Breyer’s dissent argued that Nike’s speech deserved heightened protection in part because Nike’s contribution to the debate over its foreign labor practices was central rather than peripheral.¹⁴²

Other courts have rejected the argument by companies that commercial aspects of speech are “inextricably intertwined” with noncommercial ones, or that it is impossible to “delink” the products from public debates about them.¹⁴³ Courts may ask whether the company is responsible for linking the commercial and noncommercial aspects. It is one thing for noncommercial speech to be “inextricably intertwined” with commercial speech, such that the noncommercial elements are essential to the communication,¹⁴⁴ it is quite another when a company “voluntarily intertwines” the speech.¹⁴⁵ In the *Warfarin Sodium Antitrust Litigation*, the court found that DuPont Merck’s

¹³⁵ See, e.g., *Slane v. Emoto*, 582 F. Supp. 2d 1067, 1080-83 (W.D. Wis. 2008) (reviewing a naturopath’s books discussing the therapeutic effects of water and various devices, finding that it was noncommercial speech because “[n]o statement in any of the books proposes a commercial transaction with respect to any [product]”).

¹³⁶ *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 761-65 (1976).

¹³⁷ *Kozinski & Banner*, *supra* note 9, at 640.

¹³⁸ Indeed, *Vodra* noted in 1989 that the purported rationale for drug industry speech often varied from its “true intent.” *Vodra*, *supra* note 8, at 595.

¹³⁹ See *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 67-68 (1983).

¹⁴⁰ *Id.* at 68 (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 563, n.5 (1980)).

¹⁴¹ *Stern*, *supra* note 19, at 89 (citing *Riley v. Nat’l Fed’n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988)).

¹⁴² *Nike, Inc. v. Kasky*, 539 U.S. 654, 677-78 (2003) (Breyer, J., concurring).

¹⁴³ *Commonwealth Brands v. United States*, No. 1:09-CV-117M, 2009 WL 3754273, at *6 (W.D. Ky. Nov. 5, 2009).

¹⁴⁴ *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 474 (1989) (analyzing a university rule that prohibited commercial entities from operating on campus).

¹⁴⁵ *In re Warfarin Sodium Antitrust Litig.*, No. MDL 98-1232-SLR, 1998 WL 883469, at *15 (D. Del. Dec. 7, 1998).

speech was commercial notwithstanding its noncommercial elements that discussed drug safety in scientific and medical terms.¹⁴⁶ DuPont Merck's statements "were not confined solely to defendant's efforts to influence public policy on generic substitution of warfarin sodium drugs."¹⁴⁷

And although CME seminars include scientific and medical discussions that could easily qualify as noncommercial speech in a vacuum, courts have found that these seminars increase sales and are clearly economically motivated.¹⁴⁸ Thus, companies cannot insulate promotional efforts by inserting noncommercial speech. In fact, when the Court first confronted commercial speech back in 1942, it declined to protect an advertisement that had been amended to include political statements for the purpose of insulating it from regulation.¹⁴⁹

What if the speaker's motives are mixed but skew much more heavily towards the noncommercial? The Court has held that companies deserve full First Amendment protection for noncommercial speech that directly addresses issues of public concern, even if the speaker has an obvious financial interest.¹⁵⁰ Thus, for example, it might be difficult for state or federal law to prohibit drug manufacturers from funding CME *at all* if the company has no influence over the speaker, the subject, or the content of the seminar, and does not engage in any marketing or advertising in connection with it.¹⁵¹ Likewise, a noncommercial standard might apply to speeches by medical or scientific personnel from drug companies, speaking at events that were clearly scientific or educational, for example as being one speaker on a panel of experts at a university conference.

A key question might be whether the speaker would communicate the speech if it would have no foreseeable affect, or even a negative effect, on future sales? For example, what if a drug company sponsored a CME seminar that focused on negative clinical trial results for its product? What if a company distributed reprints of a journal article that speaks favorably about a competitor's product but not its own? In *WLF v. Friedman*, the court explained that manufacturers will only disseminate studies that present their products in a "favorable light."¹⁵²

But companies will often discuss the limitations of their products, particularly if that limitation is the lack of FDA approval. For example, an executive for Genentech cautioned in an interview with a physician publication that even though retinal physicians were using its product Avastin off-label to treat age-related macular degeneration, "there have been no safety and toxicity studies conducted on Avastin" for that use.¹⁵³ The executive also

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at *14.

¹⁴⁸ *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 64 (1998).

¹⁴⁹ *Valentine v. Chrestensen*, 316 U.S. 52, 55 (1942).

¹⁵⁰ *Bolger v. Youngs Drug Prods. Corp.*, 463 60, 68 (1983); *Consol. Edison Co. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 530, 544 (1980).

¹⁵¹ See, e.g. *Wash. Legal Found.*, 13 F. Supp. 2d at 64 (noting that the speech might be noncommercial if manufacturers supported "CME regardless of whether their products would ultimately be addressed").

¹⁵² *Id.* at 65.

¹⁵³ *Genentech: Avastin Not Intended for AMD: Company Cautions on Off-Label Use of Cancer Drug, RETINAL PHYSICIAN* (Jan. 2006), <http://www.retinalphysician.com/article.aspx?article=100181>.

warned that the drug and its manufacturing standards may not be suitable as an ophthalmic drug.¹⁵⁴ Such statements, standing alone, would probably qualify as fully protected speech.

Of course, he did not stop there. The Genentech executive also stated in the same interview that physicians prescribing Avastin for off-label uses “are doing it with noble intent, which is to help patients who are going blind as we speak,” commending retinal physicians for being “a close-knit, well-informed group that has excellent communication and is motivated to do the best they can for their patients.”¹⁵⁵ A skeptical court might construe this as a wink and a nod—warning that Avastin has not been tested for ophthalmic uses, but patting prescribers on the back for using it in this way (in a publication specifically targeted to retinal physicians, no less).

Moreover, even ostensibly negative statements by a company about its products might be commercially motivated on a deeper level. For example, a company might warn the public about a product’s risks and side effects to insulate the company from future legal liability.¹⁵⁶ Even though such a statement obviously would not propose a commercial transaction, it could ultimately affect the company’s balance sheets.

Thus, *why* the speaker is speaking may be the most important inquiry in *Bolger*—and also the most difficult to prove objectively. The other factors in *Bolger* arguably point to this question. I offer additional factors to consider, but even these also arguably point to the fulcrum question of why the speaker is speaking. Is it to propose a commercial transaction or otherwise to generate sales? This so-called “forbidden territory”¹⁵⁷ seems to be the key inquiry.

F. How?

How is the speech communicated? In what form and context? From early in its commercial speech jurisprudence, the Supreme Court has recognized that simply because speech is made via an advertisement “clearly does not compel the conclusion that [it is] commercial speech.”¹⁵⁸ Although the second factor in *Bolger* asks whether the speech is an advertisement, this factor alone is not dispositive.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* For a general discussion, see Osborn, *supra* note 51, at 336-38. Although Osborn questions whether Genentech “could lawfully communicate directly to physicians *any* safety information that related to the off-label use” of Avastin for AMD during this period, this position is exceedingly cautious and of questionable accuracy. *Id.* at 338 (emphasis added). Ralph Hall and Elizabeth Sobotka also take a surprisingly restrictive view of what companies could lawfully communicate about off-label uses. Hall & Sobotka, *supra* note 79. Obviously, there is significant uncertainty over what FDA would and would not permit. But it is highly unlikely that FDA would, as an enforcement matter, pursue companies for off-label promotion on the sole basis of communicating scientific studies or sharing concerns about the safety of off-label uses without also attempting to promote that use. See FDA, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), <http://www.fda.gov/oc/op/goodreprint.html>.

¹⁵⁶ Hall & Sobotka, *supra* note 79, at 14 (doubting that a court would consider this to be a sufficient economic motivation).

¹⁵⁷ Kozinski & Banner, *supra* note 9, at 640.

¹⁵⁸ *Bolger v. Youngs Drug Prods. Corp.*, 463 60, 66 (1983) (citing *N.Y. Times v. Sullivan*, 376 U.S. 254, 265-66 (1964)).

On the flipside, courts have also been unwilling to categorize speech as noncommercial just because it is not communicated via traditional advertisements or promotion.¹⁵⁹ For example, the court in *Commonwealth Brands* recently rejected an argument that the Family Smoking Prevention and Tobacco Control Act regulated noncommercial speech because it restricted materials other than labeling or advertising about certain tobacco products.¹⁶⁰ The court explained that “press releases, booklets, and television appearances” were not necessarily pure speech if the statute targets “speech by economically-motivated tobacco-product manufacturers” that direct these communications to consumers and discuss specific products.¹⁶¹ The court also emphasized that tobacco companies have a history of using “a variety of media including scientific research papers” to mislead consumers about the health risks of tobacco products.¹⁶² Thus, courts will not hesitate to apply commercial speech standards if the speech is clearly economically motivated, regardless of the form it takes or how it is communicated.

As noted above, several courts in FDA-related cases have had no problem categorizing nontraditional forms of speech as commercial. For example, in *United States v. Harkonen*, the court rejected a drug executive’s argument that press releases discussing clinical trial results were pure scientific or even mixed speech.¹⁶³ The press release in question misrepresented study results for the drug Actimmune, and was distributed by sales representatives and faxed to over 2,000 potential prescribers.¹⁶⁴ The court applied the criteria in *Bolger* and found that: (i) the speech was a press release and not itself a peer-reviewed publication; (ii) it referred to a specific commercial product; and (iii) it was “unquestionably disseminated for commercial benefit.”¹⁶⁵ The court explained that “[t]he mere fact that Harkonen is an M.D., that the press release he prepared presented actual data and statistical analyses, and that the dissemination of the press release may have generated vigorous debate . . . do not disturb this conclusion.”¹⁶⁶ The court hammered the point home by noting that the case “would present a thorny issue for the court were it not for the fact that the allegations . . . do not trench anywhere near the outer bounds of speech deemed commercial.”¹⁶⁷ The lesson is that manipulating how the speech is communicated will not mask its content or motivations.

¹⁵⁹ Note that courts have been careful in FDA contexts not to stretch FDA’s jurisdiction to books and other publications that espouse “ideas, beliefs and mental processes.” *United States v. Undetermined Quantities of Article of Device*, Med. Devices Rep. (CCH) ¶ 15,055 (W.D. Mich. Nov. 22, 1982) (holding that FDA could use statements in books and other materials as objective evidence of “intended use,” without asserting jurisdiction over those materials directly).

¹⁶⁰ *Commonwealth Brands, Inc.* No. 1:09-CV-117-M, 2009 WL 3754273, at *6 (W.D. Ky. Nov. 5, 2009).

¹⁶¹ *Id.* at *6.

¹⁶² *Id.* (citing *United States v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1121 (D.C. Cir. 2009)).

¹⁶³ *United States v. Harkonen*, No. C08-00164 MHP, 2009 WL 1578712, at *6 (N.D. Cal. June 4, 2009).

¹⁶⁴ *Id.* at *1-3.

¹⁶⁵ *Id.* at *6.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

In fact, courts will take a hard look at how the information is packaged, presented, and distributed—the circumstances surrounding how the speech is communicated. In *Wallach v. Crawford*, the court found that a packet of information distributed by a dietary supplement manufacturer was commercial even though it included a chapter from the *Physician's Desk Reference*, a “peer-reviewed scientific reference text.”¹⁶⁸ The manufacturer sent the reprint to potential customers along with a cover letter, a list of the company's products and their prices, and stickers affixed to each page with the company's name, logo, and phone number.¹⁶⁹ The packet was clearly intended to induce sales, and the court spent very little time declaring it commercial.¹⁷⁰ Likewise, in the *Warfarin Sodium Antitrust Litigation*, the court found that press releases, computer software, letters, faxes, slide presentations, and other forms of speech by DuPont Merck were commercial because each promoted the company's product in relation to its generic competitor.¹⁷¹

Context matters here. For example, even ostensibly scientific or medical speech communicated via educational seminars and CME events can be commercial if the circumstances reveal a promotional intent.¹⁷² For example, in the *Orthopedic Bone Screw Litigation*, the court noted that if a seminar is organized by sales and marketing personnel, if these personnel track attendees or follow up with sales calls, if they distribute marketing and promotional materials at booths, and if the physician speakers have a direct financial stake, then the seminars as a whole would be commercial.¹⁷³ The Third Circuit concluded that “[i]f true, these allegations would provide strong support for characterizing the seminars as commercial speech.”¹⁷⁴

This contextual evidence also drives FDA policy. For example, when the FDA decides whether a seminar is educational (and thus largely exempt from FDA requirements) or promotional (and not exempt), it considers who is speaking, whether and how the speaker is compensated, whether there is interaction with the audience suggesting a scientific exchange, the setting in which the speech occurs, and what inducements the audience received to attend.¹⁷⁵ A genuinely educational program will not involve company representatives presenting branded information, without the chance for questions and answers, on an “expense-paid cruise to Bermuda,” for example.¹⁷⁶ Even if the content itself is scientific—for example, presenting the results of clinical trials—the context would clearly be commercial.

¹⁶⁸ *Wallach v. Crawford*, No. 04-CV-216, 2005 WL 6054963, at *1 (S.D. Cal. Mar. 29, 2005).

¹⁶⁹ *Id.* at *1.

¹⁷⁰ *See id.* at *8.

¹⁷¹ *In re Warfarin Sodium Antitrust Litig.*, No. MDL 98-1232-SLR, 1998 WL 883469, at *11-15 (D. Del. Dec. 17, 1998).

¹⁷² *See, e.g., In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 793 (3d Cir. 1999) (not finding enough evidence at the motion to dismiss stage to determine whether the speech was commercial or not).

¹⁷³ *Id.* at 793; *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1997 WL 186325, at *13.

¹⁷⁴ *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d at 793. The court, however, went on to note that this was a factual dispute that the court was not prepared to resolve at the motion to dismiss stage. *Id.* at 794.

¹⁷⁵ *Vodra, supra* note 8, at 593-94.

¹⁷⁶ *Id.* at 593.

Even speech that is inherently scientific—such as health claims about dietary supplements—is routinely treated by courts as commercial if it appears on the label or in the labeling of FDA-regulated products. For example, the claims that antioxidants reduce the risk of certain cancers or that omega-3 fatty acids may reduce the risk of coronary heart disease are, on their face, scientific. But courts recognize that marketers add these claims “presumably hoping to bolster sales by increasing the allure of their supplements’ labels”¹⁷⁷ Thus, courts will look beyond the form and even the content of speech to consider the speaker’s motivations.

Moreover, although courts are reluctant to find articles published in peer-reviewed scientific and medical journals to be commercial speech, they will not hesitate to hold that their secondary dissemination by companies is.¹⁷⁸ The original publication and its redistribution are two separate forms of speech. Moreover, FDA itself considers whether the journal is a bona fide medical journal. The agency has long been skeptical of medical journals published and funded by drug companies.¹⁷⁹ As Bill Vodra notes, the FDA has repeatedly criticized “start-up publications entitled, optimistically, Volume 1, Number 1,” that are not followed by “Volume 1, Number 2,” or that are funded entirely by one company and feature one of its products.¹⁸⁰ Again, the context can be revealing.

Finally, rarely is speech by an FDA-regulated firm a singular event. Companies often speak as part of a larger effort to promote or brand a product. Firms frequently reinforce core advertising and promotion with peripheral speech that is more difficult to categorize as commercial at first glance.¹⁸¹ Perhaps for this reason the FDA is particularly wary of preapproval promotion, aware that first impressions are lasting ones, and is sensitive to the fact that later corrections or qualifications are often lost on the audience.¹⁸²

Thus, although not dispositive, *how* the speech is communicated remains important.¹⁸³

¹⁷⁷ Pearson, 164 F.3d at 651.

¹⁷⁸ To wit, in *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, a Lanham Act case, the court held that an article published in the *New England Journal of Medicine* about x-ray contrast media was noncommercial in part because “it is a protected form of speech.” 627 F. Supp. 2d 384, 457 (D.N.J. 2009). But the court held that “secondary dissemination of the article” is commercial speech, noting that the industry uses scientific studies and articles “as an especially important and prevalent marketing tool.” *Id.* at 458 (quoting *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 63 (D.D.C. 1998)).

¹⁷⁹ Vodra, *supra* note 8, at 594.

¹⁸⁰ *Id.*

¹⁸¹ I owe the above observations in this paragraph to discussions with Bill Vodra. Telephone Interview with Bill Vodra, Senior Partner, Arnold & Porter LLP (Jan. 3, 2011).

¹⁸² Vodra, *supra* note 8, at 588.

¹⁸³ For example, in *Nike v. Kasky*, Nike had sent letters to university presidents and athletic directors, published press releases, and published arguments about its overseas labor practices in other non-advertising forms. The outcome might have been different if Nike personnel had made statements at debates on college campuses, via television or in news interviews. *Chemerinsky & Fisk, supra* note 49, at 1148 (discussing *Nike v. Kasky*, 539 U.S. 654 (2003)).

G. GOVERNMENT MOTIVATIONS?

A notable observation from reviewing the FDA-related cases is that courts sometimes examine the scope and purposes of the law being challenged to determine whether the speech it regulates is commercial or not. This approach conflates the first-order question of whether the speech is commercial (*Bolger*) with the second-order question of whether the restriction violates free speech rights (*Central Hudson*).

For example, in *Commonwealth Brands*, tobacco companies challenged the 2009 Family Smoking Prevention and Tobacco Control Act, which for the first time authorized the FDA to regulate tobacco products.¹⁸⁴ The Act heavily restricts the claims that companies can make about “modified risk” products that purport to reduce the risks or harms from tobacco-related illnesses.¹⁸⁵ The Act targets not only claims made in the labeling or advertising for modified risk products, but also “any action directed to consumers through the media or otherwise.”¹⁸⁶

This latter provision, tobacco companies argued, covers pure, noncommercial speech because it would apply to materials like “press releases, booklets, and television appearances,” among other items.¹⁸⁷ The court disagreed that the form alone could render this speech noncommercial, in part by reasoning that the *statute* targets speech by “economically-motivated” tobacco companies, and that the speech is aimed at consumers and discusses a particular product.¹⁸⁸ But this is circular reasoning: because the statute targets commercial speech, the speech it regulates must be commercial.

Similar reasoning was employed by two courts considering First Amendment challenges to state prescription confidentiality laws that limit the use and dissemination of prescriber data captured by data mining companies. In *IMS Health v. Ayotte*, the court held that gathering and disseminating prescriber data was conduct rather than speech, but that even if it was speech, it would be commercial.¹⁸⁹ Although the First Circuit did not spend much time on the commercial speech question, it treated the speech as commercial because the law targets only commercial uses of prescribing data.¹⁹⁰ Likewise, in *IMS Health v. Sorrell*, the district court noted that while prescribing data “combines commercial and noncommercial elements,” the Vermont law targets only its commercial uses in marketing and “does not regulate use of the data for non-commercial purposes such as health care research, educational communications, or safety notices.”¹⁹¹ Thus, according to both courts, the use and dissemination of prescriber data is commercial speech (if anything) because the law targets only commercial uses.

¹⁸⁴ Family Smoking Prevention and Tobacco Control Act of 2009, 21 U.S.C. § 387a.

¹⁸⁵ See 21 U.S.C. § 387k(b).

¹⁸⁶ 21 U.S.C. § 387k(b)(2)(A)(iii); *Commonwealth Brands v. United States*, No. 1:09-CV-117M, 2009 WL 3754273, at *1-2 (W.D. Ky. Nov. 5, 2009).

¹⁸⁷ *Id.* at *6.

¹⁸⁸ *Id.*

¹⁸⁹ 550 F.3d 42, 52 (1st Cir. 2008).

¹⁹⁰ *Id.* at 54-55.

¹⁹¹ 631 F. Supp. 2d 434, 447 (D. Vt. 2009) (internal quotations omitted).

These opinions focus on the law itself to determine whether the speech it regulates is commercial or not,¹⁹² conflating the *Bolger* and *Central Hudson* queries. This suggests that, given the history of litigation, courts may try to avoid invalidating on First Amendment grounds laws that target the drug and device industries. Again, the FDA's regulatory scheme depends on the use of words,¹⁹³ and courts might use this interpretive mechanism to avoid invalidating the agency's entire regulatory scheme on constitutional grounds. On the other hand, if a law expressly limits itself to regulating commercial speech—or commercial uses of speech—then the law's purpose and scope might be relevant to both the *Bolger* and *Central Hudson* queries.

H. MAKING SENSE OF THESE FACTORS

This Article takes a reductionist approach, isolating the factors courts use to distinguish commercial from noncommercial speech. I examine the *Who*, *What*, *When*, *Where*, *Why*, and *How* of the speech at issue, both in notable Supreme Court opinions and in twenty-four cases in which FDA-regulated firms claimed First Amendment protection. Reaggregating these factors yields a few noteworthy observations.

First, most of these factors essentially try to reveal *why* the speaker is speaking—whether the speech is commercially motivated. For example, “*Who* is speaking?” asks whether the speaker is a commercial entity. “*What* does the speech discuss?” asks whether the speech proposes a commercial transaction, and whether it refers to a particular product, per *Bolger*. “*When* is the speech communicated?” asks whether the timing reveals any commercial intent. “*Where* is the speech directed?” tries to ascertain if the intended audience includes potential customers. “*How* is the speech communicated?” asks whether it is an advertisement, per *Bolger*. The factors thus boil down to *why* the speaker is speaking, suggesting that, contrary to the Court's own proclamations,¹⁹⁴ commercial intent is paramount rather than “forbidden territory.”¹⁹⁵

The second notable observation is that the most frequently used proxy for determining whether speech is commercially motivated is the speaker's identity. *Who* is speaking thus holds significant predictive power in distinguishing commercial from noncommercial speech. Except for two Lanham Act cases of questionable relevance, every case involving an FDA-regulated firm found the speech to be commercial. In the next section, I explore how the right mix of factors might lead a court to find speech by an FDA-regulated firm to be noncommercial. But again, courts have yet to encounter such a mix.

¹⁹² There are hints of this approach in at least one Lanham Act case, *In re Warfarin Sodium Antitrust Litigation*. There, the court held that speech by DuPont Merck arguing that its product Coumadin presented fewer safety risks than the new generic version was commercial, in part by focusing on the nature of the legal violation alleged—product disparagement. No. MDL 98-1232-SLR, 1998 WL 883469, at *13-14 (D. Del. Dec. 17, 1998).

¹⁹³ See Request for Comment on First Amendment Issues, *supra* note 2, 67 Fed. Reg. at 34,943.

¹⁹⁴ *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761-65 (1976).

¹⁹⁵ Kozinski & Banner, *supra* note 9, at 640.

The third notable observation is that FDA-regulated firms are not internally monolithic, which can make it difficult to neatly characterize the company's motivations as commercial or not. For example, pharmaceutical firms tend to be large, complex organizations, and their scientific and medical personnel may not possess identical interests or motivations as sales and marketing personnel. Moreover, some speakers blur the line between commercial and noncommercial—in some companies, “medical liaisons” may be glorified sales representatives, but in others, they have little to no pressure to generate sales. External physicians and “thought leaders” paid to speak on behalf of companies can also blur the line for purposes of categorizing speech. Therefore, it may be crude to categorize the speech according to the organization's interests rather than the individual speaker's.

Fourth, if all these things are true, then perhaps reductionism is the wrong approach, like trying to understand a pointillist painting by staring closely at the individual dots. Greater detail does not always produce greater clarity.¹⁹⁶ If all the factors point towards a single factor—the speaker's motivations—then why bother reducing the speech into separate components?

The value, I think, in taking a reductionist approach is to more accurately isolate and evaluate the relevant factors in the difficult cases. Categorizing the speech in such cases requires courts to consider the totality of the circumstances—which itself requires courts to identify who is speaking, about what, when, where, why, and how. These queries systematically reveal the indicia of commercial speech.

VI. DISTINCTION-BLURRING SPEECH BY FDA-REGULATED FIRMS

When should speech by an FDA-regulated firm qualify as noncommercial? As I emphasize above, *who* is speaking is a powerful predictor of whether the speech is commercial, and courts almost uniformly categorize speech by FDA-regulated firms this way.

Nevertheless, there are scenarios in which speech by an FDA-regulated firm should qualify for heightened protection. The most obvious would involve a firm directly commenting on an issue of public concern within the parameters of *Bellotti* or *Consolidated Edison*.¹⁹⁷ For instance, a drug manufacturer might include with its prescribing information or package insert a separate pamphlet opposing cuts to Medicare reimbursement. Or a tobacco company might take out a page-long ad in the *New York Times* objecting to a proposed FDA regulation.¹⁹⁸ Perhaps an even clearer example would be submitting public comments during notice-and-comment rulemaking by the FDA.

But would anything less explicit qualify? Press releases offer an interesting vehicle for exploring the parameters of commercial speech. Since

¹⁹⁶ Stern, *supra* note 19, at 145.

¹⁹⁷ *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765 (1978); *Consol. Edison Co. of N.Y. v. Pub. Serv. Comm'n*, 447 U.S. 530 (1980).

¹⁹⁸ For example, the Mobil Corporation has long paid for ads in the *New York Times* and other papers advocating certain public policy positions. See, e.g., Mobil Corp., *Climate Change: A Degree of Uncertainty*, N.Y. TIMES, Dec. 4, 1997, at A31; Mobil Corp., *It's Time to Pass the Trade Bill*, N.Y. TIMES, June 30, 1988, at A23. For a discussion of this practice, see Stern, *supra* note 19, at 122-23.

the early 1980s, the FDA has taken the position that press releases disseminated by or on behalf of a manufacturer that refer to a particular product qualify under the broad definition of “labeling” in the Federal Food, Drug, and Cosmetic Act.¹⁹⁹ Based on this reasoning, the Agency has sent dozens of letters to companies objecting to press materials or the information they contain.²⁰⁰

But not every press release by an FDA-regulated firm would qualify as labeling subject to FDA jurisdiction. Likewise, not every press release would constitute commercial speech, even if it refers to a particular product. For example, imagine that a pharmaceutical manufacturer issued a press release defending its clinical research for a controversial cancer drug that it recently recalled for safety reasons. The press release addresses a public debate over whether the FDA should have approved the drug in the first place, and whether the company engaged in misconduct during clinical trials. Suppose the company has no plans to reintroduce the drug to the market, but wants to defend its scientific integrity.

Considering the factors above, one could imagine the speech qualifying for heightened protection: *Who is speaking?* The press release is issued by a pharmaceutical manufacturer, a for-profit corporation. *What is the content of the speech?* It addresses the scientific practices that supported a marketing application for its particular product. *When?* It is released when the company was no longer marketing the product and does not anticipate marketing it again. *Where?* The press release targets the scientific community, via academic publications. *Why?* The press release is intended to defend the company’s research practices in the public debate surrounding FDA’s decision to approve the product. *How?* It is published via a press release, rather than a commercial advertisement.

This communication should qualify as fully protected noncommercial speech, as all of the factors except for *who* perfectly align. But tweaking any factor would likely jeopardize its noncommercial status. For example, how much could the press release focus on the recalled product rather than the company’s research practices, if the ostensible goal is to defend the company’s scientific integrity? What if the press release is sent to both scientific and lay audiences? Or made available on its web site? What if the company implies that its other products are safe?

As emphasized above, most of the factors boil down to why the company is speaking. And a court might reasonably derive commercial intent from even minor clues, for example, by concluding that disseminating the press release

¹⁹⁹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(m) (2004); William Vodra, Nathan Cortez & David Korn, *The Food and Drug Administration’s Evolving Regulation of Press Releases: Limits and Challenges*, 61 FOOD & DRUG L.J. 623, 631 (2008) (explaining FDA’s history of notifying parties in Warning Letters that press releases qualified under the definitions of promotional labeling and advertising in 21 C.F.R. § 202.1(l), which are “labeling” under the Act).

²⁰⁰ Vodra, *supra* note 199, at 629-30 (noting that FDA sent its first letter in 1982, and sent forty such letters between 1996 and 2001). Of course, FDA’s jurisdiction over “labeling” does not automatically extend to all materials distributed by companies that refer to a particular product. Elsewhere, my coauthors and I have identified materials that would probably not be subject to FDA jurisdiction, such as materials intended for investors to meet securities law disclosure obligations, and materials provided to regulators or legislators. *Id.* at 633-34.

to physician publications is a way of assuring potential prescribers that the company's other products are safe. Given the industry's history of using creative and aggressive promotional techniques, courts might be skeptical enough to allow a hint of commercial intent to overpower several indications suggesting otherwise. Unfortunately, the Supreme Court declined an opportunity to clarify some of these points when it passed on *Nike v. Kasky*.²⁰¹

Another distinction-blurring form of speech is the video news release (VNR), a ready-made news segment produced or sponsored by drug manufacturers and sent to news channels. In the early 1990s, FDA sent a letter to the drug industry about VNRs, stating 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."²⁰² The FDA recognized that a VNR could be a cleverly disguised promotion if it "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)."²⁰³ Although Professor Stern refers to restrictions on this type of "camouflaged promotion" as existing only "in the realm of improbable speculation," the FDA has initiated enforcement actions against VNRs and other forms of publicity manipulated by companies.²⁰⁴ Although some VNRs can be blatantly promotional, it is not difficult to imagine variations that are not. But again, the factors would have to align almost perfectly for most courts to consider a VNR to be noncommercial speech.

A third example of distinction-blurring speech is speech communicated through ostensibly noncommercial activities, like charitable programs. Most major drug companies operate patient assistance programs (PAPs) that provide free or significantly discounted drugs to patients of limited means.²⁰⁵ Programs funded or sponsored by a single pharmaceutical firm might be a tempting venue for camouflaged promotion.

For example, could a company, under the guise of enrolling patients in its PAP, make claims that would draw FDA's ire? The Supreme Court has considered a series of cases involving mixed speech by charities soliciting contributions.²⁰⁶ Although these cases focus on laws that limit the act of soliciting donations, the Court has held that such speech can be "fully protected speech"²⁰⁷ after examining the circumstances in which it occurs.²⁰⁸

²⁰¹ *Nike v. Kasky*, 123 S. Ct. 2554 (2003).

²⁰² *FDA Industry-Wide Letter: VNRs and PR Materials*, [1990-1991 Transfer Binder] Food Drug Cosm. Law Rep. (CCH) ¶ 42484 (Jul. 24, 1991). FDA suggested that it would republish a new version of this letter as guidance document but never did so. Prescription Drug Advertising and Promotional Labeling; Development and Use of FDA Guidance Documents; Request for Comment, 62 Fed. Reg. 14,915 (Mar. 28, 1997).

²⁰³ *FDA Industry-Wide Letter: VNRs and PR Materials*, *supra* note 202, ¶ 42484.

²⁰⁴ *See, e.g.*, Regulatory Letter from FDA to ICN Pharmaceuticals, Inc. (Mar. 24, 1986) (on file with author) (objecting to a VNR by ICN discussing possible uses of its drug Virazole in treating AIDS-related diseases). For a general discussion of how FDA has asserted jurisdiction over press releases by regulated firms, see Vodra, *supra* note 199.

²⁰⁵ OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., Notice, Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,624 (Nov. 22, 2005).

²⁰⁶ *See, e.g.*, *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781 (1988); *Sec'y of State v. Joseph H. Munson Co.*, 467 U.S. 947 (1984); *Vill. of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620 (1980).

²⁰⁷ *Riley*, 487 U.S. at 796.

But the government is hyper-skeptical of drug promotion, and suspects that even these charitable programs are driven by the economic motivation to induce future prescriptions.²⁰⁹ Again, the factors above would have to align almost perfectly to overcome the skepticism that would lead most courts to categorize even this speech as commercial.

Of course, the speech that consistently confounds FDA is speech about unapproved, off-label uses. FDA regulations try to draw the line between illegal promotion and legitimate scientific discussion here: FDA's advertising rules prohibit manufacturers from suggesting any unapproved uses for approved products;²¹⁰ but the Agency's investigational drug rules state that while manufacturers may not promote unapproved drugs, they may engage in "the full exchange of scientific information . . . including dissemination of scientific findings in scientific or lay media."²¹¹ Although the first rule refers to approved drugs and the second to investigational ones, the two approaches reveal how the FDA distinguishes legitimate scientific speech from illegal promotion.

Interestingly, the FDA's problem has not been drawing the line between commercial and noncommercial speech, but in regulating commercial speech without violating *Central Hudson*. The FDA's past attempts to guide industry practices,²¹² and later to codify these policies,²¹³ resulted in several high-profile decisions against the agency.²¹⁴ At the end of one case, an exasperated court said that "[a]fter six years' worth of briefs, motions, opinions, Congressional

²⁰⁸ Stern, *supra* note 19, at 90-91.

²⁰⁹ Recently, many pharmaceutical manufacturers crafted PAPs to help cover out-of-pocket expenses borne by Medicare beneficiaries enrolling in Medicare's prescription drug benefit, which took effect in 2006. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified and amended in various sections of 42 U.S.C.). Before the Patient Protection and Affordable Care Act in 2010, the Medicare Part D benefit required beneficiaries to bear the full cost of drug expenses between roughly \$2,700 and \$4,350, known as the "coverage gap" or "doughnut hole." Even though Medicare subsidized the cost-sharing obligations for many low-income beneficiaries, 42 C.F.R. § 423.782 (2010), pharmaceutical companies wanted to design PAPs for beneficiaries not eligible for these subsidies. Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,624. The U.S. Department of Health and Human Services' Office of Inspector General (HHS OIG) expressed concern that PAPs sponsored by drug companies would induce higher drug spending, potentially in violation of federal fraud and abuse laws, by steering enrollees to use particular drugs, increasing costs to Medicare, creating an advantage over competing drugs, and reducing enrollee's incentives to use less expensive, but equally effective drugs. Dep't of Health and Human Servs., Office of Inspector Gen., *OIG Advisory Opinion* 07-04, 7, Mar. 30, 2007, available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-04.pdf>.

²¹⁰ 21 C.F.R. § 202.1(e)(4) (2010).

²¹¹ 21 C.F.R. § 312.7(a) (2010).

²¹² Draft Policy Statement on Industry Supported Scientific and Educational Activities, 57 Fed. Reg. 56,412, 56,412-14 (Nov. 27, 1992); Guidance for Industry: Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,093, 64,093-100 (Dec. 3, 1997); Advertising and Promotion; Guidances, 61 Fed. Reg. 52,800 (Oct. 8, 1996).

²¹³ Food and Drug Modernization Act of 1997, § 401, 21 U.S.C. § 360aaa-1 (repealed 2006); 21 C.F.R. § 99 (2010); Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 63 Fed. Reg. 64,556 (Nov. 20, 1998).

²¹⁴ See, e.g., Wash. Legal Found. v. Kessler, 128 F. Supp. 2d 11 (D.D.C. 2000); Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000); Wash. Legal Found. v. Friedman, 36 F. Supp. 2d 16 (D.D.C. 1999); Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998); Wash. Legal Found. v. Kessler, 880 F. Supp. 26 (D.D.C. 1995).

acts, and more opinions, the issue remains 100% unresolved, and the country's drug manufacturers are still without clear guidance as to their permissible conduct."²¹⁵ Since then, major drug companies have paid billions to settle claims relating to allegations of off-label promotion.²¹⁶

During this time, the FDA tried to provide much-needed guidance by proposing and finalizing a Guidance for Good Reprint Practices, encouraging drug and device firms to disseminate reprints discussing off-label uses only when taking certain precautions.²¹⁷ The Draft Guidance drew some media scrutiny²¹⁸ and generated a scornful letter from Congressman Waxman, who said it "would carve a large loophole in the law and create a pathway by which drug and device manufacturers can promote unapproved (off-label) uses of their products. . . ."²¹⁹

The Guidance is a clear attempt by the FDA to limit commercial uses of such information, and as such, might be interpreted as encapsulating FDA's criteria for distinguishing commercial from noncommercial speech. For example, the Guidance encourages companies to disseminate only independent, peer-reviewed scientific or medical journal articles, not special supplements or other materials funded, edited, or influenced by manufacturers.²²⁰ Reprints should be unabridged and "not be marked, highlighted, summarized, or characterized by the manufacturer in any way."²²¹ And companies should distribute reprints "separately from information that is promotional in nature," meaning sales representatives should not discuss them, and they "should not be distributed in promotional exhibit halls or during promotional speakers' programs."²²² However, they "may be distributed at medical or scientific conferences in settings appropriate for scientific exchange."²²³

Thus, the Guidance attempts to render these documents as noncommercial as possible, perhaps following the holdings of cases like *Consolidated Edison* and *Pacific Gas & Electric*, in which the Court struck down restrictions on political statements made separately from commercial

²¹⁵ *Henney*, 128 F. Supp. 2d at 15.

²¹⁶ The stakes for companies go far beyond liability under the FDCA. For example, companies have paid billions to settle civil and criminal claims alleging violations of the False Claims Act, anti-kickback statute, and other laws for off-label and other forms of promotion. For a concise citation of recent cases, 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, 302 n.3 (2010).

²¹⁷ Dep't of Health and Human Servs., Office of the Comm'r, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices*, Jan. 2009, available at <http://www.fda.gov/oc/op/goodreprint.html>.

²¹⁸ See, e.g., Christopher Lee, *FDA Considers Easing Curbs on Drug Makers*, WASH. POST, Dec. 1, 2007 at A4, available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/11/30/AR2007113002300.html>.

²¹⁹ Letter from Representative Henry A. Waxman, Chairman of the House Comm. on Oversight and Gov't Reform, to Honorable Andrew von Eschenbach, Comm'r of the Food & Drug Admin., (Nov. 30, 2007) available at http://online.wsj.com/public/resources/documents/waxmanletter_113007.pdf.

²²⁰ Guidance for Industry, *supra* note 212.

²²¹ *Id.*

²²² *Id.*

²²³ *Id.*

speech.²²⁴ As long as the document is clearly separate from commercial items and directly addresses an issue of public concern, it deserves heightened protection.

Nevertheless, every court considering off-label speech has treated it as commercial.²²⁵ Again, the factors would have to align almost perfectly for skeptical courts to consider speech by an FDA-regulated firm to be noncommercial.

VII. CONCLUSION

The distinction between commercial and noncommercial speech determines the extent to which the government can regulate it, if at all. The distinction arose somewhat inauspiciously, but evolved into a fault line for regulators like the FDA, whose core regulatory schemes frequently depend on articulating what firms may and may not say. A review of relevant Supreme Court decisions and lower court opinions involving FDA-regulated firms reveals that the three-part test in *Bolger* really asks more than three questions. Nevertheless, these questions generally try to ascertain whether the speech is commercially motivated. Moreover, the most frequently used proxy for commercial intent is whether the speaker is a commercial entity. All of which raises the question: Can speech by FDA-regulated firms ever be noncommercial?

The short answer, of course, is *yes*. But in FDA contexts, courts have been exceedingly skeptical of speech by regulated firms—particularly drug and device manufacturers—eager to find hidden commercial motivations. Thus, even speech that truly blurs the distinction between commercial and noncommercial will be subject to commercial standards unless the relevant factors align almost perfectly—even a hint of commercial intent may eclipse several indicia of noncommercial speech. This may be the price to pay for decades of aggressive, perhaps even manipulative, marketing and promotional techniques. Nevertheless, given all the possible permutations of speech by FDA-regulated industries, and all the potential responses by the FDA, this issue will recur.

²²⁴ 447 U.S. 530, 544 (1980); *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 20 (1986) (plurality) (rejecting requirement that Pacific Gas & Electric must include statements by those with alternative viewpoints in utility bills).

²²⁵ Hall & Sobotka, *supra* note 79, at 13.