

**THE FIRST AMENDMENT AND  
THE EMERGING TORT OF  
OFF-LABEL “PROMOTION”**

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## INTRODUCTION

In the wake of U.S. Supreme Court rulings finding personal injury failure to warn claims preempted by the Food and Drug Cosmetic Act (FDCA), new state law tort theories are emerging. None may be more potently poised to alter the medical product litigation landscape than purported state law tort claims for “off-label promotion.” As the courts reexamine the power granted to the Food and Drug Administration (FDA) and limit the scope of its enforcement in light of Due Process and First Amendment considerations, state tort claims may find a new footing in the emerging void.

The FDA places restrictions on what, when, where, why, and who may disseminate information concerning regulated products. Over decades, the statutory and regulatory framework has expanded, placing more restrictions on information that may be disseminated. This expanding regulatory framework continually inches closer to infringing on constitutional protections. As enforcement and market competition increase, the tension among regulated industry, the regulators, the medical profession, and the consuming public has likewise increased.

Increasingly aggressive enforcement of marketing claims under the FDCA has ushered in a new era and a fresh look at how the FDA enforces rules governing labeling and the dissemination of truthful scientific and medical information concerning FDA-regulated products. Nowhere is the impact of this enforcement effort more profoundly focused than in connection with criminal and civil penalties for communicating reliable scientific and medical information, prosecuted and punished under the law as “unapproved” drugs and devices (i.e., “off-label promotion”).

Off-label use presents a conundrum: Physicians, consumers, and even academia are unrestrained in recommending any product for any use, irrespective of whether there is scientific or medical support for the use. Manufacturers with reliable scientific and medical information regarding a use not in the FDA-approved labeling are throttled under the rubric of off-label promotion, and silenced or prosecuted. From this conundrum, an urgent moral and ethical imperative exists to provide more—not less—reliable scientific and medical information.

The provision of medical care implicates a number of stakeholders—

manufacturers, health care providers, consumers, and government.<sup>1</sup> The interplay among the stakeholders creates a discernible matrix. Manufacturers have varying degrees of knowledge concerning post-market experience and methods of disseminating information. Physicians' sophistication with regards to off-label uses and their motivation for doing so varies significantly as well. Consumers' understanding ranges from highly educated concerning the products they use to existing at the mercy of their doctors. The FDA sits in judgment of how the manufacturer informs health care providers and, increasingly, the public, through a set of rules, guidances, draft guidances, and policies that permit the exercise of discretion by the government to determine whether truthful medical and scientific information constitutes "false" information and evidence of criminal conduct. This complex matrix is on a collision course with fundamental Due Process and First Amendment principles. These constitutional underpinnings are increasingly poised to serve a vital role in furthering the public health and restricting the scope of government control and power, but with the right and financial incentive to speak, new obligations, duties and claims may arise.

## **I. FDA'S MISSION**

In establishing the FDA, Congress set the "mission" of the FDA to:

promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;<sup>2</sup>

protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled... drugs are safe and effective... there is reasonable assurance of the safety and effectiveness of devices... cosmetics are safe and properly labeled....<sup>3</sup>

...reduce the burden of regulation, harmonize the regulatory requirements, and achieve reciprocal arrangements [with other nations];<sup>4</sup> and

...carry out [its mission] in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.<sup>5</sup>

In defending the increasing regulatory landscape of the FDA, the commissioner has stated:

Now I know that in some circles regulation is viewed as a roadblock to innovation and economic growth. But in actuality, *when done right*,

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<sup>1</sup> 21 U.S.C. 393(b)(4).

<sup>2</sup> 21 U.S.C. § 393(1).

<sup>3</sup> 21 U.S.C. § 393(2)(A-D).

<sup>4</sup> 21 U.S.C. § 393(3).

<sup>5</sup> 21 U.S.C. § 393(b)(4).

*regulation isn't a roadblock; it's the actual pathway to achieving real and lasting innovation... Going forward, smart regulation requires regulatory flexibility that responds to changing situations, new information and new challenges.*<sup>6</sup>

## **II. OFF-LABEL USE: THE “PRESCRIBER’S PRIVILEGE”**

The use of FDA-regulated products for purposes not in FDA-approved labeling is recognized as appropriate in the practice of medicine. In the prescription drug context, “clinically appropriate medical practice at times requires the use of pharmaceuticals for ‘off-label’ indications.”<sup>7</sup> But that is not to say that when a physician prescribes a medication for a use or in a manner not approved by the FDA that she is not obligated to know she is prescribing a “new drug” and to be well informed. In its Guidance for Institutional Review Boards and Clinical Investigators, the FDA states:

Good medical practice and the best interests of the patient require physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product’s use and effects.<sup>8</sup>

In published remarks, the now-former deputy commissioner of the FDA made a number of significant comments concerning the positive health benefits that result from relying on physician judgment in using products off-label, but concerning manufacturers’ participation, he warned: “policy forces are tugging in exactly the opposite direction by placing restrictions on the exchange of some of the most pertinent information.”<sup>9</sup>

In *Buckman Co. v. Plaintiffs’ Legal Comm.*, a case involving a medical device, the Supreme Court noted:

In effect, then, fraud-on-the-FDA claims could cause the Agency’s reporting requirements to deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of

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<sup>6</sup> Margaret Hamburg, M.D., [50 Years after Thalidomide: Why Regulation Matters](#), FDA VOICE (Feb. 7, 2012).

<sup>7</sup> See Memorandum of the AMA House of Delegates, Resolution 820, [Off Label Use of Pharm.](#), Amer. Med. Assoc. (2005); see also *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 351 (2001); *Sigma-Tau Pharm., Inc. v. Schwetz*, 288 F.3d 141 (4th Cir. 2002); *Huntsman v. Danek Medical, Inc.*, No. 97-2155-IEG, 1998 U.S. Dist. Lexis 13431 (S.D. Cal., July 27, 1998); *Washington Legal Found. v. Kessler*, 880 F. Supp. 26, 28 (D.D.C. 1995).

<sup>8</sup> [Off-Label and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet](#), last accessed Feb. 10, 2013.

<sup>9</sup> Scott Gottlieb, M.D., Deputy Comm’r Med. & Sci. Affairs F.D.A., [Speech before Windhover’s FDA/CMS Summit](#) (Dec. 5, 2006).

medicine, see 21 U.S.C. § 396 and even though off-label use is generally accepted.<sup>10,11</sup>

While it has been long understood and recognized by the courts that “off-label” uses of medical products is accepted, in its Proposed New Drug, Antibiotic, and Biologic Drug Product Regulation, the FDA stated:

Current regulations are silent on the act’s applicability to the use of approved drugs for unapproved uses. This issue has caused considerable confusion both inside and outside the agency. In the Federal Register of August 15, 1972,<sup>12</sup> the agency proposed a regulation that would have put forth the legal status of approved labeling; although no final rule has been issued on this subject, the agency has continued to apply the principles set forth in the preamble to the 1972 proposal. In FDA’s Drug Bulletin of April 1982, the agency sought to clarify and reiterate the position that the act does not regulate the ‘practice of medicine.’ Once a drug product has been approved for marketing, a physician may, in treating patients, prescribe the drug for uses not included in the drug’s approved labeling. *The primary legal constraints in that situation are State laws on medical practice and products liability law.*<sup>13</sup>

It is significant that FDA has stated that the “act does not regulate the practice of medicine” but, instead, the profession polices itself with state tort law of “medical malpractice and products liability” as the backstop.

### III. THE FIRST AMENDMENT

The command of the First Amendment relevant to this paper is a mere ten words: “Congress shall make no law ... abridging the freedom of speech ...”

As the Supreme Court continues its retreat from permitting wholesale bans on speech by commercial enterprises and wrestles with framing a coherent rule for when

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<sup>10</sup> Citing Green & Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L. J. 2119, 2133 (2000) (“Physicians may prescribe drugs and devices for off-label uses”); Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act*, 55 FOOD & DRUG L. J. 245, 251-252 (2000) (discussing off-label use in terms of the “practice of medicine doctrine[, which] stands firmly for the proposition that regulatory efforts are directed primarily at device marketing by manufacturers, not device use by physicians”); Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L. J. 71, 72 (1998) (“Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize”).

<sup>11</sup> 531 U.S. 341, 351 (2001).

<sup>12</sup> 37 Fed. Reg. 16503.

<sup>13</sup> [21 CFR Part 312, Docket No. 82N-0394](#) (48 FR 26720) June 9, 1983. In prohibiting promotional activities related to investigational drugs, the rules state: “This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or law media.” 21 CFR 312.7

the government is permitted to silence a business enterprise, the marketplace continues to evolve in new and complex ways. Until recently, the FDA defeated challenges to the constitutionality of its regulation of speech by commercial enterprises using two tactics. First, the FDA has denied the applicability of constitutional protections altogether on the basis that marketing is conduct, not speech. Second, and in the alternative, the FDA has argued that if it is speech, the speech was not FDA approved and is therefore “false” and not entitled to First Amendment protection even under a lower level of scrutiny.<sup>14</sup>

While the legal framework protecting the speech of commercial enterprises has evolved over the past thirty years, it is only relatively recently that the courts have seriously considered applying the doctrine in the context of the FDCA:

Defendants’ lead argument is that the Food, Drug, and Cosmetic Act violates the first amendment by restricting promotional materials to those that the FDA has approved. The argument starts from the premise that federal law allows customers of any approved medical device or drug to put it to any use that the customer sees fit. These ‘off-label uses’ being lawful, the argument goes, it must be lawful to tell customers about them. *Until the last 30 years, such an argument would have been laughed out of court.*<sup>15</sup>

The laughter has stopped and, increasingly, the question is how to balance promotional and risk information:

The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some are of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment.<sup>16</sup>

Indeed, the Court has been skeptical of regulations that bar speech based on a paternalistic assumption concerning the inability of the consuming public to discern what is good for them:

Bans against truthful, nonmisleading commercial speech...usually rest solely on the offensive assumption that the public will respond irrationally to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.<sup>17</sup>

Of course, the text of the First Amendment itself is silent on any distinction

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<sup>14</sup> 62 Fed. Reg. 64074, 64082.

<sup>15</sup> *U.S. v. Caputo*, 517 F.3d 935, 937 (7th Cir. 2008) (emphasis added).

<sup>16</sup> *Thompson v. Western States Med Ctr.*, 535 U.S. 357, 367 (2002), citing *Edenfield v. Fane*, 507 U.S. 761, 767 (1993).

<sup>17</sup> *Thompson.*, 535 U.S. at 375, citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501, 510-14 (1996).

*between* individual and enterprise speech. For decades, enterprise speech, or “commercial speech,” was assumed by the Supreme Court not only to exist, but to be fully within the power of government to restrict and control without much concern for the First Amendment. In the seven decades since the Supreme Court declared commercial speech not within the protections granted by the First Amendment, the Court has been gradually rethinking this issue and correcting its thinking, including abandoning some of its early pronouncements.

### **A. The Burden is on the Government**

In those rare cases where a manufacturer raises the defense that FDA enforcement infringes its First Amendment protections, the burden falls on the government, not the manufacturer, to establish that its regulation meet the requirements of the First Amendment. In addressing this issue, the Supreme Court held that: “It is well-established that ‘the party seeking to uphold a restriction on commercial speech carries the burden of justifying it.’”<sup>18</sup> “If the First Amendment means anything, it means that regulating speech must be a last—not first—resort. Yet here it seems to have been the first strategy the Government thought to try.”<sup>19</sup>

### **B. The Birth and Evolution of Commercial Speech**

During World War II, in a case involving a submarine and a prior Justice Roberts, the Supreme Court in *Valentine v. Chrestensen* made a profound and admittedly erroneous assumption that has taken the Court decades to gradually walk back.<sup>20</sup> In *Valentine*, the Supreme Court held:

[T]he Constitution imposes no such restraint on government as respects purely commercial advertising. Whether, and to what extent, one may promote or pursue a gainful occupation in the streets, (and) to what extent such activity shall be adjudged a derogation of the public right of use, are matters for legislative judgment.<sup>21</sup>

For decades after *Valentine*, the Court was confounded in cases involving a variety of commercial content and wrestled to frame a jurisprudential construct that would harmonize the text of the First Amendment while also permitting restrictions on the speech of commercial enterprises to conform to ever-changing social mores.

### **C. The Recognition of Commercial Speech**

Thirty years after *Valentine*, in the 1976 ruling *Virginia Pharmacy Board v. Virginia Consumer Counsel*, the Court stated: “[a]s to the particular consumer’s interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day’s most urgent political debate.”<sup>22</sup> In

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<sup>18</sup> *Edenfield v. Fane*, 507 U.S. at 770 (1993) (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. at 71, n. 20 (1983)).

<sup>19</sup> *Thompson*, 535 U.S. at 373.

<sup>20</sup> *Valentine v. Chrestensen*, 316 U.S. 52 (1942).

<sup>21</sup> *Id.* at 54.

<sup>22</sup> *Va. Pharmacy Bd.*, 425 U.S. 748, 783 (1976).

*Bolger v. Youngs Drug Products Corporation*, the Supreme Court noted that “beginning with *Bigelow v. Virginia*,<sup>23</sup> this Court extended the protection of the First Amendment to commercial speech. Before that time, purely commercial advertising received no First Amendment protection.”<sup>24</sup>

Forty years after pronouncing that commercial speech was not subject to First Amendment protection, in *Schaumburg v. CBE*, the Supreme Court took a very different view of the issue and pronounced *Valentine* and its progeny invalid:

To the extent that any of the Court’s past decisions ... hold or indicate that commercial speech is excluded from First Amendment protections, those decisions, to that extent, are no longer good law.<sup>25</sup>

## **D. What Constitutes Commercial Speech**

### **1. Bolger v. Youngs Drug Products Corp.**

*Bolger v. Youngs Drug Products Corp.* is often cited for its definition of commercial speech and the three part test the Court articulated for determining if speech is commercial or noncommercial.<sup>26</sup> In *Bolger*, Youngs Drug Products sent unsolicited mass mailings related to condoms despite a federal law that prohibited unsolicited advertisements for such contraceptives.<sup>27</sup> Youngs brought an action for declaratory relief claiming that the statute, as applied, violated its free speech rights under the First Amendment.<sup>28</sup>

The Court found that “Because the degree of protection afforded by the First Amendment depends on whether the activity sought to be regulated constitutes commercial or noncommercial speech, we must first determine the proper classification of the mailings at issue here.” Youngs sought to mail three types of materials:

- 1) A multi-page, multi-item flyer promoting a large variety of products available at a drugstore, including prophylactics;
- 2) Flyers exclusively or substantially devoted to promoting prophylactics;
- 3) Informational pamphlets discussing the desirability and availability of prophylactics in general or Youngs’ products in particular.<sup>29</sup>

The Court found that although “[m]ost of appellee’s mailings fall within the core notion of commercial speech – ‘speech which does no more than propose a commercial transaction,’” the third category, informational pamphlets, could not be

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<sup>23</sup> 421 U.S. 809 (1975) (*Bigelow v. Virginia*, 421 U.S. 809 (1975)).

<sup>24</sup> *Bolger*, 463 U.S. at 60.

<sup>25</sup> *Schaumburg v. Citizens for a Better Env’t*, 444 U.S. 620, 632 (1980).

<sup>26</sup> See, e.g., *Gibson v. Texas Dept. of Ins.*, No. 11-11136, 2012 U.S. App. LEXIS 22375 at \*9 (5th Cir. Oct. 30, 2012)(citing *Bolger*, 463 U.S. at 60); see also *Nike v. Kasky*, 27 Cal. 4th 939, 956-57 (Cal. 2002).

<sup>27</sup> *Bolger*, 463 U.S. at 61.

<sup>28</sup> *Id.* at 63.

<sup>29</sup> *Id.* at 62.

characterized merely as proposals to engage in commercial transactions.<sup>30</sup>

The *Bolger* Court stated that classifying the informational pamphlets as either commercial or noncommercial speech “present[ed] a closer question” because, (1) the fact that they are advertisements does not compel the conclusion that they are commercial speech, (2) the reference to a product does not by itself render the pamphlets commercial, and (3) Youngs’ economic motivation alone is insufficient to turn the materials into commercial speech.<sup>31</sup> Despite the finding that each of these elements alone could not establish that the speech was commercial, the *Bolger* Court concluded that the combination of all three elements provided “strong support” for the lower court’s holding that the pamphlets constituted commercial speech “notwithstanding the fact that they contain discussions of important public issues such as venereal disease and family planning.”<sup>32</sup>

The Fifth Circuit, among other courts, has since adopted this three part test for determining if speech is commercial when it does more than merely propose a commercial transaction. In *Gibson*, for example, the Fifth Circuit, citing *Bolger*, held that speech will be considered commercial if:

- 1) It is an advertisement of some form;
- 2) It refers to a specific product; and
- 3) The speaker has an economic motivation for the speech.<sup>33</sup>

## **2. Gibson v. Texas Department of Insurance**

*Gibson v. Texas Dept. of Ins.*, involved attorney advertising and a challenge that the state’s prohibition against using the words “Texas’ and “Workers’ Comp” in a web domain name was unconstitutional under the First, Fifth and Fourteenth Amendments. The Fifth Circuit wrote:

We agree with *Gibson* that his domain name and blog may do ‘more than propose a commercial transaction.’ The domain name may nevertheless be considered commercial speech if (i) it is an advertisement of some form; (ii) it refers to a specific product; and (iii) the speaker has an economic motivation for the speech. As with many new issues involving the Internet, the proper method of analysis to determine whether a domain name is commercial speech or a more vigorously protected form of speech is *res nova*. A domain name, which in itself could qualify as ordinary communicative speech, might qualify as commercial speech if the website itself is used almost exclusively for commercial purposes. This is an issue we need not reach or decide in this appeal without a record of all of the surrounding facts and circumstances involving the website’s domain name. As discussed in more detail below, even if the domain name amounts to commercial speech, *Gibson* has nevertheless stated a claim under the First

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<sup>30</sup> *Id.* at 66 (quoting *Va. Pharmacy Bd.*, 425 U.S. at 762.)

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at 67-68.

<sup>33</sup> *Gibson*, 2012 U.S. App. LEXIS 22375 at \*9 (citing *Bolger*, 463 U.S. at 66.)

Amendment. Therefore, we reverse and remand the case for further proceedings on that basis. But we also reserve to Gibson his right in those proceedings to argue for and adduce evidence in support of stronger protection of his domain name as ordinary, communicative speech, and not merely as commercial speech.

While Texas fears that Gibson's domain name may confuse the public, there is no showing that the domain name is incapable of being viewed in a non-deceptive manner. Second, there have been no factual findings to support an allegation that the domain name is actually deceptive. Therefore, the domain name at issue is entitled to some First Amendment protection.<sup>34</sup>

Despite cases like *Gibson* and *Bolger* that purport to provide a clear, easy to apply test for distinguishing between commercial and noncommercial speech, some courts (including the Supreme Court) recognize that the *Bolger* test is incomplete and may not be sufficient to define the parameters distinguishing commercial from noncommercial speech.<sup>35</sup>

### 3. Nike v. Kasky

The U.S. Supreme Court had an opportunity in 2003 to clarify this area of law but dismissed an appeal from the California Supreme Court before reaching the issue. In *Nike v. Kasky*, the California Supreme Court grappled with the definition of commercial speech under *Bolger*.<sup>36</sup> An individual brought an action against Nike under a California law designed to prevent false advertising and unfair competition.<sup>37</sup> The plaintiff alleged that Nike, in response to public criticism related to its labor practices overseas, made false statements to the public to entice consumers to continue buying its products.<sup>38</sup> The Court stated that "The issue here is whether defendant corporation's false statements are commercial speech or noncommercial speech for purposes of constitutional free speech analysis under the state and federal constitutions."<sup>39</sup> Although the California superior court and the court of appeals held that the speech at issue was non-commercial, and therefore subject to the greatest measure of protection, the Supreme Court of California disagreed, overturning the lower courts.

After discussing the *Bolger* decision at length, the court recognized that the

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<sup>34</sup> *Id.* at \*14 (internal citations omitted).

<sup>35</sup> See e.g. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 495 (1995) ("the borders of the commercial speech category are not nearly as clear as the court has assumed"); *Edenfield v. Fane*, 507 U.S. 761, 768 (1993) ("ambiguities may exist at the margins of the category of commercial speech"); see also *Cincinnati v. Discovery Network Inc.*, 507 U.S. 410, 426 (1993) (recognizing "the difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category"); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985) (stating that "the precise bounds of the category of ... commercial speech are "subject to doubt, perhaps.")

<sup>36</sup> 27 Cal. 4th 939, 45 P.3d 243 (Cal. 2002).

<sup>37</sup> *Id.* at 946.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 946.

U.S. Supreme Court “has not adopted an all-purpose test to distinguish commercial from noncommercial speech.”<sup>40</sup> The Court held:

A close reading of the high court’s commercial speech decisions suggests, however, that it is possible to formulate a limited-purpose test. We conclude therefore, that when a court must decide whether particular speech may be subjected to the laws aimed at preventing false advertising or other forms of commercial deception, categorizing a particular statement as commercial or noncommercial speech requires considerations of *three elements: the speaker, the intended audience, and the content of the message.*<sup>41</sup>

Expanding on the three elements, the *Nike* court stated that “in typical commercial speech cases, the speaker is likely to be someone engaged in commerce;” the intended audience is likely to be “actual or potential buyers or customers of the speaker’s goods or services” or persons likely to influence potential buyers; the content should be “commercial in character” which means “that the speech consists of representations of fact about the business operations, products, or services of the speaker made for purpose of promoting sales of, or other commercial transactions in, the speaker’s products or services.”<sup>42</sup> The Court went on to state that this definition was consistent with the *Bolger* factor of “product references,” which the *Nike* court broadly interpreted to include:

Statements about the manner in which the products are manufactured, distributed, or sold, about repair or warranty services that the seller provides to purchasers of the product, or about the identity or qualifications of persons who manufacture, distribute, sell, service, or endorse the product. Similarly, references to services would include not only statements about the price, availability, and quality of the services themselves, but also, for example, statements about the education, experience, and qualifications of the persons providing or endorsing the services.<sup>43</sup>

The Court added:

This broad definition of ‘product references’ is necessary, we think, to adequately categorize statements made in the context of a modern, sophisticated public relations campaign intended to increase sales and profits by enhancing the image of a product or of its manufacturer or seller.<sup>44</sup>

Applying its own three part test to the facts of *Nike*, the California Supreme Court found that the three elements (the speaker – Nike, a commercial speaker, the intended audience – consumers of Nike products, and the content – representations

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<sup>40</sup> *Id.* at 959.

<sup>41</sup> *Id.* at 960 (emphasis added).

<sup>42</sup> *Id.* at 960-61.

<sup>43</sup> *Id.* at 961.

<sup>44</sup> *Id.* at 961-62.

of fact of a commercial nature) were all satisfied by the circumstances.<sup>45</sup> Accordingly, the Court held that:

Because 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, we conclude that these messages are commercial speech for purposes of applying state laws barring false and misleading commercial messages.<sup>46</sup>

The dissenting justices in *Nike* took the position that the newly announced test was overbroad, and that "taken to its logical conclusion, [it] renders all corporate speech commercial speech."<sup>47</sup> Justice Brown argued that because a corporation's product includes the corporation itself, and since all corporate speech about a public issue reflects on the corporate image, the majority's test inevitably makes all corporate speech commercial.<sup>48</sup> Accordingly, Justice Brown found that "the majority's limited-purpose test unconstitutionally chills a corporation's ability to participate in the debate over matters of public concern."<sup>49</sup> Much of the dissents' analyses focused on the distinction between commercial and noncommercial speech and the difficulties associated with categorizing a particular statement as either commercial or noncommercial speech, particularly when the speech at issue represents a combination of both.<sup>50</sup>

#### **4. "Novel Constitutional Questions" – Nike – What Happened Next and Why Defining Commercial Speech Remains Unresolved**

Nike appealed the California Supreme Court's ruling to the U.S. Supreme Court and that Court granted *certiorari*. After receiving 34 briefs on the merits and hearing oral arguments, the Court dismissed the previously granted writ as "improvidently granted," and refused to decide the questions presented.<sup>51</sup> The majority opinion dismissed the claims on the grounds that (1) the judgment entered by the California Supreme Court was not final, (2) neither party has standing to invoke the jurisdiction of federal court; and (3) the potential for premature adjudication of novel constitutional questions.<sup>52</sup> On the third issue, the court recognized that "This case presents novel First Amendment questions because the speech at issue represents a blending of commercial speech, noncommercial speech, and debate on an issue of public debate."<sup>53</sup> However, the Court appeared to reserve

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<sup>45</sup> *Id.* at 963.

<sup>46</sup> *Id.* at 946.

<sup>47</sup> *Id.* at 984.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> 539 U.S. 654, 667 (2003).

<sup>52</sup> *Id.* at 657.

<sup>53</sup> *Id.* at 663.

its decision on that subject to a later date, or perhaps, a later case.

The dissenting opinion authored by Justice Kennedy, joined by Justices Breyer and O'Connor, took the opportunity to theorize as to how "blended" speech should be handled under the First Amendment.<sup>54</sup> Justice Kennedy stated that *Nike* would have required the court to reconcile conflicting principles in First Amendment jurisprudence, including, (1) that the First Amendment protects only truthful commercial speech, and (2) that the First Amendment requires liberty to discuss publicly all matters of public concern.<sup>55</sup> Justice Kennedy opined that he would favor the latter principle over the former.<sup>56</sup>

The dissent went further to find that "the communications at issue are not purely commercial in nature. They are better characterized as involving a mixture of commercial and noncommercial (public-issue-oriented) elements."<sup>57</sup> Describing some of Nike's speech, the dissent found that "it concerns a matter that is of significant public interest and active controversy, and it describes factual matters related to that subject in detail."<sup>58</sup> Justice Kennedy distinguished this type of speech from purely commercial speech "usually defined as speech that does *no more* than propose a commercial transaction."<sup>59</sup> Accordingly, the dissent opined that "If this Court were to reach the merits, it would hold that heightened scrutiny applies..."

The High Court dismissed *Nike v. Kasky*, and has not directly addressed the question again, nor has it established a framework for analyzing restrictions on "blended" speech that includes both commercial and noncommercial elements.

No discussion of commercial speech is complete without recognizing, if not deciding, the issue of what constitutes "commercial speech" in the first instance. Yet, many if not most cases that touch on the First Amendment do not do so. Increasingly, courts are finding that the speech at issue is protected speech subject to heightened scrutiny *and* finding it protected applying the intermediate scrutiny of *Central Hudson*.

As the Supreme Court continues looking at how government goes about its business of controlling what, when, where, why, and how information may be communicated, it has matured significantly in recognizing the simplicity of the command of the Constitution. For example, in *Linmark Associates Inc. v. Township of Willingboro*, a case involving residential "for sale" signs, the Court recognized that what was at issue was often more than a regulation of a commercial transaction—it was suppression of facts and information for the purpose of controlling conduct.<sup>60</sup>

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<sup>54</sup> *Id.* at 665-686 (J. Kennedy, dissenting).

<sup>55</sup> *Id.* at 676.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.* at 677.

<sup>59</sup> *Id.* (emphasis added).

<sup>60</sup> *Linmark Assoc., Inc. v. Willingboro*, 431 U.S. 85 (1977).

## **E. If the Speech Is Commercial: *Central Hudson Gas and Electric***

The Supreme Court set out a test for commercial speech in the seminal case *Central Hudson Gas & Electric v. Public Service Commission of New York*, rejecting what it viewed as the “highly paternalistic” view that government has complete power to suppress or regulate commercial speech, and went on to recognize that:

‘[People] will perceive their own best interests if only they are well enough informed, and ... the best means to that end is to open the channels of communication, rather than to close them....’ Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.<sup>61</sup>

Culling out false and fraudulent speech and speech in furtherance of criminal activity, the Supreme Court ventured down a new trail, one far better reasoned than its approach in *Valentine* but no less woven of whole cloth stating:

The First Amendment’s concern for commercial speech is based on the informational function of advertising. Consequently, there can be no constitutional objection to accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity. If the communication is neither misleading nor related to unlawful activity, the government’s power is more circumscribed.<sup>62</sup>

### **1. “Clear and Present Danger” Using Speech Bans to Pursue Non-Speech Related Policy**

The *Central Hudson* opinion was not without controversy. The five-member majority was joined by three concurring justices who filed a separate opinion, and Justice Rehnquist filed a strongly worded dissent. In his concurring opinion, Justice Blackmun discussed a concept that the Court has frequently addressed since *Central Hudson* – that government should not be permitted to enforce a speech policy it could not establish by direct regulation. Addressing this issue, Justice Blackmun stated:

[I]t is a covert attempt by the State to manipulate the choices of its citizens, not by persuasion or direct regulation, but by depriving the public of the information needed to make free choice. As the Court recognizes, the State’s policy choices are insulated from the visibility and scrutiny that direct regulation would entail and the conduct of citizens is molded by the information that government chooses to give them. (‘We review with special care regulations that entirely suppress commercial speech in order to pursue non-speech-related policy. In

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<sup>61</sup> *Central Hudson Gas & Elec. Corp. v. NY Public Service Comm.*, 447 U.S. 557, 562 (1980) (internal citations omitted).

<sup>62</sup> *Id.* at 563-64 (internal citations omitted).

those circumstances, a ban on speech could screen from public view the underlying governmental policy.’)

If the First Amendment guarantee means anything, it means that, absent clear and present danger, government has no power to restrict expression because of the effect its message is likely to have on the public.<sup>63</sup>

This concept of not allowing the state to act through enforcement where it either has not or cannot act or regulate directly is a matter of significance that bears on the analysis of issues related to FDA enforcement of the dissemination of medical and scientific information by FDA-regulated industry.

In considering how the Court should view the dissemination of truthful medical or scientific information, particularly as it relates to dissemination of information that is considered the “standard of care” in the practice of medicine, but not in the FDA-approved labeling (and thus according to the government, *per se* false and misleading and subject to criminal and civil penalties under FDA’s enforcement regime), we might heed the wisdom of Justice Blackmun, who, referring to the Court’s landmark decision in *Va. Pharmacy Bd.*, stated:

What is at issue is whether a State may completely suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information’s effect upon its disseminators and its recipients.... [We] conclude that the answer to this [question] is in the negative.<sup>64</sup>

## **2. *Even Shakespeare was Motivated by Money***

In their concurring opinion in *Central Hudson*, Justices Stevens and Brennan put the issue even more colorfully:

Neither labor leader’s exhortation to strike, nor an economist’s dissertation on the money supply, should receive any lesser protection because the subject matter concerns only the economic interests of the audience. Nor should the economic motivation of a speaker qualify his constitutional protection; even Shakespeare may have been motivated by the prospect of pecuniary reward. Thus, the Court’s first definition of commercial speech is unquestionably too broad ...

Those who won our independence by revolution were not cowards ... no danger flowing from speech can be deemed clear and present, unless the incidence of the evil apprehended is so imminent that it may befall before there is opportunity for full discussion. If there be time to expose through discussion the falsehood and fallacies, to avert the evil by the processes of education, the remedy to be applied is more speech, not enforced silence. Only an emergency can justify repression. Such

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<sup>63</sup> *Id.* at 575 (internal citations omitted).

<sup>64</sup> *Id.* at 576; see also *Carey v. Population Serv. Int’l*, 431 U.S. 678, 700-702 (1977); *Brandenburg v. Ohio*, 395 U.S. 444, 447 (1969).

must be the rule if authority is to be reconciled with freedom. Such, in my opinion, is the command of the Constitution.<sup>65</sup>

Nowhere may this sentiment be more appropriate than concerning off-label promotion, where the physician, a learned intermediary, is charged to assess the validity of the information in exercising his medical judgment for a patient.

Equally strong in dissent, and finding that the restrictions on speech are no more than economic regulations, Justice Rehnquist believed the *Central Hudson* Court had gone too far, stating: “the test adopted by the Court thus elevates the protection accorded commercial speech that falls within the scope of the First Amendment to a level that is virtually indistinguishable from that of non-commercial speech.”<sup>66</sup>

While it remains debatable that Justice Rehnquist was correct and, ultimately, commercial speech will be relegated to the trash bin of constitutional jurisprudence, Justice Rehnquist may have foreseen a new realm of litigation arising from the ashes of commercial speech as the Court relieves government from its stranglehold on dissemination of commercial information when he stated:

The notion that more speech is the remedy to expose ‘falsehood and fallacies’ is wholly out of place in the commercial bazaar, where if applied logically, the remedy of one who was defrauded would be merely a statement, available upon request, reciting the Latin maxim ‘*caveat emptor*.’ But since ‘fraudulent speech’ in this area is to be remediable under *Virginia Pharmacy Board*, the remedy of one defrauded is a lawsuit or an agency proceeding based on common law notions of fraud that are separated by a world of difference from the realm of politics and government.<sup>67</sup>

### **3. The Central Hudson Test**

In the thirty years since the Supreme Court decided *Central Hudson*, the rule has been applied in a number of contexts, and refined and embellished. The *Central Hudson* test today can be articulated as follows:

1. The commercial speech must concern unlawful activity and not be misleading.<sup>68</sup>
  - a. If the information is “inherently” misleading, it may be banned entirely.<sup>69</sup>

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<sup>65</sup> *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 579-80, 582.

<sup>66</sup> *Id.* at 591-92 (internal citations omitted).

<sup>67</sup> *Id.* at 598-99.

<sup>68</sup> *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 367 (2002).

<sup>69</sup> See *Pearson v. Shalala*, 164 F.3d 650, at 655 (D. D.C. 1999) (citing *In re R.M.J.*, 455 U.S. 191, 203 (1982)).

- b. Claims already found by the Court to have been “misleading or equivalent deceptive representations” are not entitled to First Amendment protections.<sup>70</sup>
  - c. In the case of “potentially misleading commercial speech,” a court reviewing a challenge to such a government regulation must employ the remaining *Central Hudson* criteria.<sup>71</sup>
2. The asserted governmental interest in regulating the speech must be substantial.
  3. The regulation must directly advance the governmental interest asserted, and
  4. The regulation may not be more extensive than is necessary to serve that interest. In determining whether the regulation is more extensive than necessary, courts have considered:
    - a. “Whether the fit between the government’s end and the means chosen to accomplish those ends is not necessarily perfect, but reasonable.”<sup>72</sup>
    - b. A “reasonable fit” is not a “least restrictive means” test.<sup>73</sup>
    - c. Courts do not ask where there is “no conceivable alternative,” but instead, the courts look to whether the “regulations not burden substantially more speech than is necessary to further the government’s interests.”<sup>74</sup> “[I]f the Government c[an] achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.”<sup>75</sup>

## IV. APPLYING THE FIRST AMENDMENT TO CLAIMS UNDER THE FDCA

### A. *Washington Legal Foundation v. Henney*

In *Washington Legal Foundation v. Henney*, Judge Lamberth of the U.S. District Court for the District of Columbia held that FDCA’s provisions on off-label dissemination were subject to First Amendment scrutiny under *Central Hudson* and rejected the FDA’s argument that it was regulating conduct and not speech.<sup>76</sup> The court entered a permanent injunction prohibiting the FDA from enforcing “any regulation, guidance, policy, order or other official action” to “prohibit, restrict,

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<sup>70</sup> See *F.T.C. v. Direct Marketing Concepts, Inc.*, 648 F. Supp. 2d 202, 217 (D. Mass. 2009).

<sup>71</sup> *Pearson*, 164 F.3d at 655.

<sup>72</sup> *Id.* at 656.

<sup>73</sup> *Clear Channel Outdoor, Inc. v. City of New York*, 594 F.3d 94, 104 (2d Cir. 2010).

<sup>74</sup> *Bd. of Trs. State Univ. of N.Y. v. Fox*, 492 U.S. 469, 478 (1989).

<sup>75</sup> *Thompson*, 535 U.S. 357.

<sup>76</sup> 13 F. Supp. 2d 51, 59 (D.D.C. 1998).

sanction, or otherwise seek to limit any pharmaceutical or medical device manufacturer or any other person from” doing the following:

1. Disseminating reprints of materials from “bona fide peer-reviewed professional journals”
2. Disseminating textbooks or portions of textbooks
3. Suggesting content or speakers to an independent program provider.

The court found that the FDA regulation was more than what was necessary to serve the government’s interests in regulating off-label communications and that there were less restrictive alternatives.<sup>77</sup>

On appeal, the D.C. Circuit noted that “as a result of the government’s clarification at oral argument, the dispute between the parties has disappeared before our eyes.”<sup>78</sup> The appeal was dismissed, and the trial court’s injunction was vacated in part. What remains of the injunction has long been disputed. When asked on remand to answer that question, Judge Lamberth simply threw up his hands. While stating that he “sensed” that he would be called upon once again to address First Amendment limitations on the FDA’s authority, he concluded, “For now, however, the issue must be given a temporary rest.”<sup>79</sup>

### **B. *Sorrell v. IMS Health Inc.***

In *Sorrell v. IMS Health Inc.*,<sup>80</sup> for the first time, the United States Supreme Court recognized that “[s]peech in aid of pharmaceutical marketing, however, is a form of expression protected by the Free Speech Clause of the First Amendment.” This one phrase stated matter-of-factly what was unthinkable a generation earlier. *Sorrell* represents the most significant pronouncement of how the Supreme Court views the First Amendment in the context of FDA-approved products. In *Sorrell*, the Court struck down a Vermont statute barring disclosure of prescribing information (PI) to be used for marketing purposes.<sup>81</sup> The Vermont statute prohibited drug companies from using prescription information for “marketing or promoting a prescription drug...” The defendants were “data miners” and an association of brand-name drug manufacturers who sought an injunction against the state from implementing the statute.

The Supreme Court found that the statute at issue “disfavors marketing, that is speech with a particular content ... and [t]he law on its face burdens disfavored speech by disfavored speakers.”<sup>82</sup> Accordingly, the Court found that heightened scrutiny was warranted because the Vermont law “is designed to impose a specific, content-based burden on protected expression.” The Court further stated: “[t]he First

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<sup>77</sup> *Id.*

<sup>78</sup> 202 F.3d 331, 334 (D.C. Cir. 2000).

<sup>79</sup> 128 F. Supp. 2d 11, 15 (D.D.C. 2000).

<sup>80</sup> No. 10-779, 564 U.S. \_\_\_\_, 131 S. Ct. 2653 (2011).

<sup>81</sup> *Id.* at 2659.

<sup>82</sup> *Id.* at 2663.

Amendment requires heightened scrutiny whenever the government creates a 'regulation of speech because of disagreement with the message it conveys.'"<sup>83</sup>

In disposing of the "burden" on and harassment of prescribing physicians, the Court simply stated that "[p]hysicians can, and often do, simply decline to meet with detailers ..." According to the Supreme Court:

Those who seek to censor or burden free expression often assert that disfavored speech has adverse effects. But the 'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. These precepts apply with full force when the audience, in this case prescribing physicians, consists of 'sophisticated and experienced consumers.' ... That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers.<sup>84</sup>

### **C. *United States v. Caronia.***

December 3, 2012 was a good day for Alfred Caronia, a sales rep for a drug manufacturer. It was three years after a trial for off-label promotion which resulted in a conviction for a misdemeanor and subjected him to a \$50 fine and 100 hours of community service. Not happy was a former codefendant, Dr. Gleason, who settled before trial and, as a result of his federal criminal plea, spiraled downward, taking his own life. So why is this sad case tearing the fabric of FDA enforcement of off-label promotion? And how is it that this landmark decision is being ignored, as though it didn't happen, by the FDA?

Not unlike the iceberg that sank the Titanic or the stone that felled Goliath, seemingly small things sometimes present surprising outcomes. And by all accounts, Mr. Caronia's misdemeanor prosecution was a small thing. But, on December 3, 2012, two years to the day from hearing oral arguments in the case, the Second Circuit, in *United States v. Caronia*,<sup>85</sup> ruled that the FDA's enforcement of the FDCA against Mr. Caronia violated his First Amendment rights, stating:

We conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.<sup>86</sup>

*Caronia* concerned a sleep-inducing depressant, Xyrem. The drug included a black box warning and was labeled for serious potential side effects. A government informant, Dr. Charno, who had pled guilty to submitting fraudulent medical insurance bills, participated in a sting operation and contacted Caronia, asking for

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<sup>83</sup> *Id.* at 2664.

<sup>84</sup> *Id.* at 2671.

<sup>85</sup> 703 F.3d 149 (2d Cir. 2012).

<sup>86</sup> 703 F.3d 149, 169 (2d Cir. 2012).

information on off-label use and for a presentation by a medical liaison. Caronia arranged the presentation, and the sting operation resulted in prosecution. Unfortunately for Caronia, his employer admitted to a conspiracy to misbrand and took a plea bargain, and the former manager testified that he had personally instructed the medical liaison to misbrand the product on prior occasions.

In denying Mr. Caronia's motion to dismiss, the trial court was prescient in stating:

Reduced to its essence, Caronia's argument is that the government cannot restrict truthful, non-misleading promotion by a pharmaceutical manufacturer (or its employees) to a physician of the off-label uses of an FDA-approved drug ... Squarely, Caronia's constitutional attack calls into question America's regulatory regime for the approval and marketing of prescription drugs.<sup>87</sup>

The trial court went on to echo the court in *WLF v. Henney*, stating: "The Constitutional issues raised in Caronia's motion are very much unsettled, not only in the circuit but nationwide."<sup>88</sup>

In deciding Mr. Caronia's appeal, the Second Circuit noted that the FDCA makes it a crime to misbrand or conspire to misbrand a drug, but the statute and its accompanying regulations do not expressly prohibit or criminalize off-label promotion. Based on the statutory and regulatory framework, the Second Circuit elected to avoid deciding the constitutionality of the FDCA, instead questioning the government's prosecution. The result is the same for Mr. Caronia, but it enabled the court to reach its result without finding the law unconstitutional. In this regard, the court stated:

Thus, under the principle of constitutional avoidance, explained *infra*, we construe the FDCA as not criminalizing the simple promotion of a drug's off-label use because such a construction would raise First Amendment concerns. Because we conclude from the record in this case that the government prosecuted Caronia for mere off-label promotion and the district court instructed the jury that it could convict on that theory, we vacate the judgment of conviction.<sup>89</sup>

The court went on to state:

To the extent there is any ambiguity as to whether off-label promotion is tantamount to illegal misbranding, we construe the FDCA narrowly to avoid a serious constitutional question. As we now explain, we decline the government's invitation to construe the FDCA's misbranding provisions to criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives because such a construction – and a conviction obtained under the

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<sup>87</sup> *U.S. v. Caronia*, 576 F. Supp. 2d 385, 393 (E.D.N.Y. 2008).

<sup>88</sup> *Id.* at 394.

<sup>89</sup> *Caronia*, 703 F.3d at 160.

government's application of the FDCA – would run afoul of the First Amendment.<sup>90</sup>

In arguing the case to the Second Circuit, the government took a position it had not taken at the trial court level, arguing that the speech at issue “was not speech at all but was conduct evidence of intent to misbrand.” The Second Circuit was unimpressed with the government's ploy rejecting it as “simply not true,” “the government clearly prosecuted Caronia for his words – for his speech.”<sup>91</sup>

Following the Supreme Court in *Sorrell*, the Second Circuit analyzed the case under both strict scrutiny and intermediate scrutiny stating:

First, we conclude that the government's construction of the FDCA's misbranding provisions imposes content and speaker based restrictions on speech subject to heightened scrutiny. Second, we conclude the government cannot justify a criminal prohibition of off-label promotion even under *Central Hudson's* less rigorous intermediate test.<sup>92</sup>

The court found heightened scrutiny because the “government's construction of FDCA's misbranding provisions” is “content and speaker based” and therefore subject to heightened scrutiny.<sup>93</sup> Content based because it distinguishes “favored speech” on the basis of ideas expressed. Particularly notable to the Second Circuit was that off-label speech is prohibited while off-label use is not. In addressing the “speaker based” aspect, the Second Circuit observed that the government's construction only barred manufacturers from speaking where others are free to speak.

Despite finding that strict scrutiny applied to the speech at issue, the *Caronia* court applied the four-part intermediate scrutiny test for commercial speech in *Central Hudson*.<sup>94</sup> In addressing the fourth prong of *Central Hudson*, the Second Circuit found the regulation is more extensive than is necessary to serve the government's interest. According to the court, “if the government is concerned about the use of drugs off-label, it could more directly address the issue” and the court set out six potential alternatives.<sup>95</sup> Among those alternatives the court stated:

The FDA could further remind physicians and manufacturers of, and even perhaps further regulate, the legal liability surrounding off-label promotion and treatment decisions.<sup>96</sup>

In its Footnote 12, the *Caronia* court stated, “Physicians and pharmaceutical manufacturers can be held accountable for off-label drug use through medical

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<sup>90</sup> *Id.* at 162.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 164.

<sup>93</sup> *Id.* at 165.

<sup>94</sup> *Id.* at 165-166 (*citing Central Hudson*, 447 U.S. at 562).

<sup>95</sup> *Id.* at 168.

<sup>96</sup> *Id.*

malpractice and negligence theories of liability.”<sup>97</sup> This statement echoed that made by Justice Rehnquist in his *Central Hudson* dissenting opinion. It certainly lays bare the double-edged sword that decisions like *Caronia* pose for medical product companies. Trading criminal prosecutions and penalties for private litigation could prove as intrusive as and perhaps even more expensive than governmental prosecutions.

The Second Circuit went on to apply the now well-known *Central Hudson* four part test holding as follows:

First, the commercial speech must concern unlawful activity and not be misleading. The court found the off-label promotion at issue concerned a lawful conduct and the information was “truthful.”<sup>98</sup>

Second, the Second Circuit found the asserted governmental interest in drug safety and public health was substantial.

Third, in finding that the prohibition failed the third prong of *Central Hudson*, the court found that the prohibition did not directly advance the governmental interest asserted and stated:

[I]t does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government’s goals of preserving the efficacy and integrity of the FDA’s drug approval process and reducing patient exposure to unsafe and ineffective drugs.<sup>99</sup>

Not only did the court find that the prohibition failed to advance the government’s interest, it found the opposite:

[P]rohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use ‘paternalistically’ interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public’s detriment, informed and intelligent treatment decisions.<sup>100</sup>

Recognizing that it is the physician’s role to consider multiple factors to determine the best course of action for a patient, the court stated:

The government’s construction of the FDCA essentially legalizes the outcome – off-label use – but prohibits the free flow of information that would inform that outcome. If the government’s objective is to shepherd physicians to prescribe drugs only on-label, criminalizing manufacturer promotion of off-label use while permitting others to promote such use to physicians is an indirect and questionably effective

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<sup>97</sup> *Id.* at 168, n. 12.

<sup>98</sup> *Id.* at 164.

<sup>99</sup> *Id.* at 165-66.

<sup>100</sup> *Id.* at 166.

means to achieve that goal. Thus, the government's construction of the FDCA's misbranding provisions does not directly advance its interest in reducing patient exposure to off-label drugs or in preserving the efficacy of the FDA drug approval process because the off-label use of such drugs continues to be generally lawful. Accordingly, the government's prohibition of off-label promotion by pharmaceutical manufacturers provides only ineffective or remote support for the government's purpose.<sup>101</sup>

Fourth, concerning the final prong of *Central Hudson* – whether the regulation is more extensive than necessary or whether there is a “reasonable fit” – the Second Circuit found the regulation more extensive than necessary to serve the government's interest. According to the court, “if the government is concerned about the use of drugs off-label, it could more directly address the issue” and the court set out six potential alternatives:

1. It could guide physicians and patients in differentiating between misleading and false promotion, exaggerations and embellishments, and truthful or non-misleading information.
2. The government could develop its warning or disclaimer systems, or develop safety tiers within the off-label market, to distinguish between drugs.
3. The government could require pharmaceutical manufacturers to list all applicable or intended indications when they first apply for FDA approval, enabling physicians, the government, and patients to track a drug's development.
4. To minimize off-label use, or manufacturer evasion of the approval process for such use, the government could create other limits, including ceilings or caps on off-label prescriptions.
5. The FDA could further remind physicians and manufacturers of, and even perhaps further regulate, the legal liability surrounding off-label promotion and treatment decisions. In its Footnote 12, the court states, “Physicians and pharmaceutical manufacturers can be held accountable for off-label drug use through medical malpractice and negligence theories of liability.”
6. Finally, where off-label drug use is exceptionally concerning, the government could prohibit the off-label use altogether.

According to the Court, “[t]he possibilities are numerous indeed.”

While the Second Circuit purports to merely state a “simple” holding, and the FDA is also pretending this decision either was never issued or is of no consequence, the ramifications are breathtaking:

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<sup>101</sup> *Id.* at 167 (internal quotations and citations omitted).

We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs. Our conclusion is limited to FDA-approved drugs for which off-label use is not prohibited, and we do not hold, of course, that the FDA cannot regulate the marketing of prescription drugs. *We conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.*<sup>102</sup>

The Second Circuit opinion was not unanimous, and the government waived its right to seek *en banc* review. FDA did take action on December 17, 2012, issuing a “Drug Safety Communication” concerning the product at issue in *Caronia* noting that “[m]any of the deaths occurred in patients who were prescribed Xyrem for unapproved uses such as fibromyalgia...”<sup>103</sup> Notably, fibromyalgia was among the uses promoted off-label in *Caronia*.

Off-label promotion cases are simply too big and the stakes (i.e. losing the ability to conduct business) are simply too great for a company to seriously consider defending an off-label marketing claim. While the government has poured over \$14.1 billion dollars in fines and penalties into its coffers since January 2009,<sup>104</sup> a federal circuit court has now found that enforcement regime to be in violation of the First Amendment to the U.S. Constitution. Ironically, massive off-label promotion plea agreements involving pharmaceutical companies have been the fodder of daily news reports for a generation; yet, it took a small case involving an individual pharmaceutical sales rep to question the constitutionality of FDA’s enforcement of off-label promotion.

While *Caronia* will provide real and immediate comfort to a great many sales representatives, and manufacturers and distributors of FDA-regulated products may see this case as the watershed, a real and lasting impact may have yet to be realized. As suggested at footnote 12 in the *Caronia* opinion and by Justice Rehnquist in his dissenting opinion in the landmark *Central Hudson* case, private litigants may replace governmental prosecutions, and nationwide off-label promotion tort claims could pose a significant new threat to companies with products used off-label. Aboard the Titanic of FDA regulation of off-label promotion rode very potent cargo for manufacturers; deference to agency determinations, and preemption. Both may be going down with the ship.

#### **D. *U.S. v Harkonen***

On March 4, 2013 the Ninth Circuit ruled very differently from *Caronia*, affirming the conviction and sentence of the physician/CEO Dr. Harkonen, who was convicted of wire fraud in connection with the off-label marketing of Actimmune, a product approved by the FDA for rare pediatric diseases.<sup>105</sup> Perhaps it didn’t help Dr.

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<sup>102</sup> *Id.* at 169 (emphasis added).

<sup>103</sup> <http://www.fda.gov/Drugs/DrugSafety/ucm332029.htm> (last accessed Mar. 9, 2013).

<sup>104</sup> <http://www.justice.gov/opa/pr/2013/March/13-civ-270.htm> (last accessed Mar. 9, 2013).

<sup>105</sup> *U.S. v Harkonen*, 2013 U.S. App. LEXIS 4472 2013 (9<sup>th</sup> Cir. Mar. 3, 2013).

Harkonen that the company's "former Senior Director of Biostatistics testified that post-hoc analyses are "good science" in the sense that they may generate hypotheses for future study, but that he 'winc'd' when he saw the Press Release because 'the conclusiveness of the results was overstated.'"<sup>106</sup>

At trial, Harkonen received three years' probation, six months' home detention, community service and a \$20,000 fine. On appeal, the U.S. sought a greater sentence and Harkonen sought to reverse the verdict. In denying Harkonen's motion to exclude protected speech at trial, the trial court stated:

The *First Amendment* does not shield fraud. Contrary to the government's allegation, however, this does not mean that a prosecution for fraudulent misbranding 'cannot present *First Amendment* concerns.' The court must do more than accept the government's legal conclusions and must test the indictment by its sufficiency to charge an offense.<sup>107</sup>

The trial court decided this case prior to the Second Circuit ruling in *Caronia*,<sup>108</sup> which held that "the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."<sup>109</sup> While the Ninth Circuit affirmed Harkonen's conviction 90 days after the Second Circuit decided *Caronia*, it did not once mention the Second Circuit opinion.

The trial court in *Harkonen* did comment on *Caronia*, stating that unlike *Caronia* where the Government called speech evidence, *Harkonen* concerned both speech and conduct (i.e. the dissemination of speech):

The government is not trying to get protected speech in through back-door means by asserting the statements at issue are merely 'evidence' of a crime Harkonen committed. Rather, the government contends the fraud charges turn on a series of communications, stemming from the press release and continuing with deceptive disseminations to doctors and to patients, all of which together constituted a scheme to defraud. These allegations involve both the content of speech (the press release and copies and excerpts thereof in writings) and conduct (dissemination of those items). Thus, Harkonen is wrong when he claims that 'no conduct extrinsic to the speech is being prosecuted' because the government stated a conviction could be based upon both the press release and its disseminations. The court refers to both 'speech' and 'conduct' where appropriate in this Order.<sup>110</sup>

The trial court went on to wallow in a quagmire of "bona fide," "pure" and "less pure" speech stating:

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<sup>106</sup> *Id.* at \*12.

<sup>107</sup> *U.S. v Harkonen* 2009 U.S. Dist. LEXIS 47255 (N.D. Cal. 2009) (citations omitted).

<sup>108</sup> *United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012)

<sup>109</sup> *Id.* at 169.

<sup>110</sup> *Harkonen* 2009 U.S. Dist. LEXIS 47255 \*15 fn. 2 (N.D. Cal. 2009).

With the case law still in an unsettled state, *see, e.g., United States v. Caputo*, 517 F.3d 935, 939 (7th Cir. 2008); *Caronia*, 576 F. Supp. 2d at 394, this would present a thorny issue for the court were it not for the fact that the allegations of the indictment do not trench anywhere near the outer bounds of speech deemed controversial. As best can be gleaned from the case law and from the government's position in prior cases and in this case, speech is protected by the *First Amendment* if it is a *bona fide* scientific and educational speech that appears in independent and peer-reviewed sources, such as a journal article reprint or a medical textbook. While questions remain about when such 'pure' speech gets converted to a 'less pure' form of commercial speech when a drug company is involved, e.g., by funding the studies or by disseminating the speech through various promotional activities, they are of no moment here because *nowhere does the indictment invoke any 'pure' scientific speech.*

The 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 in the pulmonological and pharmaceutical analyst community, do not disturb this conclusion. That the speech is a press release and not a peer-reviewed publication, that it refers to a specific commercial product on the market (Actimmune(R)), and that it was unquestionably disseminated for commercial benefit (e.g., the first line notes InterMune's Nasdaq stock symbol), are allegations that take the speech at issue outside the realm of pure science speech and move it towards the realm of commercial speech.<sup>111</sup>

What the indictment alleges, and what the law does not protect as a *First Amendment* carve-out to liability under the FDCA, is that the press release and associated speech incorporates, reformats and post hoc reinterprets scientific results in a false and misleading manner and is then disseminated at Harkonen's direction to physicians and patients. As the government affirms, 'the [d]efendant is under indictment not because he promoted Actimmune[(R)] for an unapproved use . . . but because he made knowingly false and misleading statements in doing so.'<sup>112</sup>

In essence, concluding what the government commonly claims that false speech is not entitled to First Amendment protections. In discussing the alleged fraudulent nature of the Government's claims, the trial court observed that the data that Harkonen was indicted for promoting had already been submitted to and rejected by the FDA:

This was not a mere statement by an FDA employee that did not represent the views of the FDA but rather, as alleged, it constituted the underlying basis for the FDA's refusal to approve Actimmune(R) to treat IPF. Harkonen's argument that the FDA may not establish scientific truth *vel non* is misplaced. The allegation goes to the non-approved status of Actimmune(R) in treating IPF and the fraudulent representations made in the press release and its

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<sup>111</sup> *Id.* at \*17-18.

<sup>112</sup> *Id.* at \*20.

disseminations in spite of this non-approved status.<sup>113</sup>

In its unpublished opinion in *Harkonen*, the Ninth Circuit reviewed the First Amendment challenges “in two steps: (1)...whether sufficient evidence supports the verdict; and (2) ...whether the facts...establish the core constitutional facts.”<sup>114</sup> The “core constitutional fact” for *Harkonen* was a fraud finding by the jury, which the Ninth Circuit found supported by sufficient evidence. In a footnote, the Ninth Circuit noted that *Harkonen* presented evidence “that most firmly supported his case” but the Ninth Circuit court did not consider the evidence because it had not been presented to the jury.<sup>115</sup>

The Ninth Circuit opinion sidesteps any in-depth analysis of the First Amendment or Due Process issues raised by *Harkonen* on appeal. In addressing the government’s request to enhance the sentence, the Ninth Circuit observed that the government failed to “articulate a loss theory that made sense.” Citing the trial court, the Ninth Circuit noted that the government failed to prove an “actual pecuniary loss” by a “vulnerable victim” and “[t]his is clear from the district court’s conclusion that ‘we can’t even figure out who is a victim in this case, and whether the victims were benefited in some way.’”<sup>116</sup>

## **V. HOW DOES THE GOVERNMENT (FDA AND FTC) VIEW COMMERCIAL SPEECH?**

### **A. *Par Pharm., Inc v. U.S.***

On March 5, 2013, the Department of Justice issued a press release announcing “Par Pharmaceuticals Pleads Guilty and Agrees to Pay \$45 Million to Resolve Civil and Criminal Allegations Related to Off-Label Marketing.”<sup>117</sup> The plea and agreement to a five year Corporate Integrity Agreement resolved criminal and civil liability for promotion of the prescription drug Megace ES for unapproved uses. While perhaps lacking precision, DOJ release states:

Once approved, a drug may not be *distributed* in interstate commerce for unapproved or ‘off-label’ uses until the company receives FDA approval for the new intended uses.<sup>118</sup>

The Settlement also resolved the action *Par Pharmaceutical, Inc. v. U.S.*, a suit seeking declaratory relief to prohibit the FDA from, among other things, enforcing “FDA’s unconstitutional and invalid regulations” restricting truthful non-misleading speech.<sup>119</sup> In seeking to dismiss *Par*, the FDA submitted a declaration of

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<sup>113</sup> *Id.* at \*23.

<sup>114</sup> *U.S. v Harkonen*, 2013 U.S. App. LEXIS 4472 2013 \*5 (9<sup>th</sup> Cir. Mar. 3, 2013).

<sup>115</sup> *Id.* at \*8, fn. 2.

<sup>116</sup> *Id.* at \*13.

<sup>117</sup> <http://www.justice.gov/opa/pr/2013/March/13-civ-270.html> (last accessed Mar. 9, 2013).

<sup>118</sup> *Id.* (emphasis added).

<sup>119</sup> *Par Pharm., Inc. v. U.S.* No. 11-cv-01820-RC, (D.D.C. filed October 14, 2011), ECF No. 1.

the Associate Director of Medical Policy and Director of its Office of Medical Policy (OMP) at the Center for Drug Evaluation and Research (CDER). In the Declaration, the FDA purports to “describe ... FDA’s procedures and policies with respect to the communication of promotional information about off-label uses.”<sup>120</sup> To the extent FDA’s procedures and policies are stated, they are stated like a riddle, not stating specifically what is permitted:

FDA does not consider a manufacturer’s truthful and non-misleading speech to healthcare professionals concerning the approved use of an FDA-approved drug as establishing, by itself, a manufacturer’s objective intent that the drug be used for an unapproved use.

Nor does FDA regard a manufacturer’s knowledge that an FDA-approved drug was being prescribed by healthcare professionals for an unapproved use as establishing, by itself, a manufacturer’s objective intent that the drug be used for an unapproved use.<sup>121</sup>

While the FDA sheds dim light on what evidence will suffice to render “truthful speech” or knowledge of facts illegal stating: “determining ...the manufacturer’s ‘objective intent,’... can be based on ... the circumstances surrounding the drug’s distribution ... and may include “additional evidence suggesting ...a deliberate strategy to encourage off-label prescribing.”<sup>122</sup>

In its motion seeking to depose the FDA on the issues raised in the declaration, Par stated:

These statements which cannot be found in any FDA regulation or other official agency issuance, raise more questions than they answer. The Government tellingly does not explain how a company could ever engage in speech consistent with Dr. Sherman’s ‘by itself,’; i.e. without some ‘additional evidence’ that the government has left open would expose company officials to imprisonment.<sup>123</sup>

The Government has conveyed to Par positions inconsistent with Dr. Sherman’s assurances time and again in meetings throughout 2010 and 2011 between one or more of undersigned counsel and Government agencies... For example:

At meetings on April 29, 2010 and July 28, 2010, attorneys with the New Jersey U.S. Attorney’s Office and FDA questioned Par about promotion of Megace® *ES* in oncology and long-term care settings. The discussion focused on questions such as how Par could legally promote the use of Megace® *ES* for AIDS in those settings without first verifying the number of AIDS patients there.

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<sup>120</sup> *Id.*, ECF No. 14, at 1.

<sup>121</sup> *Id.*, ECF No. 14, at 7.

<sup>122</sup> *Id.*, ECF No. 14, at 8.

<sup>123</sup> *Id.* at 1:11-cv-01820, Doc 23, at 1-2.

In a telephone conference on September 2, 2010, prosecutors with the New Jersey U.S. Attorney's Office acknowledged that certain Par marketing materials related to the *on-label* use of Megace® ES, but said that fact did not absolve Par of wrongdoing if the communications went to physicians who had prescribed Megace® ES for off-label uses.

During a meeting on June 21, 2011, officials with the U.S. Attorney's Office, FDA, and DOJ Civil Fraud Section repeatedly suggested that the legality of promotional speech about Megace® ES turned on the number of AIDS patients the doctor treated. A senior DOJ official also indicated that promotion consisting of on-label speech that takes place in a setting where off-label use occurs is not protected by the First Amendment and, if Par believed otherwise, the issue would need to be litigated. *The senior DOJ official further indicated that the Government's view regarding the constitutionality of its position would not change unless and until a court told them otherwise.*

At a meeting on September 20, 2011, officials from DOJ Civil Fraud, in the presence of HHS OIG and U.S. Attorney's Office representatives who did not dissent, characterized the presence of Par sales representatives in long-term care facilities as inherently constituting off-label promotion regardless of whether the content of the speech related to on-label or off-label uses.<sup>124</sup>

Thus, the materials in *Par* demonstrate the government's broad and expansive view of conduct that constitutes off-label promotion if not a palpable hostility towards the constitutional protections for regulated industry.

## **B. *U.S. v Caronia***

In *Caronia* the government took the position that, speech was evidence of intent stating:

The fact that Xyrem was promoted for unapproved uses plays an evidentiary role in this regulatory scheme; it shows that the unapproved uses were intended by the manufacturer, and hence that the lack of directions for those uses in the drug's labeling renders the drug misbranded under 35 U.S.C. 352(f)(1). The constitutionality of using speech as evidence of intent was expressly sustained in *Wisconsin v. Mitchell*.<sup>125</sup> Even if *Caronia's* conviction were predicated solely on off-label promotion, and even if off-label promotion were a prohibited act (neither of which is true), such a prohibition would be reviewed under the First Amendment standards of *Central Hudson Gas & Elec. Co. v. Pub. Service Commission*.<sup>126</sup> And the FDCA readily satisfies those standards.<sup>127</sup>

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<sup>124</sup> See *Par Pharmaceutical, Inc. v. US*, 1:11-cv-01820 Doc 23 filed 3-23-12, Plaintiff's Reply Memorandum in Support of Motion for Limited Discovery at pp. 10-11.

<sup>125</sup> 508 U.S. 476 (1993).

<sup>126</sup> 447 U.S. 557 (1980).

<sup>127</sup> See Supp. Brief for the United States at 1.

Thus, the government declares that what was at issue in *Caronia* was not speech but speech that was mere evidence of intent and, thus, not really speech:

Moreover, even if *Sorrell* had raised the level of judicial scrutiny for restrictions on commercial speech, it would not affect this case. As noted above, *Caronia* was not convicted for conspiring to promote off-label uses of Xyrem, but instead for conspiring to distribute Xyrem without adequate directions for use. The Supreme Court and this Court have long employed a more relaxed standard of judicial review when the government requires disclosure of commercial information<sup>128</sup> ('rules 'mandating that commercial actors disclose commercial information' are subject to the rational basis test'). *Sorrell* does not address, much less alter, the constitutional standards governing disclosure statutes. Nor does *Sorrell* disturb the Court's holding in *Wisconsin v. Mitchell* that the First Amendment is not offended by laws, like the one here, that use a defendant's speech as evidence of intent.<sup>129</sup>

The Second Circuit was not persuaded by the government's argument that the First Amendment was not implicated based on the positions it took at trial. The court noted: "the government's contention that it did not prosecute *Caronia* for promoting the off-label use of an FDA-approved drug is belied by its conduct and arguments at trial and the government's assertion now that his used *Caronia*'s efforts to promote Xyrem for off-label use only as evidence of intent is simply not true."<sup>130</sup>

### **C. *In the Matter of POM Wonderful LLC***

On January 10, 2013, the Federal Trade Commission (FTC) issued its Opinion, a long awaited next-step in the arduous journey of *In the Matter of POM Wonderful LLC et al.*<sup>131</sup> In *POM Wonderful*, a case involving food labeling, the FTC deftly declared the speech "false" and then declared the First Amendment inapplicable:

Once the Commission has determined that Respondents' ads are actually misleading, no further analysis is necessary because misleading commercial speech is not protected by the First Amendment. Each of the cases cited by Respondents acknowledges that '[t]he Federal Government [is] free to prevent the dissemination of commercial speech that is false, deceptive, or misleading."<sup>132</sup> The three-part analysis for determining whether regulation of commercial speech is constitutional under *Central Hudson* – whether the regulation is based on a substantial governmental interest, whether the regulation directly advances the governmental interest asserted, and whether the regulation is not more extensive than necessary to serve that interest –

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<sup>128</sup> See, e.g., *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 650-51 (1985); *New York State Restaurant Ass'n v. New York City Board of Health*, 556 F.3d 114, 132-34 (2d Cir. 2009).

<sup>129</sup> *Id.* at pg. 6.

<sup>130</sup> *Caronia*, 703 F.3d at 161.

<sup>131</sup> <http://www.ftc.gov/os/adjpro/d9344/130116pomopinion.pdf>.

<sup>132</sup> *Zauderer*, 471 U.S. at 638.

is applicable only if a threshold inquiry determines that the speech in question is not false or misleading.<sup>133</sup>

#### **D. *U.S. v. Harkonen***

In *Harkonen*, the Government argued that the issue concerned both speech and conduct (i.e. the dissemination of speech).

The government is not trying to get protected speech in through back-door means by asserting the statements at issue are merely ‘evidence’ of a crime Harkonen committed... These allegations involve both the content of speech (the press release and copies and excerpts thereof in writings) and conduct (dissemination of those items).<sup>134</sup>

In prosecuting off-label promotion, the government has taken the position that any “suggest[ion] that [a] drug is safe and effective” for an off-label use is “false or misleading,” irrespective of the scientific support for the suggestion.<sup>135</sup>

## **VI. OTHER CONSTITUTIONAL CONSIDERATIONS**

### **A. FDA’s Use of “Guidance”**

Manufacturers and sellers of FDA-regulated products exist in a dynamic world of change and innovation. They are constantly adapting to new products, technology, and market forces where the flow of information serves to both promote and educate. Manufacturers and sellers often look to the FDA for “guidance” on how to navigate the changing waters of commerce. Although the FDA regularly issues “guidance” on how it interprets the FDCA and regulations, its guidance documents should come with its own black box warning:

It is the FDA’s “current thinking” “does not confer any rights ... does not operate to bind the FDA or the public.” AND, according to the FDA, “[y]ou may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.” According to the FDA, guidances “should be viewed only as recommendations.”

The FDA’s “rules” on the dissemination of information concerning off-label or unapproved new uses are contained in the following rules and Guidance or Draft Guidance documents. The following are the attempts by the FDA (and the FTC) over the past approximately twenty years to address who, what when, where, why and how a manufacturer may disseminate information related to new uses:

- *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of*

<sup>133</sup> See *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 566; *Edenfield v. Fane*, 507 U.S. 761, 768 (1993); *Daniel Chapter One*, 2009 WL 5160000 at \*19-20.

<sup>134</sup> 2009 U.S. Dist. LEXIS 47255, \*14 (N.D. Cal. 2009).

<sup>135</sup> See *Warner-Lambert Sentencing Memo* at 8–9. No. 04-10150 (D. Mass. 2004) (“*Warner-Lambert Sentencing Memo*”); 21 U.S.C. § 352(a).

*Approved Drugs and Approved Drugs and Approved or Cleared Medical Devices.*<sup>136</sup>

• *Industry Guidance on Industry Supported Scientific and Educational Activities.*<sup>137</sup>

• *Promotion of FDA – Regulated Medical Products Using the Internet and Social Media Tools.* This is the FDA’s anticipated Guidance on the Internet. The FDA held a two-day meeting in 1996 and an additional two days of hearings on November 12-13, 2009 to attempt to fashion rules on industry’s use of the internet.<sup>138</sup> Astonishingly, since advent of the Internet, no rule or guidance has issued despite the FDA stating that “policy and guidance development for promotion of FDA-regulated medical products using the Internet and social media tools are among our highest priorities.”<sup>139</sup>

• *Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices,* issued on December 27, 2011.<sup>140</sup>

• *Notice and Request for Comments concerning “Communications and Activities related to Off-Label Uses of Marketed Products and Products Not Yet Legally Marketed (i.e. Scientific Exchange).*<sup>141</sup> This Notice was issued on December 28, 2011 and no guidance has issued.

• *Off-Label and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices – Information Sheet,* Guidance for Institutional Review Boards and Clinical Investigators.<sup>142</sup>

• *Guides Concerning the Use of Endorsements and Testimonials in Advertising.* 16 CFR 255. The Federal Trade Commission published this “Guide” in October 2009.<sup>143</sup>

• *Draft Guidance for Industry on Direct-to-Consumer Television Advertisements – the Food and Drug Amendments Act of 2007 Direct-to-Consumer Television Ad Pre-Dissemination Review Program.*<sup>144</sup> The FTC issued this Draft Guidance on March 13, 2012.

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<sup>136</sup> 21 CFR 99.1 implementing Sec. 401 of FDAMA which expired in 2006. [FDA Guidance](#) January 2009.

<sup>137</sup> [62 Fed. Reg. 64074, 64092.](#)

<sup>138</sup> <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm>.

<sup>139</sup> *Id.*

<sup>140</sup> <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm285145.pdf>.

<sup>141</sup> [Federal Register Vol. 76, no. 249; 81508.](#)

<sup>142</sup> <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm>.

<sup>143</sup> <http://www.ftc.gov/os/2009/10/091005revisedendorsementguides.pdf>.

<sup>144</sup> [Federal Register Vol.77, no. 49; 1481.](#)

•*Online and Mobile Media.* On March 12, 2013, the FTC issued its “FTC staff guidance” “updating [its 2000] guidance known as Dot Com Disclosures.” The new Staff Guidance addresses the “online and mobile advertising environment.”<sup>145</sup>

Despite all the decades government has had to tackle the conundrum of disseminating truthful information, one inescapable truth endures: fundamentally, the First Amendment and who we are as Americans is shaped by the free flow of information. While much has been written on the issue of off-label promotion and principled opinions reside on each side of the debate, no one has ever died or been injured from having too much truthful information about a product.

## **B. Prior Restraint: *Citizens United v. FEC***

In *Citizens United v. Fed. Election Comm’n*,<sup>146</sup> the Supreme Court stated:

This regulatory scheme may not be a prior restraint on speech in the strict sense of that term, for prospective speakers are not compelled by law to seek an advisory opinion from the FEC before the speech takes place. As a practical matter, however, given the complexity of the regulations and the deference courts show to administrative determinations, a speaker who wants to avoid threats of criminal liability and the heavy costs of defending against FEC enforcement must ask a governmental agency for prior permission to speak. These onerous restrictions thus function as the equivalent of prior restraint ... analogous to licensing laws implemented in 16th and 17th-century England, laws and governmental practices of the sort that the First Amendment was drawn to prohibit... Premised on mistrust of governmental power, the First Amendment stands against attempts to disfavor certain subjects or viewpoints.

...

When Government seeks to use its full power, including the criminal law, to command where a person may get his or her information or what distrusted source he or she may not hear, it uses censorship to control thought. This is unlawful. The First Amendment confirms the freedom to think for ourselves.<sup>147</sup>

The Supreme Court is increasingly scrutinizing government’s full, unbridled discretion to define what may constitute a “misleading” communication. The Supreme Court’s recent pronouncements question “governmental discretion” to restrict First Amendment speech applying the rigors of heightened scrutiny under the Due Process Clause. While the FDA no doubt has a daunting task in proscribing speech, its haphazard series of guidance documents, draft guidance documents, notices and statements concerning the dissemination of truthful information have yet

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<sup>145</sup> <http://www.ftc.gov/os/2013/03/130312dotcomdisclosures.pdf>.

<sup>146</sup> 130 S. Ct. 876, 895, (2010).

<sup>147</sup> *Id.* at 908.

to be scrutinized by the Supreme Court. Nor has the Court examined the extent to which the FDA's determinations applying these guidances should be given deference.

## **C. Deference and Due Process**

### **1. Deference: Christopher v. Smithkline Beecham Corp.**

In *Christopher v. Smithkline Beecham Corp.*,<sup>148</sup> the Supreme Court addressed the plight of regulated businesses which operate at the mercy of government regulators and their interpretations of their own rules. The Court refused to defer to an agency's interpretation of its own ambiguous regulations, stating:

[deference] creates a risk that agencies will promulgate vague and open-ended regulations that they can later interpret as they see fit, thereby 'frustrat[ing] the notice and predictability purposes of rulemaking.' It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference ... We instead accord the Department's interpretation a measure of deference proportional to the "thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade."<sup>149</sup>

### **2. Impermissibly Vague: FCC v. Fox Television Stations, Inc.**

Last year, the Court also considered the issue of deference to regulatory agencies in the context of the First Amendment and applied a strict standard of review to the Due Process requirements of the policy being enforced. For example, in *FCC v. Fox Television Stations Inc.*, the Court held that the Federal Communication Commission's (FCC's) decency policy failed on fair notice grounds under the Due Process Clause.<sup>150</sup>

The Supreme Court stated that Due Process requires that "regulated parties should know what is required of them so they may act accordingly;" and "precision and guidance are necessary so that those enforcing the law do not act in an arbitrary and discriminatory way."<sup>151</sup> The Court stated that "when speech is involved, rigorous adherence to those requirements is necessary to ensure that ambiguity does not chill protected speech."<sup>152</sup> Thus, before the Court addressed the First Amendment question, it required rigorous adherence to the Due Process requirements and, citing

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<sup>148</sup> 132 S. Ct. 2156 (2012).

<sup>149</sup> *Id.* at 2168.

<sup>150</sup> 132 S. Ct. 2307 (2012).

<sup>151</sup> *Id.* at 2316.

<sup>152</sup> *Id.*

well-established precedent, stated:

A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required. ('[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law.') ('Living under a rule of law entails various suppositions, one of which is that '[all persons] are entitled to be informed as to what the State commands or forbids.') This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment. It requires the invalidation of laws that are impermissibly vague. A conviction or punishment fails to comply with due process if the statute or regulation under which it is obtained 'fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement.'<sup>153</sup>

As the Court recognized, regulated industry should not be content with vague and unenforceable pronouncements from the government in Guidance documents and the wink and nod from the government that it would "never bring an action." It is the lack of coherent, predictable, and enforceable rules that lies at the heart of this conundrum and promises from the government are no substitute. Highlighting this issue, in its Supplemental Brief for the United States in *U.S. v Caronia*, the government states:

The amicus also objects that FDA guidances are not 'binding' on the agency and are not embodied in formal rules. But FDA and DOJ have never brought an enforcement action against a manufacturer on the basis of conduct that conforms to the guidances. The risk of liability for a manufacturer who engages in such conduct is nil.<sup>154</sup>

The Supreme Court has rejected this government "policy of forbearance" as sufficient to render the constitutional issue moot, stating that "due process protection against vague regulations 'does not leave [regulated parties] ... at the mercy of *noblesse oblige*' ... [and] the government's assurance that it will elect not to [take regulatory action] is insufficient to remedy the constitutional violation."<sup>155</sup>

#### **D. Corrective Disclaimers: *Pearson v. Shalala*<sup>156</sup>**

In the first of a string of cases involving the same parties in the D.C. Circuit, in *Pearson I*, the court considered whether the FDA had run afoul of the First Amendment where it precluded "the approval of less-well supported claims

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<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 19.

<sup>155</sup> *Fox*, 132 S. Ct. at 2318.

<sup>156</sup> 164 F.3d 650 (D.C. Cir. 1999).

accompanied by a disclaimer.”<sup>157</sup> The FDA had declined to consider the alternative of requiring corrective disclaimers for claims that did not meet the significant scientific agreement (SSA) standard arguing that even if the proposed disclaimers were only potentially misleading under *Central Hudson*, the government was “not obligated to consider requiring disclaimers in lieu of an outright ban on all claims that lack significant scientific agreement.”<sup>158</sup> The court in *Pearson I* held:

the APA [Administrative Procedures Act] requires the agency to explain why it rejects their proposed health claims—to do so adequately necessarily implies giving some definitional content to the phrase ‘significant scientific agreement.’ We think this proposition is squarely rooted in the prohibition under the APA that an agency not engage in arbitrary and capricious action.<sup>159</sup> It simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved.<sup>160</sup> (“The agency must ... articulate a satisfactory explanation for its action...”). To refuse to define the criteria it is applying is equivalent to simply saying no without explanation.<sup>161</sup>

### **E. Is Untruthful or Misleading Speech not Entitled to First Amendment Protection?**

In *Zauderer v. Office of Disciplinary Counsel*, the Supreme Court began to refine its approach to restrictions on commercial speech requiring regulators to distinguish the “truthful from the false, the helpful from the misleading, and the harmless from the harmful.”<sup>162</sup> The Court recognized the government’s power to “prevent the dissemination of commercial speech that is false, deceptive, or misleading, or that proposes an illegal transaction.” The Court further reasoned that where the commercial speech is not false or deceptive and does not concern unlawful activities, speech “may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest.”<sup>163</sup>

*Zauderer* is often cited to support the notion that “false” speech is not afforded First Amendment protection. However, in *U.S. v. Alvarez*,<sup>164</sup> the Supreme Court directly addressed this notion stating that it “has never endorsed the categorical rule the Government advances: that false statements receive no First Amendment protection.” The notion that the government urges that “false” speech is not subject to First Amendment protection is only now being questioned by the Supreme Court. In enforcing the FDCA, the FDA assumes that there is a fundamental distinction

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<sup>157</sup> *Id.* at 654.

<sup>158</sup> *Id.* at 655.

<sup>159</sup> See 5 U.S.C. § 706(2)(A) (1994).

<sup>160</sup> See *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>161</sup> *Id.* at 660.

<sup>162</sup> 471 U.S. 626, 646 (1985).

<sup>163</sup> *Id.* at 638 (internal citations omitted).

<sup>164</sup> 132 S. Ct. 2537 (2012).

under the First Amendment between truthful information and false information.

Though *Alvarez* was a case involving “stolen valor” and not “commercial speech,” the Court addressed the constitutional issue broadly, holding that the government may not define truthful information as “false and misleading” through *ipse dixit* (i.e. on its own say so) for the purpose of exacting a penalty. While it is widely recognized and cited that government may ban false statements, the scope of this exception may not be nearly as broad as the government has assumed in prosecuting claims under the FDCA. In *Alvarez*, the defendant had represented himself falsely as a recipient of the Congressional Medal of Valor and the Court stated:

[A]s a general matter, the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content. As a result, the Constitution ‘demands that content-based restrictions on speech be presumed invalid ... and that the Government bear the burden of showing their constitutionality.’<sup>165</sup>

In light of the substantial and expansive threats to free expression posed by content-based restrictions, this Court has rejected as ‘startling and dangerous’ a ‘free-floating test for First Amendment coverage ... [based on] an ad hoc balancing of relative social costs and benefits.’<sup>166</sup> Instead, content-based restrictions on speech have been permitted, as a general matter, only when confined to the few ‘historic and traditional categories [of expression] long familiar to the bar.’<sup>167</sup> Among these categories are advocacy intended, and likely, to incite imminent lawless action;<sup>168</sup> obscenity;<sup>169</sup> defamation;<sup>170,171</sup>; speech integral to criminal conduct;<sup>172</sup> so-called ‘fighting words’;<sup>173</sup> child pornography;<sup>174</sup> fraud;<sup>175</sup> true threats;<sup>176</sup> and speech presenting some grave and imminent threat

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<sup>165</sup> 132 S. Ct. 2537, 2543 (June 28, 2012) (citing *Ashcroft v. American Civil Liberties Union*, 542 U.S. 656, 660 (2004)).

<sup>166</sup> *United States v. Stevens*, 130 S. Ct. 1577, 1585 (2010)).

<sup>167</sup> *Id.* at 1584 (quoting *Simon & Schuster, Inc. v. Members of N. Y. State Crime Victims Bd.*, 502 U.S. 105, 127 (1991) (KENNEDY, J., concurring in judgment)).

<sup>168</sup> See *Brandenburg v. Ohio*, 395 U.S. 444 (1969) (per curiam).

<sup>169</sup> See, e.g., *Miller v. California*, 413 U.S. 15 (1973).

<sup>170</sup> See, e.g., *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964) (providing substantial protection for speech about public figures).

<sup>171</sup> *Gertz v. Robert Welch, Inc.*, 418 U.S. 323 (1974) (imposing some limits on liability for defaming a private figure).

<sup>172</sup> See, e.g., *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490 (1949).

<sup>173</sup> See *Chaplinsky v. New Hampshire*, 315 U.S. 568 (1942).

<sup>174</sup> See *New York v. Ferber*, 458 U.S. 747 (1982).

<sup>175</sup> See *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976).

<sup>176</sup> See *Watts v. United States*, 394 U.S. 705 (1969) (per curiam).

the government has the power to prevent,<sup>177</sup> although a restriction under the last category is most difficult to sustain.<sup>178</sup> These categories have a historical foundation in the Court's free speech tradition. The vast realm of free speech and thought always protected in our tradition can still thrive, and even be furthered, by adherence to those categories and rules.<sup>179</sup>

These “historic and traditional categories [of expression] long familiar to the bar” are not found within the text of the Constitution but are categories crafted and divined by the Court itself. Whether we are better off with the proscriptions that the Court allows is secondary to the notion that the Constitution stands as a barrier to such laws.

In recognition of the value of not restraining speech, even that which is universally found repulsive, the Court recognized:

Absent from those few categories where the law allows content-based regulation of speech is any general exception to the First Amendment for false statements. This comports with the common understanding that some false statements are inevitable if there is to be an open and vigorous expression of views in public and private conversation, expression the First Amendment seeks to guarantee.<sup>180</sup>

The First Amendment does not recognize an exception for false statements nor does it allow an exception for truthful information that the government disfavors.

In *Alvarez*, the government disagreed arguing that false statements have no value and hence no First Amendment protection. In response, and distinguishing perjury, the Court stated that it “has never endorsed the categorical rule the Government advances: that false statements receive no First Amendment protection.”

The Government has not shown, and cannot show, why counter speech would not suffice to achieve its interest. The facts of this case indicate that the dynamics of free speech, of counter speech, of refutation, can overcome the lie. This is true also with off-label use, where the physician sits as an intermediary and can overcome the manufacturer's speech.

## **VII. THE EMERGING TORT OF OFF-LABEL PROMOTION**

### **A. Off-Label Tort Claims – A Misnomer and Parallel Claims**

The term “off-label” does not exist in the FDCA nor is it in the regulations. Off-label use relates to the use of a regulated product by a consumer or prescriber's health care provider that differs from what the FDA has approved. “Off-label use” as

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<sup>177</sup> See *Near v. Minnesota ex rel. Olson*, 283 U.S. 697, 716 (1931).

<sup>178</sup> See *New York Times Co. v. United States*, 403 U.S. 713 (1971) (per curiam).

<sup>179</sup> 132 S. Ct. at 2544.

<sup>180</sup> See *Sullivan, supra*, at 271 (“Th[e] erroneous statement is inevitable in free debate”). 132 S. Ct. at 2544.

it relates to a manufacturer is misnomer. The FDA regulates and enforces “promotional” conduct of manufacturers where the manufacturer “intends” a product be used for an indication, dose, duration or population different than that approved by the FDA. When the FDA determines that a manufacturer “intends” a product be used for a new use, the FDA considers the new use a “new drug” or device requiring FDA approval or clearance. Thus, what is at issue is whether a private plaintiff may sue under state law for an unapproved new drug or device.

### **1. “Intended Use”**

The FDA regulates foods, drugs, and devices based on intended uses—intended use as expressed by the person legally responsible for the labeling:

Intent is determined by such person’s expressions or may be shown by circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.<sup>181</sup>

Intent is determined by a host of factors. In describing what constitutes “intended use,” the FDA has stated:

This objective intent may ... be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.<sup>182</sup>

“Intended Use” for labeling purposes even includes information disseminated by or on behalf of manufacturers at scientific and educational meetings or symposia. Any activity that can create “new intended uses for the products which must be reflected in the approved labeling of the products” is “Intended Use.”<sup>183</sup>

### **2. “Label” and “Labeling”**

The term “label” means a display of written, printed, or graphic matter upon the immediate container of any article.<sup>184</sup> The term “labeling” means all labels and

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<sup>181</sup> 21 C.F.R. § 201.128.

<sup>182</sup> 41 Fed. Reg. 6911, Feb. 13, 1976.

<sup>183</sup> *Final Guidance on Industry Supported Scientific and Educational Activities*, 62 Fed. Reg. 64074, 64075 (Dec. 3, 1997).

<sup>184</sup> 21 U.S.C. § 321(k).

other printed, or graphic matter (1) upon any article or any of containers or wrappers, or (2) accompanying such article.<sup>185</sup>

The FDCA defines “label” and “labeling” as a means of display of written, printed, or graphic matter upon the immediate container of any article. This labeling includes printed or graphic matter upon any article or any of its containers or wrappers or accompanying such article.<sup>186</sup> The courts have construed the term more broadly, and “... the term [labeling] has also been construed to include nearly every form of drug company promotional activity, including booklets, pamphlets, mailing pieces, bulletins, and all literature that supplements, explains, or is otherwise textually related to the product.”<sup>187</sup> More recently, in *United States v. Sarcona*, the court stated: “where material ‘supplements or explains’ a product and ‘was designed for use in the distribution and sale of the [product] [t]he fact that it went in a different mail [is] wholly irrelevant ... it is the textual relationship,’ not a ‘physical attachment’ that is significant.”<sup>188</sup>

### **3. “Misbranding”**

Federal rules relate: “Misbranded: If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof ...”<sup>189</sup>

The rules add: “A drug is misbranded if, *inter alia*, it is ‘dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.’ That provision applies to any ‘drug,’ whether or not it has been approved by FDA.”<sup>190, 191</sup>

Thus, under the FDCA, the FDA may construe any transfer of information, irrespective of the medium, as labeling, and if, in the judgment of the agency, the information does not conform to its approved “labeling,” the communication can be construed as misleading and form the basis for criminal and civil enforcement. The consequences of FDA’s exercise of judgment are profound, as the force of its resources threatens not only the life of any business enterprise, but also the liberty of those employed.

### **4. “New Drug”**

While courts generally defer to FDA authority in labeling issues, recent

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<sup>185</sup> 21 U.S.C. §321(m).

<sup>186</sup> 21 U.S.C. § 321(k)-(m) (2009).

<sup>187</sup> See *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 54 (D.D.C. 1998).

<sup>188</sup> *United States v. Sarcona*, 457 F. App’x. 806, 814 (11th Cir. 2012) (citing *Kordel v. United States*, 335 U.S. 345, 350 (1948)).

<sup>189</sup> 21 U.S.C. § 321(n).

<sup>190</sup> 21 U.S.C. § 321(g)(1), 352.

<sup>191</sup> See Brief for the United States, *Mutual Pharmaceutical Company, Inc. v. Bartlett*, No. 12-142 (US Supreme Court) (Jan. 2013).

Supreme Court decisions raise the specter that courts may begin to curtail the scope of FDA's unfettered control. Under the FDCA, a new drug is defined as "any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experienced to evaluating the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed." Thus when a product is prescribed for use other than that in the FDA-approved labeling, it is a new drug under the Act.<sup>192</sup>

The issue that has not yet been decided is whether the courts will recognize "intent" as a determination that is solely within the expertise of the FDA to determine and, thus, deference to the FDA and to the exclusion of the state tort law. If intent is not solely within the ambit of the FDA, then a state tort law seeking to hold a manufacturer liable for marketing a "new drug" without appropriate labeling would not run afoul of federalism concerns. By definition there is no warning that can accompany an unapproved new drug that can render it safe and effective.

As the courts recognize greater rights for manufacturers to disseminate truthful scientific information, manufacturers will face a Hobson's Choice: they may choose to disseminate information in the hope that the horse they have chosen will not result in federal prosecution or tort law claims, or they can choose no horse at all, not disseminate information, avoiding government prosecution and providing potent preemption protection from any state tort law claims.

Those practicing in this area long enough to recall the early days of medical products liability litigation will recall the well-worn refrain of plaintiffs recounting their discussion with their doctor before beginning a therapy: "the doctor was God, I did whatever he said to do." With those "innocent" days in the rearview mirror, the scope of off-label use of medications today presents an urgent public health imperative.

With hundreds of millions of prescriptions written every year lacking scientific support for the use, off-label prescribing is not prohibited because it is widely recognized that often lifesaving therapy and the medical standard of care demands a product be used off-label.<sup>193</sup> The standard of care and sound medical science develops and evolves in the practice of medicine, yet there too is a large volume of off-label prescribing without science and, thus, a conundrum.

Beyond the question of whether a manufacturer may be liable under state tort law for marketing an "unapproved new drug without adequate warnings," if manufacturers have the constitutional right to speak, do they have a tort duty when their products are known to be used off-label. Up until now a manufacturer speaking about off-label was a potential crime but if, as is suggested by *Sorrell* and *Caronia*, such speech may not be proscribed. It may well be that Justice Rehnquist was prescient in *Central Hudson* when stating in dissent, "the remedy of one defrauded is a lawsuit or an agency proceeding based on common law notions of fraud..."<sup>194</sup>

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<sup>192</sup> See 21 U.S.C. § 321(p).

<sup>193</sup> *Buckman* at 350 Similarly, "off-label" usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.

<sup>194</sup> 447 U.S. at 598-99.

Whether state tort law will supplant criminal prosecutions may not be known until or unless the Supreme Court addresses the issue.

## **B. A Survey of Off-Label Tort Case Decisions**

Whether the alleged injury in these cases drives the outcomes is not clear but each of the cases has compelling facts on alleged injuries.

In *Arters v. Sandoz Inc.*,<sup>195</sup> plaintiffs alleged that defendant failed to warn consumers of the significant risks of amiodarone; that the drug is unreasonably dangerous; and that defendants improperly promoted “off-label” use of the drug. In crafting a path around federal preemption of labeling claims under the Supreme Court’s *PLIVA v. Mensing* decision, based on off-label promotion, the court stated:

Plaintiffs allege that defendants promoted the off-label use of amiodarone as a routine treatment, rather than a drug of last resort...Instead, each of plaintiffs’ legal theories is based on the idea that defendants promoted the drug in a fraudulent or unreasonably dangerous way. Nothing in the FDCA requires defendants to promote their drug for an off-label use, nor is the federal law otherwise at odds with the negligence, breach of implied warranty, and fraud claims brought by plaintiffs.

Defendants argue that plaintiffs may not seek to privately enforce FDA regulations that prevent defendants from promoting the off-label use of amiodarone. Just so.<sup>196</sup> However, this argument misunderstands plaintiffs’ claims. They do not seek to enforce FDA regulations regarding the promotion of off-label use. Plaintiffs assert that defendants violated their duty not because the use they promoted was off-label, but because they promoted a use of amiodarone that was in violation of Ohio law.

In *In Re Pradaxa*,<sup>197</sup> the Defendant was subject to a Corporate Integrity Agreement (“CIA”) and among the allegations at issue were claims that the defendant improperly promoted and marketed their products by making unsubstantiated, unwarranted, and/or off-label claims. The Court reviewed the pleadings and determined:

The plaintiffs have clearly asserted allegations related to the manner in which Pradaxa was marketed. Whether the plaintiffs’ have specifically used the terms ‘off-label marketing’ or ‘kick-backs’ is not determinative. Accordingly, discovery into issues related to the marketing of Pradaxa, whether there was off-label promotion, over-promotion, misleading promotion, and the like is clearly relevant.

The qui tam lawsuit involves allegations that between 2000 and 2008, BIPI engaged in activity that amounted to off-label marketing and over-

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<sup>195</sup> 2013 U.S. Dist. LEXIS 10268 (S.D. Ohio Jan. 25, 2013).

<sup>196</sup> See 21 U.S.C. § 337.

<sup>197</sup> 2013 U.S. Dist. LEXIS 7979 (S.D. Ill. Jan. 18, 2013).

promotion of four BIPI products. The lawsuit also contains allegations that BIPI offered improper financial inducements to encourage doctors to write prescriptions for these four products. Certainly, the plaintiffs are entitled to inquire into allegations of improper marketing conduct similar to the improper marketing conduct alleged here.

The fact that the qui tam action involved drugs other than Pradaxa does not make the information irrelevant for purposes of discovery. It is entirely possible that the marketing policies and strategies at issue in the qui tam action extended to BIPI's marketing of Pradaxa. Thus, the plaintiffs' inquiry into those marketing practices and the individuals involved in those marketing practices appears to be reasonably calculated to lead to discovery of admissible evidence and is an appropriate subject of discovery.

In *In re Prem Pro*, in response to defendants' motion on the pleadings to dismiss based on the *Mensing* opinion, plaintiffs sought to amend their complaints. The court gave plaintiffs limited time to replead and required them to

set out, in plenary detail, the factual basis for the plaintiff's claims. For example, if the plaintiff is asserting 'off-label promotion,' the complaint must set out sufficient facts to support this claim. In other words, the specific who, what, when, and where will be required (considering that Plaintiffs have been accumulating discovery against defendants for nearly 10 years, this requirement is reasonable). Each plaintiff all will be required to show, with specificity, how she was directly affected by each Defendant's conduct.<sup>198</sup>

In *Anderson v. Abbott Laboratories*, the court dismissed plaintiffs' claims under a Texas statute concerning off-label promotion. Notable in the Texas statute is an exception for claims of off-label promotion. In dismissing the claims for lack of specificity, the court stated:

As previously noted, '[w]hile a complaint need not contain detailed factual allegations, it must set forth more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.' Plaintiffs' allegations are nothing more than a formulaic recitation of the first two elements under section 82.007(b)(3), and Plaintiffs allege no facts whatsoever in support of the third causation element. Accordingly, the court determines that Plaintiffs have failed to state a claim under section 82.007(b)(3), and Abbott is entitled to dismissal of Plaintiffs' claims under this section.<sup>199</sup>

It is an uphill climb in Texas for a defendant to argue that Texas does not recognize off-label promotion claims, where the statute expressly addresses such claims. But the *Anderson* case suggests that specificity is required.

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<sup>198</sup> *In re Prem Pro*, 10-cv-128 at 2 (E.D. AK 2012).

<sup>199</sup> 2012 U.S. Dist. LEXIS 141585, \*15.

In *Murthy v Abbott*,<sup>200</sup> Plaintiff signed consent to participate in the clinical trial and received a free supply of the product. The prescribing physician participated in the study and was compensated by the manufacturer. Plaintiff claimed that a video she had been shown in advance “paint[ed] a rosy picture of therapy.”

The court was faced with a motion to dismiss under 12(b)(6) and, in an earlier decision in the case, had dismissed the failure-to-warn claims on federal preemption grounds. Plaintiff filed a motion to vacate the dismissal, relying on the exceptions to the Texas law presumption of no liability under CPRC Section 82.007(a) on the grounds set forth under (b)(3) and (4). Plaintiff sought to rebut the presumption based upon off-label promotion by the manufacturer and by the physician.

Plaintiff attempted to prove “off-label” promotion by establishing that the FDA had approved labeling only for patients with moderate-to-severe active rheumatoid arthritis who had an inadequate response to one or more DMARDs (that is, disease modifying antirheumatic drugs). Plaintiff submitted testimony from a physician that she had early rheumatoid arthritis (RA) and that she was responding well to a DMARDs, and therefore the prescriptions of the drug to the Plaintiff would have been “off-label.”

The court found that Plaintiff had pled sufficient facts to raise a plausible “off-label promotion claim” by alleging that the “Abbott sales representatives repeatedly promoted and encouraged Dr. Popovich to use Humira, in patients with ‘early’ RA and in patients that did not fit the HERO study ‘criteria.’” The court further stated:

However, in the call notes cited by Plaintiff, Abbott sales representative contrasted ‘severe’ with ‘early,’ and thus expressly tied the use of Humira to disease severity. In the sales representative’s calls notes, he writes that he and Popovich ‘[t]alked about using it for severe RA PTS. Stressed to him, Dr. Popovich, that Humira can be used in early RA PTS as well.’ The contrast here between severe and early is sufficient to raise a fact issue, even if most scientific studies do not equate severity and duration.

The court found it “plausible” that the prescribing physician could have been considered an “agent of the manufacturer,” and thus the court did not need to “make a determination about the ultimate applicability of Section 82.007(b)(4) at this stage, but rather finds the Plaintiff has alleged sufficient facts alleging a plausible claim.”

In *Whitener v. PLIVA*,<sup>201</sup> on a motion to dismiss the court granted Plaintiffs leave to amend their pleadings to “attempt to assert a non-preempted state-law claim predicated on “alleged promotion of metoclopramide for off-label purposes in violation of federal law.” The court addressed the preemption issue stating:

The harder question . . . is whether the *Mensing* analysis changes if a generic defendant actively promotes the drug for off-label use in violation of federal law. . . . [T]here is something troubling about permitting a generic defendant to violate federal law by actively and

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<sup>200</sup> 2012 U.S. Dist. LEXIS 171246 (S.D. Tex. Dec. 3, 2012).

<sup>201</sup> 2012 U.S. Dist. LEXIS 127993 (E.D. La. Sept. 10, 2012).

aggressively promoting a drug for a purpose not contemplated by the label approved by the FDA while also hiding behind an inability to provide warnings connected to that off-label use because it cannot change the approved label.

Plaintiffs argued that they were using Defendants' alleged violations of federal regulations to establish that Defendants breached a standard for the purposes of a state tort claim citing the Supreme Court in *In re Medtronic v. Lohr*.<sup>202</sup> The court found that "Plaintiffs had 'barely' satisfied the standard required to defeat a motion to dismiss. According to the court:

However, Defendants simply have not managed to overcome the fundamental distinction between this case and *Mensing*: unlike in *Mensing*, Plaintiffs in this case do not allege that Defendants should have changed the contents of the label in violation of federal law. Instead, they allege that Defendants simultaneously violated both state and federal law by actively engaging in off-label promotion despite known risks not listed on the label.

The court found "[t]his distinction is significant because the conflict between state and federal law was the crucial factor upon which the *Mensing* Court rested its holding... The Supreme Court simply did not reach the issue of whether federal regulations preempt state tort claims that are not based on failure to change the label in violation of federal regulations. Based upon this holding and the lack of case law directly on point, the court permitted the claim to proceed because it was "hesitant to hold as a matter of law that there is not a kernel of a viable claim somewhere in Plaintiffs' allegations" and denied Defendants' motion.

*Cornett v. Johnson & Johnson*<sup>203</sup> involved a drug-eluting stent which is a Class III medical device that had been subject to the "rigorous pre-market approval process." The New Jersey Supreme Court permitted failure to warn and express warranty claims to survive a pre-answer motion to dismiss stating: failure to warn claims survive where they fall "within a traditional area of state concern and regulation because fraud on the FDA is not an element of the claim and it can be proved by evidence other than by evidence of fraud on the FDA." The Court further noted that "[t]o the extent, however, plaintiffs' failure to warn claim is founded on promotion by defendants of off-label uses of the device beyond the safe harbor, the claim is not preempted." In permitting some express warranty claims to proceed, the Court stated: "to the extent plaintiffs allege defendants have deviated from the labeling and instructions for use through voluntary statements to third parties in the course of its marketing efforts, this claim is not preempted."

In *Teater vs. Pfizer*,<sup>204</sup> a plaintiff brought a number of claims related to the marketing of Neurontin. According to the complaint, defendants marketed and promoted Neurontin "off-label" for dosages and uses not in the approved labeling with knowledge of numerous risk factors including suicidal behavior by persons with

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<sup>202</sup> 518 U.S. 470, 495 (1996).

<sup>203</sup> 2012 N.J. LEXIS 831 (N.J. Aug. 9, 2012).

<sup>204</sup> 2012 U.S. Dist. LEXIS 122848 (D. Or. June 27, 2012).

underlying psychological diagnoses. The plaintiff further alleged that based on the promotional conduct of the manufacturer, her physicians prescribed Neurontin and suffered various adverse effects... including a list of ailments and “she also missed her daughter’s wedding and attempted to commit suicide...” With respect to the plaintiff’s Unlawful Trade Practices Act claim, the court noted:

I agree that Plaintiff’s Amended Complaint fails to allege any connection between Defendants’ marketing or advertising campaigns and Plaintiff’s unnamed physicians’ decision to prescribe her Neurontin. As Defendants’ counsel points out, ‘Plaintiff does not identify a single statement or misrepresentation by Defendants to which Plaintiff or her prescribing physicians were even exposed, no less relied upon, nor does she allege any facts regarding her healthcare provider’s decision to prescribe Neurontin.’ Even accepting Plaintiff’s allegations as true, Plaintiff has failed to plead factual content that allows a reasonable inference to be drawn that Defendants are liable for the misconduct alleged.

Despite this finding, the court granted plaintiff time to conduct a deposition of a corporate representative and to replead fraud, UTPA, and unjust enrichment claims holding, “I must accept all of Plaintiff’s material factual allegations as true and view all facts in the light most favorable to her. When so viewed, Plaintiff’s Amended Complaint sets forth facts supporting plausible product liability claims based on theories of negligence, strict liability and breach of warranty...”

*In re Epogen & Aranesp Off-Label Marketing & Sales Practices Litigation*,<sup>205</sup> the court, in addressing the issue of off-label claims, stated:

Although Plaintiffs have avoided explicit references to ‘misbranding’ in their Complaint, their RICO and state law claims are primarily based on allegations that Defendants promoted EPO for off-label uses. For example, Plaintiffs allege that Defendants ‘engaged in a massive scheme to defraud Plaintiffs and the Class . . . and substantially increase sales of [EPO] by unlawfully promoting the use of these drugs for unsafe purposes and at dangerous doses not specified on the drugs’ [FDA-approved labels (i.e., off label promotion).’ The Complaint is rife with similar references to illegal off-label promotion, and Plaintiffs seek to enjoin the illegal promotion. These allegations of off-label promotion are, in essence, misbranding claims that should be reviewed by the FDA.<sup>206</sup>

...the main thrust of their allegations is that Defendants illegally promoted EPO for off-label uses, *not* that Defendants promoted EPO through false, misleading, or otherwise fraudulent statements...Thus, Plaintiffs seem to assume that off-label promotion is inherently fraudulent.... The Complaint does not identify a single statement made

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<sup>205</sup> 590 F. Supp. 2d 1282 (C.D. Cal. 2008).

<sup>206</sup> See *Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769, 786 (W.D. Tex. 2001).

... that Plaintiffs claim was false, misleading, or contained a material omission.

... A fact-finder could determine whether this alleged omission was misleading or otherwise fraudulent without reference to FDA regulations governing the advertisement of prescription drugs.<sup>207</sup> Moreover, the FDA does not have special expertise that the Court should defer to in resolving this question. Therefore, Plaintiffs' RICO and state law causes of action, to the extent which they allege fraud *not* dependent on the FDCA's prohibition on off-label promotion, are valid.<sup>208</sup> To hold to the contrary would mean that the FDA, not courts, would be responsible for resolving all questions of whether a statement made in connection with prescription drug advertising was false, misleading, or omitted a material fact. This Court would not extend the FDA's primary jurisdiction so far.<sup>209</sup>

In sum, insofar as Plaintiffs' claims are based solely on allegations that Defendants promoted EPO for off-label purposes, they constitute an impermissible attempt to bring a private suit for violations of the FDCA. However, insofar as Plaintiffs can identify specific representations by Defendants that are literally false, misleading, or contain material omissions, the claims are actionable under RICO and California consumer fraud laws.

What is notable about these "off-label" cases is that where plaintiffs have traditionally relied upon failure-to-warn with respect to medical products liability claims, given the overwhelming weight of Supreme Court authority finding such claims pre-empted, there is an expanding body of case law recognizing "off-label promotion" as an alternative to supplant traditional failure to warn theories. The court rulings in these cases suggest that detailed factual allegations supporting purported "off-label" promotion theories should be required in the complaint and claims should be dismissed where facts are lacking. With survey data suggesting that hundreds of millions of prescriptions are written for uses not approved by the FDA each year, a cottage industry of off-label tort cases may be emerging.

### **C. Parallel Claims in the Ninth, Seventh, and Fifth Circuits**

Courts that recognize state law claims based on violations of federal law and regulations, rely on "parallel" claims derived from the Supreme Court's holdings in *Buckman*, *Riegel*, and *Lohr*. In *Buckman* the Supreme Court noted that "[i]n the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Buckman* can be read to allow certain state-law causes of action that parallel federal safety requirements, it does not and cannot stand for

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<sup>207</sup> See *Summit II*, 933 F. Supp. at 933; *Grove Fresh*, 720 F. Supp. 2d at 716.

<sup>208</sup> See *Summit II*, 933 F. Supp. at 943 (California UCL and FAL claims were not preempted by federal law so long as they were not merely vehicles for claims under the FDCA or FDA regulations).

<sup>209</sup> See *Healthpoint*, 273 F. Supp. 2d at 792-93.

the proposition that any violation of the FDCA will support a state-law claim.<sup>210</sup> The *Buckman* Court went on to state that:

In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.<sup>211</sup>

In *Bausch v. Stryker Corp.*,<sup>212</sup> Plaintiff alleged injury from a Class III ceramic hip replacement and a resulting violation of state-law duties “parallel” to federal-law duties under the MDA. Plaintiff alleged the product was implanted shortly after the FDA found the product “adulterated” and that the company’s manufacturing processes failed to comply with federal standards. Plaintiff’s implant failed and required removal and replacement. The district court dismissed the complaint on federal preemption grounds and the Seventh Circuit reversed finding the alleged violations of federal law not preempted. According to the Seventh Circuit,

The central issue in this appeal is whether federal law preempts product liability claims against manufacturers of Class III medical devices where a patient claims that she was harmed by the manufacturer’s violation of federal law. That statement of the issue may be a little startling. The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive. Nevertheless, manufacturers in this case and in others have asserted this theory of defense. As we explain below, the manufacturer’s theory tries to stretch the Supreme Court’s decisions in this field beyond the boundaries that were made clear in those decisions. Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they *comply* with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer’s *violation* of federal law.<sup>213</sup>

The court reasoned that neither *Riegel* nor *Lohr* held “that state lawsuits premised on violations of federal law are preempted under section 360k(a). In fact, the Court’s opinions in *Lohr* and *Riegel* expressly left the door open for state law claims based on violations of federal law.”<sup>214</sup> In *Lohr* the Supreme Court stated:

Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those

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<sup>210</sup> *Buckman*, 531 U.S. at 353-354.

<sup>211</sup> *Id.* at 353.

<sup>212</sup> 630 F.3d 546, 549 (7th Cir. 2010), *cert. denied*, 132 S. Ct. 498 (2011).

<sup>213</sup> *Id.* at 549.

<sup>214</sup> *Id.* at 550.

duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be ‘different from’ the federal rules in a literal sense, such a difference would surely provide a strange reason for finding preemption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different ‘requirement’ that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing ‘requirements’ under federal law.<sup>215</sup>

The court in *Bausch* discussed *Riegel* at length, remarking that the state requirements implicit in the Riegels’ common law claims were different from or in addition to the federal requirements and were thus preempted under section 360k. In this regard, the court stated:

The *Riegel* Court took care, however, to limit its holding to claims that the device at issue ‘violated state tort law *notwithstanding compliance with the relevant federal requirements*.’<sup>216</sup> The Court gave lower courts clear instructions to allow claims to proceed when they are based on claimed violations of federal law: ‘§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.’<sup>217</sup>

The Supreme Court thus has made clear that section 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law. In other words, where state law is parallel to federal law, section 360k does not preempt the claim.

In *Hughes v. Boston Scientific Corp.*,<sup>218</sup> plaintiff suffered severe burns when hot liquid leaked from a Class III medical device. Hughes brought suit under Mississippi law, alleging a violation of a state-law duty to warn.<sup>219</sup> The Fifth Circuit held that Hughes’s state-law failure-to-warn claim was not preempted “to the extent that this claim is predicated on Boston Scientific’s failure to comply with the applicable federal statutes and regulations.”<sup>220</sup> The Fifth Circuit stated that *Riegel* and *Lohr* also “make clear” that a manufacturer is not protected from state tort

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<sup>215</sup> *Lohr*, 518 U.S. at 495 (reversing dismissal of complaint).

<sup>216</sup> 552 U.S. at 330 (emphasis added).

<sup>217</sup> See 518 U.S. at 495.

<sup>218</sup> 631 F.3d 762, 765 (5th Cir. 2011).

<sup>219</sup> *Id.*

<sup>220</sup> *Id.* at 764.

liability when the claim is based on the manufacturer's violation of applicable federal requirements.

In *Riegel*, the Court established a two-prong test for determining if a state-law tort claim is preempted by § 360k. First, we ask if the FDA has established requirements applicable to the particular device at issue.<sup>221</sup> Second, we ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is 'different from or in addition to' the federal requirement."<sup>222</sup>

In setting up this two-prong test, the court confirmed that state common-law causes of action are considered "requirements" under this test that cannot vary from federal requirements pursuant to § 360k. Specifically, the court held that New York common-law tort claims of negligence, strict liability, and breach of warranty imposed requirements that were preempted by federal requirements pertaining to medical devices to the extent that these state tort claims required the device "to be safer, but hence less effective, than the model the FDA has approved. . . ."<sup>223</sup>

The court found that state law products liability claims that purport to impose liability despite compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties and are expressly preempted.<sup>224</sup> However, the court reached a different conclusion where the state law claims were based on failure to comply with federal regulations:

Assuming that a failure to warn claim may be pursued under Mississippi law as Hughes argues, it is clear that such a claim is preempted only to the extent that it purports to impose liability despite Boston Scientific's compliance with FDA regulations. *Riegel*;<sup>225</sup> *Gomez*.<sup>226</sup> To the extent that Hughes asserts a failure to warn claim based only on Boston Scientific's failure to comply with FDA regulations, however, such a claim is not expressly preempted.

Rather, a failure to warn claim limited to an assertion that the defendant violated a relevant federal statute or regulation is 'parallel' to federal requirements as defined in *Riegel*, in which the Court stated that '§ 360k does not prevent a State from providing a damages remedy for claims premised on violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.'<sup>227</sup>

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<sup>221</sup> 552 U.S. at 322.

<sup>222</sup> *Id.*

<sup>223</sup> *Riegel*, 552 U.S. at 325.

<sup>224</sup> *Id.* at 325.

<sup>225</sup> 522 U.S. at 325.

<sup>226</sup> 442 F.3d at 933.

<sup>227</sup> 552 U.S. at 330 (quoting *Medtronic*, 518 U.S. at 495, 513 (O'Connor, J., concurring in part and dissenting in part)).

Thus, *Riegel* is no bar to this claim. Hughes's failure to warn claim is comparable to the negligent failure to warn claim in *Lohr* and the negligent manufacturing claims in *Gomez*, *Howard*, and *Bausch*. These authorities make clear that Hughes's claim is not expressly preempted to the extent she asserts that Boston Scientific violated the state duty to warn by failing to accurately report serious injuries and malfunctions of the HTA device as required by the FDA's MDR regulations. The MDR regulations are related to the manufacturer's duty to provide the FDA with information regarding a device's safety and effectiveness, and this information is disseminated to the public. A factfinder could infer that a manufacturer's failure to provide this information as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device's risks.<sup>228</sup>

In *Bass v. Stryker*,<sup>229</sup> the plaintiff claimed that a hip replacement product malfunctioned and caused him injury. Bass raised a number of state-law claims, including strict liability, negligence, breach of warranty, and violation of the DTPA.

In *Hughes*, we noted that any claim asserting a state-law tort action despite compliance with FDA regulations was preempted by the MDA.<sup>230</sup> However, state common law claims 'are not preempted, provided that such claims are premised entirely on violation of the applicable federal requirements.'<sup>231</sup> Importantly, a formal finding of a violation by the FDA was not required to plead a parallel action.<sup>232</sup> We ultimately held that the cause of action survived where the plaintiff provided expert testimony showing that the medical device manufacturer had 'violated the plain text of the [Medical Device Reporting] regulations.'<sup>233, 234</sup>

The court went on to state:

We therefore hold that if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the CGMPs themselves *and* that this failure caused the injury, the plaintiff will have pleaded a parallel claim. To illustrate, suppose a manufacturer had represented to the FDA in its pre-approval documentation that each hip implant component would be sterilized for ten minutes at 800 degrees. We would accept a parallel claim that pleaded that the manufacturer instead sterilized the component at only 200 degrees for

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<sup>228</sup> *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011).

<sup>229</sup> 669 F.3d 501 (5th Cir. 2012).

<sup>230</sup> 631 F.3d at 768.

<sup>231</sup> *Id.* at 770.

<sup>232</sup> *See id.* at 772 ("We are persuaded that any additional 'formal' finding or enforcement action by the FDA is not an 'implicit precondition' to suit under the facts of this case.")

<sup>233</sup> *Id.* at 773.

<sup>234</sup> *Id.* at 510.

five minutes, as that would ‘violate’ what it told the FDA. However, if the plaintiff’s claim was that proper sterilization required twenty minutes at 1000 degrees or some other method of sterilization altogether, this claim would not be allowed, as it would ‘add to’ the regulatory requirements. Thus, we reject Stryker’s argument that the regulations are too vague to be enforced because Bass will have to prove violations of the more specific, FDA-approved PMA process for this device.<sup>235</sup>

Moreover, the court permitted claims premised on violations of good manufacturing processes, but the factual predicate in *Bass* was significant:

Under these standards, Bass sufficiently alleged a concrete injury and a connection between a defect in Stryker’s manufacture of the Shells and Bass’s injury. Notably, unlike the plaintiffs in *In re Medtronic* and *Wolicki-Gables*, Bass does not allege that his injury simply arises from Stryker’s failure to abide by the CGMPs, but rather alleges that the failure to abide by its own manufacturing standards required to satisfy the CGMPs and the PMA approval process resulted in an unacceptable level of bioburden on his Shell.<sup>236</sup> *Furthermore, the FDA itself determined that Stryker was in violation of the CGMPs.*<sup>237</sup>

The Fifth Circuit rejected the notion that the FDCA precludes private actions to enforce its provisions stating: “This case is premised on state-law tort claims rather than any duties independently created by FDA regulations.”<sup>238</sup>

In *Stengel v. Medtronic*,<sup>239</sup> Plaintiffs sued under state law claiming defendant’s product rendered the plaintiff permanently paraplegic. In light of the defendants’ motion to dismiss on preemption grounds, Plaintiffs moved to amend their complaint to add a new state-law alleging defendant had “violated a state-law duty of care by failing to report known risks associated with use of its medical device to the Food and Drug Administration (“FDA”).” The district court held that the MDA preempted all of the Plaintiffs’ claims and the central question for the Ninth Circuit was “whether the MDA preempts a state-law claim in which the state-law duty of care ‘parallels’ a federal-law duty imposed by the MDA.”

When it received FDA approval of its SynchroMed EL Pump and Catheter, Medtronic was not aware of certain risks associated with the device. Before Stengel was paralyzed, however, Medtronic had become well aware of those risks but had allegedly failed to inform the FDA, even though the MDA required Medtronic to do so. The FDA discovered the risks, and discovered that Medtronic already knew about them, when it inspected a Medtronic facility in late 2006 and early 2007. The FDA sent a Warning Letter to Medtronic in July 2007, stating that Medtronic had

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<sup>235</sup> *Id.* at 513.

<sup>236</sup> *See* Warning Letter at 3 (noting Final Rinse Tank nonconformances).

<sup>237</sup> *Id.* at 513.

<sup>238</sup> *Id.* at 776.

<sup>239</sup> 2013 U.S. App. LEXIS 621 (9th Cir. Jan. 10, 2013).

“misbranded” its Class III device by concealing known risks, in violation of 21 C.F.R. §§ 803.50(a)(1), 806.10(a)(1). In response to the FDA’s Warning Letter, Medtronic sent a Medical Device Correction letter to doctors in January 2008. Medtronic recalled the device in March 2008. Stengel had been paralyzed in 2005.

The court reviewed the Supreme Court medical device preemption cases (*Lohr*, *Buckman* and *Riegel*) and found that

[t]he rule that emerges from these cases is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.<sup>240</sup>

In finding the state law claims that are premised specifically on a violation of federal law not preempted, the Ninth Circuit concluded:

State requirements are pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law.<sup>241</sup> Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.<sup>242</sup>

Finding further support for its permissive view of preemption, the court, citing *Lohr*, stated:

. . . Given the ambiguities in the statute and the scope of the preclusion that would occur otherwise, we cannot accept Medtronic’s argument that by using the term ‘requirement,’ Congress clearly signaled its intent to deprive the States of any role in protecting consumers from the dangers inherent in many medical devices.<sup>243</sup>

The Stengels’ proposed new claim under Arizona law, insofar as the state-law duty parallels a federal-law duty under the MDA, is not preempted. Arizona state law has long been concerned with the protection of consumers from harm caused by manufacturers’ unreasonable behavior. Plaintiffs’ claim is brought under settled Arizona law that protects the safety and health of Arizona citizens by imposing a general duty of reasonable care on product manufacturers. “The whole modern law of negligence, with its many developments, enforces the duty of fellow-citizens to observe in varying circumstances an appropriate measure of prudence to avoid causing harm to one another.” Arizona tort law includes a cause of action for failure to warn. Under Arizona law, ‘negligence standards impose a duty to produce products with appropriate warning instructions.’ (Citations omitted).

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<sup>240</sup> *Id.* at \*7.

<sup>241</sup> § 360k(a)(1).

<sup>242</sup> *Lohr*, 518 U.S., at 495, *Riegel*, 552 U.S. at 330.

<sup>243</sup> *Id.* at 486–87, 489.

If a more precise parallel were necessary, the Stengels have alleged it and Arizona law provides it. The Stengels' new claim specifically alleges, as a violation of Arizona law, a failure to warn the FDA. Arizona law contemplates a warning to a third party such as the FDA. Under Arizona law, a warning to a third party satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third party, there is "reasonable assurance that the information will reach those whose safety depends on their having it."

We do not decide whether plaintiffs can prevail on their state-law failure-to-warn claim. That question is not before us. But we do hold, under *Lohr*, *Buckman*, and *Riegel*, that this claim is not preempted, either expressly or impliedly, by the MDA. It is a state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*. The claim rests on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*. In holding that the Stengels' failure-to-warn claim is not preempted, we join the Fifth and Seventh Circuits, which reached the same conclusion with respect to comparable state-law claims in *Hughes* and *Bausch*.<sup>244</sup>

A separate concurring opinion purported to clarify the murky waters:

In this case, Medtronic's failure to report was more than a mere misrepresentation to the FDA because it simultaneously misled the device's current and potential users, to whom Medtronic owed an independent duty under state law. There is no question that state law has an important and legitimate role to play in regulating the adequacy of post-sale warnings for products already on the market. That Arizona law did not previously address reporting duties to the FDA specifically is irrelevant; nothing in *Buckman* suggests that the preexisting state law needs to mirror the federal requirement at that level of specificity to avoid preemption. It is sufficient here that, in contrast to *Buckman*, the Stengels' claim is grounded in a traditional category of state law failure-to-warn claims that predated the federal enactments in question, and that the claim therefore does not exist solely by virtue of those enactments.<sup>245</sup>

The Ninth Circuit denied *en banc* and Medtronic has announced it will be filing a *cert* petition with the Supreme Court.

## CONCLUSION

Court decisions such as *Caronia* and *Sorrell*, which recognize Due Process and First Amendment protections for drug and medical device producers' dissemination of information, stand as important victories for those who have long been seeking judicial recognition of such rights. Ironically, however, those precedents may also

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<sup>244</sup> *Stengel v. Medtronic*, 2013 U.S. App. LEXIS 621 \*23-24 (9th Cir. Jan. 10, 2013).

<sup>245</sup> *Id.* at \*29

empower private plaintiffs whose tort lawsuits previously foundered because of government's unquestioned authority over industry activity. Because the FDA may not have the stranglehold it once had over the dissemination of information, new theories and approaches to state tort liability are emerging. None is more potentially poised than tort claims related to unapproved new uses or off-label uses. Similarly emergent are theories claiming "parallel" state court tort damages based upon violation of the FDCA.

Aboard the Titanic of FDA regulation of off-label promotion rides potent cargo for manufacturers: deference to agency determinations and federal preemption. The currently emerging tort claims may be poorly fashioned and are initially being dismissed, plaintiffs' lawyers will adapt and continue to advance more sophisticated pleadings and nuanced theories. It will be years before this area of the law is settled. As industry sets course in these treacherous waters, it is uncertain how courts will fashion relief and whom they will favor. As Due Process, First Amendment and parallel state court claims mature, what is certain is that facts matter and any manufacturer with products used off-label should view *Caronia* as the tip of the iceberg.