



## United States v. *Caronia*: A Brief Look at the Broader Implications for the Food Industry

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Over the past couple of decades, billions of dollars in penalties have been assessed against dietary supplement and pharmaceutical manufacturers, often based on the communication of truthful, reliable scientific information that the Food and Drug Administration (“FDA”) deemed “false and misleading” constituting “misbranding” under the Food and Drug Cosmetic Act (“FDCA”). However, the FDA’s aggressive enforcement efforts have increasingly been judicially rebuked as violating the free speech protections of the First Amendment.

Most recently, in *United States v. Caronia*<sup>2</sup> the U.S. Court of Appeals for the Second Circuit held that FDA enforcement

efforts violated the First Amendment because the government could not demonstrate an appropriate “fit” between the means (restricting speech) the FDA uses to achieve its ends (protecting the public health). In so finding, the Second Circuit reversed on free speech grounds the criminal conviction of a pharmaceutical sales representative for off-label marketing and cast doubt on the government’s authority to regulate or criminalize the dissemination by pharmaceutical and dietary supplement manufacturers and their employees of truthful information regarding the use of their products. The *Caronia* decision represents a significant development in the regulation and enforcement of



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pharmaceutical and dietary supplement sales and marketing practices.

### The Caronia Decision

Alfred Caronia, a pharmaceutical sales representative who was convicted of misbranding a pharmaceutical product by discussing off-label uses, challenged his conviction on free speech grounds. Caronia argued that the application of the FDCA's misbranding provisions to his truthful, non-misleading off-label promotional statements unconstitutionally restricted his right to free speech under the First Amendment. The government contended that the First Amendment was not implicated in the case because Caronia's prohibited conduct was not his actual promotional statements about the off-label uses of the drug but that the promotional statements were evidence of Caronia's intent to sell the products for unapproved indications. The majority of the court disagreed, finding that the jury instructions and the government's summation "would have led the jury to believe that Caronia's promotional speech was, by itself, determinative of his guilt" and, therefore, that the conduct for which Caronia was prosecuted was in fact his speech in aid of pharmaceutical marketing.<sup>3</sup>

The majority then examined whether the FDCA's prohibition of off-label marketing was constitutionally permissible by applying the analyses developed in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011) and *Central Hudson Gas & Elec. v. Public Serv. Comm'n*, 447 U.S. 557 (1980). In *Sorrell* the Court developed a two-part analysis to determine if government regulation of speech was subject to "heightened" scrutiny and presumptively invalid.<sup>4</sup> In *Sorrell*, the Supreme Court struck down a Vermont statute that prohibited the dissemination of certain prescription data to pharmaceutical companies for marketing purposes but

allowed other recipients access to the same data for other purposes. The *Sorrell* Court reasoned that "[b]ecause the [Vermont statute] disfavored speech with a particular content (marketing) when expressed by certain disfavored speakers (pharmaceutical manufacturers), ... [the statute] unconstitutionally restricted speech."<sup>5</sup> Under *Sorrell*, in order to prevail Vermont needed to demonstrate that the law directly advanced a substantial government interest; however, the Court found Vermont did not meet its burden to justify its content-based law as consistent with the First Amendment. Importantly, the *Sorrell* Court held that the result was the same whether "a special commercial speech inquiry or a stricter form of judicial scrutiny is applied."<sup>6</sup>

Applying the *Sorrell* analysis to the facts of the case, the Second Circuit concluded that the FDCA's misbranding provisions that prohibit and criminalize the promotion of off-label drug use by pharmaceutical manufacturers is content-based [off label uses] and speaker-based [pharmaceutical manufacturers], and, therefore, subject to heightened scrutiny.<sup>7</sup> The Second Circuit then addressed whether the restrictions imposed on Caronia's speech could withstand constitutional scrutiny under the *Central Hudson* test, which outlines the standard for protection of commercial speech subject to intermediate scrutiny. The *Central Hudson* analysis, as clarified by the Supreme Court in *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002), consists of four parts: 1) "whether 'the speech concerns lawful activity and is not misleading;'" 2) if the speech is protected, "whether the asserted government interest [in regulation] is substantial;" 3) "whether the regulation directly advances the governmental interest asserted;" and 4) "whether [the regulation] is not

more extensive than is necessary to serve that interest."<sup>8</sup>

With regard to the first prong, the Second Circuit determined that the speech at issue (promoting off-label use) concerned a lawful activity (off-label use of approved drugs), and therefore was protected by the First Amendment.<sup>9</sup> With respect to the second prong, the Second Circuit determined that the government had a substantial interest in drug safety and public health, which could justify some form of restriction on the protected speech.<sup>10</sup> The Second Circuit concluded, however, that the government could not satisfy the third and fourth prongs of the *Central Hudson* test.

With respect to *Central Hudson's* requirement that the regulation at issue directly advance the governmental interest asserted, the Second Circuit stated that: "[a]s off-label drug use itself is not prohibited, it 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>11</sup> With respect to the fourth prong of *Central Hudson*, the requirement that the regulation at issue be narrowly tailored to further the asserted governmental interest, the Second Circuit determined that "the government's construction of the FDCA to impose a complete and criminal ban on off-label promotion by pharmaceutical manufacturers is more extensive than necessary to achieve the government's substantial interests."<sup>12</sup> The Second Circuit reasoned that the restriction of the free flow of information not only fails to advance directly the government's substantial interests in drug safety and public health, but also is far more

restrictive of protected speech than necessary to achieve the government's stated ends. Accordingly, the Second Circuit vacated Caronia's conviction, holding 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>13</sup>

### How does this Affect Dietary Supplement Manufacturers?

Dietary supplement manufacturers like pharmaceutical manufacturers are subject to FDCA rules related to the promotion of certain health claims for dietary supplements.<sup>14</sup> FDA and the Federal Trade Commission ("FTC") share jurisdiction over dietary supplements through a liaison agreement.<sup>15</sup> FTC has jurisdiction over advertising, and the FDA has jurisdiction over labeling.<sup>16</sup> Similar to the FDCA, the FTC prohibits "unfair and deceptive acts" and prohibits advertisements from being false, misleading, unsubstantiated or unbalanced.<sup>17</sup> Under both the FTC and the FDCA, it is illegal to make claims that a food or dietary supplement can cure, treat, prevent or mitigate disease without approval from the FDA or the FTC.<sup>18</sup> The FDA may consider a dietary supplement labeled with an unauthorized health claim to be a misbranded food, a misbranded drug, and/or an unapproved new drug.<sup>19</sup> Likewise, the FTC may consider the dietary supplements manufacturer's advertisements deceptive if they do not meet the FTC's substantiation requirements. A dietary supplement labeled with such a claim, or a claim that is false or misleading, is subject to seizure, and the Agency may enjoin the product's distribution or seek criminal penalties against its manufacturer.<sup>20</sup>

How broadly the Second Circuit's decision may be interpreted remains to be

seen. The Second Circuit analysis is not limited to pharmaceutical manufacturers and could be equally applicable to dietary supplement manufacturers who make truthful, non-misleading health claims. As such, the *Caronia* decision could serve as a strong defense against FDA and FTC enforcement actions. While the FDA and FTC takes the position that there is no First Amendment protection for advertisements and labels that are false, misleading or deceptive, the FDA and FTC have often relied on their own subjective determination that there was a lack of substantiation or scientific proof to support dietary supplement manufacturers health related claims rather than bright line rules. Based upon the Second Circuit's holding that content-based and speaker-based speech restrictions are subject to heightened review and the government bears the burden of proof that any such restriction complies with the First Amendment under the applicable level of heightened scrutiny, it is questionable whether the FDA and FTC's restrictions on dietary supplement manufacturers use of truthful health related claims would be enforced. Particularly, in light of the fact, that the FDA and FTC routinely take the position that the dietary supplement manufacturer bears the burden of proving that its health related claims are adequately substantiated and absent such proof, the health related claim is deemed deceptive. Regardless of how broadly the *Caronia* decision is applied in future cases, the First Amendment issues before the Second Circuit in *Caronia* are very significant, making eventual Supreme Court review likely. ▲

1. The authors note that as of the date of the submission of this article, the United States has allowed the time for seeking an *en banc* hearing to pass.
2. *United States v. Caronia*, 2012 U.S. App. LEXIS 24831 (2d Cir. 2012).

3. 2012 U.S. App. LEXIS 24831 at \* 27.
4. 2012 U.S. App. LEXIS 24831 at \* 33.
5. *Id.*
6. 2012 U.S. App. LEXIS 24831 at \* 34, quoting *Sorrell*, 131 S. Ct. at 2667.
7. 2012 U.S. App. LEXIS 24831 at \* 36-38.
8. *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 8-9 (D.D.C. 2002) (quoting *Western States*, 535 U.S. at 367)
9. 2012 U.S. App. LEXIS 24831 at \* 38.
10. 2012 U.S. App. LEXIS 24831 at \* 39.
11. 2012 U.S. App. LEXIS 24831 at \* 41.
12. 2012 U.S. App. LEXIS 24831 at \* 45.
13. 2012 U.S. App. LEXIS 24831 at \* 48.
14. A "dietary supplement" is a "product (other than tobacco) intended to supplement the diet that bears or contains" one or more of certain dietary ingredients, including vitamins, minerals, herbs or botanicals, amino acids, concentrates, metabolites, constituents, or extracts. 21 U.S.C. § 321(ff)(1)(A)-(F). A "health claim" is "any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition." 21 C.F.R. § 101.14(a)(1); see also 21 U.S.C. § 343(r)(1)(A)-(B).
15. FTC-FDA Liaison Agreement, 4 Trade Reg., Rep.(CCH) paragraph 9851 (1971).
16. Labeling includes packaging, product inserts, websites, advertisements and any other promotional materials.
17. See Federal Trade Commission Act §§ 5(a), 12; 15 U.S.C. §§ 45(a), 52.
18. FDA uses three methods to determine if health claims may be used for a dietary supplement: (1) Nutrition Labeling and Education Act of 1990 ("NLEA"); (2) Food and Drug Administration Modernization Act of 1997 ("FDAMA"); and (3) FDA Consumer Health Information for Better Nutrition Initiative of 2003. Under the FDA's rules, a dietary supplement manufacturer may make a health claim related to a dietary supplement without FDA new drug approval if the FDA determines that "significant scientific agreement," based on the "totality of publicly available scientific evidence," supports the claim. 21 C.F.R. § 101.14(c) ("FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence . . . that there is significant scientific agreement . . . that the claim is supported by such evidence?").
19. 21 U.S.C. §§ 343(r)(1)(B), 352(a), 352(f).
20. 21 C.F.R. § 331(a), 332, 334.