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FIRST AMENDMENT — COMMERCIAL SPEECH — DISTRICT COURT GRANTS PRELIMINARY INJUNCTION PREVENTING FDA PROSECUTION OF TRUTHFUL AND NONMISLEADING STATEMENTS AFTER MODIFYING TEXT. — *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

The 1962 Amendments to the Federal Food, Drug, and Cosmetic Act<sup>1</sup> (FDCA) were passed with broad public support: in the wake of disasters like the thalidomide tragedy, in which prescription of the sedative thalidomide to pregnant women was found to cause serious birth defects, the country recognized the importance of granting broad authority to the Food and Drug Administration (FDA) to regulate both the safety and the efficacy of drug products.<sup>2</sup> This authority included criminal sanctions for misbranding drugs,<sup>3</sup> giving teeth to the FDA's regulatory regime in order to ensure that manufacturers disseminate information that reflects the FDA's rigorous approval process. However, with the development of a muscular First Amendment commercial speech doctrine in recent years, the FDA has found its regulatory regime increasingly curtailed.<sup>4</sup> Recently, in *Amarin Pharma, Inc. v. FDA*,<sup>5</sup> the U.S. District Court for the Southern District of New York granted a preliminary injunction to prevent an FDA enforcement action, holding that a drug manufacturer had a First Amendment right to circulate truthful and nonmisleading materials promoting off-label (unapproved) use of a drug, and that the materials in question — as modified by the court — were truthful and nonmisleading.<sup>6</sup> *Amarin* underscores the gauntlet faced by agencies seeking to preserve their regulatory regimes in the face of commercial speech challenges. Yet the zealous protection of commercial speech need not unduly impact the assessment of whether the speech is misleading; instead, the court should have deferred to agency expertise in issuing this assessment.

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<sup>1</sup> Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended in scattered sections of 21 U.S.C.); see also 21 U.S.C. § 355(a), (d) (2012) (requiring FDA approval before new drugs may be sold and calling for “adequate tests” before approval will be issued, *id.* § 355(d)).

<sup>2</sup> See Sue McGrath, *Only a Matter of Time: Lessons Unlearned at the Food and Drug Administration Keep Americans at Risk*, 60 FOOD & DRUG L.J. 603, 609 (2005).

<sup>3</sup> See 21 U.S.C. § 331(a) (prohibiting “[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded”); *id.* § 333 (providing for sanctions).

<sup>4</sup> See, e.g., Aaron S. Kesselheim & Michelle M. Mello, *Prospects for Regulation of Off-Label Drug Promotion in an Era of Expanding Commercial Speech Protection*, in FDA IN THE 21ST CENTURY 184, 187–89 (Holly Fernandez Lynch & I. Glenn Cohen eds., 2015); Christopher Robertson, Essay, *When Truth Cannot Be Presumed: The Regulation of Drug Promotion Under an Expanding First Amendment*, 94 B.U. L. REV. 545, 551–52 (2014).

<sup>5</sup> 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

<sup>6</sup> See *id.* at 237.

In 2013, Amarin applied for FDA approval to market the drug Vascepa to patients on cholesterol-lowering therapy with elevated triglyceride levels.<sup>7</sup> The FDA had already approved Vascepa for the limited class of patients with very high triglyceride levels,<sup>8</sup> and the manufacturer was eager to begin marketing the drug to a wider customer base. Amarin anticipated FDA approval on the second usage, having recently completed a clinical trial for the broader use of Vascepa that met all benchmarks stipulated by the FDA.<sup>9</sup> To Amarin's surprise, however, the FDA denied approval in April 2015<sup>10</sup> and indicated that Vascepa might be considered "misbranded under the [FDCA] if . . . marketed with this [information] before approval."<sup>11</sup> As this move would effectively bar Amarin from sharing its trial results with physicians, the manufacturer filed a complaint with the U.S. District Court for the Southern District of New York, alleging that the threatened criminal sanctions regarding Amarin's truthful, nonmisleading promotion of off-label drug usage restricted its commercial speech rights.<sup>12</sup> Two weeks later, Amarin moved for preliminary relief.<sup>13</sup>

At issue were materials that Amarin sought to distribute to physicians regarding the second, unapproved use of Vascepa. Specifically, Amarin sought to disseminate thirteen peer-reviewed scientific publications, a statement and chart summarizing its clinical trial, three textual statements, and five textual disclosures.<sup>14</sup> In response to Amarin's complaint, the FDA issued a letter indicating that if Amarin provided additional disclosures, amended several of its current disclosures, and removed a promotional statement that Vascepa may reduce the risk of coronary heart disease, the FDA would not pursue misbranding sanctions.<sup>15</sup> Amarin refused to moot the controversy in this manner, responding that it would adopt some alterations, but would accept others only with its own additional revisions; further, Amarin insisted

<sup>7</sup> *Id.* at 209–11.

<sup>8</sup> *Id.* at 209.

<sup>9</sup> *Id.* at 210–11. In 2009 Amarin had entered into a "special protocol assessment" (SPA) agreement for a clinical trial, which generally guarantees FDA approval. *Id.* at 210. See generally U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH AND HUMAN SERVS., GUIDANCE FOR INDUSTRY: SPECIAL PROTOCOL ASSESSMENT (2002), <http://www.fda.gov/downloads/Drugs/. . . /Guidances/ucm080571.pdf> [<http://perma.cc/34A7-N4V8>].

<sup>10</sup> *Amarin*, 119 F. Supp. 3d at 211–12.

<sup>11</sup> *Id.* at 212 (first alteration in original). The FDA cited unforeseen concerns raised by studies not conducted by Amarin, indicating that a second Vascepa trial currently underway would likely be sufficient to obtain approval. *Id.*

<sup>12</sup> *Id.* The complaint sought general relief indicating that commercial speech protections enable Amarin to promote Vascepa for off-label use with truthful and nonmisleading statements as well as confirmation regarding specific statements that the manufacturer wished to share with physicians. See *id.* at 214.

<sup>13</sup> *Id.* at 215.

<sup>14</sup> *Id.* at 229.

<sup>15</sup> *Id.* at 215–18.

upon its right to disseminate the coronary heart disease statement challenged by the FDA.<sup>16</sup>

The court granted Amarin's application for a preliminary injunction.<sup>17</sup> Judge Engelmayer held first that the FDA could not pursue misbranding sanctions against Amarin for statements that were truthful and nonmisleading, and second, that — after some tinkering with competing suggestions by the parties — the statements and disclosures proposed were in fact truthful and nonmisleading.<sup>18</sup>

First, Judge Engelmayer clarified that *United States v. Caronia*<sup>19</sup> controlled the misbranding issue and read that case to prohibit the FDA from bringing a misbranding action “based on truthful promotional speech alone.”<sup>20</sup> The 2012 Second Circuit opinion concerned a pharmaceutical sales representative facing criminal sanctions under the misbranding provision for off-label drug promotion.<sup>21</sup> Although the *Caronia* court had specified that it would narrowly interpret the misbranding provision “as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs,”<sup>22</sup> the court's focus on the specific jury instructions in that case suggested to some, including the FDA, that its holding might be limited to the facts of the case.<sup>23</sup> The FDA argued that the broad application of *Caronia* would seriously undermine its regulatory regime by allowing drug manufacturers to skirt the FDA's thorough drug approval process.<sup>24</sup> However, Judge Engelmayer clarified that *Caronia* would apply whenever the FDA pursued criminal sanctions against truthful and nonmisleading off-label commercial speech.<sup>25</sup>

A First Amendment commercial speech challenge generally requires application of the *Central Hudson* test, a form of intermediate scrutiny that balances the government and speaker interests at issue.<sup>26</sup>

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<sup>16</sup> *Id.* at 218–19.

<sup>17</sup> *See id.* at 237.

<sup>18</sup> *Id.*

<sup>19</sup> 703 F.3d 149 (2d Cir. 2012).

<sup>20</sup> *Amarin*, 119 F. Supp. 3d at 224.

<sup>21</sup> *Caronia*, 703 F.3d at 152; *see also* Recent Case, *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), 127 HARV. L. REV. 795 (2013).

<sup>22</sup> *Caronia*, 703 F.3d at 168.

<sup>23</sup> *See Amarin*, 119 F. Supp. 3d at 223–24; *see also* Alison Frankel, *Why U.S. Is Forgoing Appeal of Landmark 2nd Circuit Off-label Ruling*, REUTERS: ON THE CASE (Jan. 24, 2013), <http://blogs.reuters.com/alison-frankel/2013/01/24/why-u-s-is-forgoing-appeal-of-landmark-2nd-circuit-off-label-ruling> [<http://perma.cc/XYE9-5VBZ>].

<sup>24</sup> *Amarin*, 119 F. Supp. 3d at 226.

<sup>25</sup> *Id.* at 226–27. Rejecting the FDA's position, the court firmly asserted that *Caronia* was not a “ticket good for one day only.” *Id.* at 226 (citing *Smith v. Allwright*, 321 U.S. 649, 669 (1944) (Roberts, J., dissenting)).

<sup>26</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). The four-part test considers whether the speech, as a threshold matter, “concern[s] lawful activity” and isn't “misleading,” whether there is a “substantial” government interest in restricting the speech,

As *Amarin* “merely applie[d], to one drug, the construction of the misbranding statute adopted in *Caronia*,”<sup>27</sup> Judge Engelmayer incorporated the *Caronia* court’s application of three of the *Central Hudson* test’s four steps.<sup>28</sup> However, the *Amarin* court addressed the one step of the *Central Hudson* test that had not been at issue in *Caronia*<sup>29</sup> — the FDA argued that some of *Amarin*’s speech was not “truthful and nonmisleading,” and thus should not receive First Amendment protections.<sup>30</sup> The misleadingness determination usually serves as a “threshold step” under *Central Hudson*, prior to the balancing of interests in the other three steps.<sup>31</sup> Here, by contrast, having relied upon *Caronia*’s application of the other three steps of the *Central Hudson* test, the court addressed this final question largely in isolation.

The court focused its misleadingness analysis on the two disclosures and one statement contested by the parties.<sup>32</sup> On the first disclosure, concerning the FDA’s basis for not approving the broader use of Vascepa, the court drew “upon both parties’ drafts,” along with some words of its own, to generate a statement that it held to be nonmisleading.<sup>33</sup> Turning to the second, which cited the studies that had led the FDA to deny approval for the second use of Vascepa, the court decided to “err on the side of caution” in favor of providing more information, holding that a draft incorporating all proposed changes by both parties was truthful and nonmisleading.<sup>34</sup> Finally, the court considered the statement opposed by the FDA: “Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease.”<sup>35</sup> The FDA had approved the statement for dietary supplements, but argued that it could be misleading in the drug context.<sup>36</sup> Finding that the statement was “an accurate account of the current state of scientific research,”<sup>37</sup> however, the court held that the statement would not mis-

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whether the regulation “directly advances” that government interest, and whether the regulation is “more extensive than is necessary to serve that interest.” *Id.*

<sup>27</sup> *Amarin*, 119 F. Supp. 3d at 237.

<sup>28</sup> *Id.* at 223–29. The *Caronia* court had found that the misbranding provision did not directly advance the FDA’s interest in regulating off-label drug use, 703 F.3d 149, 166–67 (2d Cir. 2012), and that the regulation was not narrowly drawn to serve that interest, *id.* at 167–69.

<sup>29</sup> *Caronia*, 703 F.3d at 165 n.10.

<sup>30</sup> *Amarin*, 119 F. Supp. 3d at 234.

<sup>31</sup> *All. for Nat. Health US v. Sebelius (Alliance II)*, 786 F. Supp. 2d 1, 13 (D.D.C. 2011).

<sup>32</sup> *Amarin*, 119 F. Supp. 3d at 231–36.

<sup>33</sup> *Id.* at 232.

<sup>34</sup> *Id.* at 233.

<sup>35</sup> *Id.* at 214 (quoting Complaint at 43, *Amarin*, 119 F. Supp. 3d 196 (No. 15-CV-3588), 2015 WL 2128126).

<sup>36</sup> *Id.* at 234–36. The FDA expressed several concerns, including that doctors might improperly prescribe Vascepa in lieu of other treatments that lower the risk of heart disease. *Id.* at 234.

<sup>37</sup> *Id.* at 235.

lead physicians.<sup>38</sup> As modified by the court, then, all contested disclosures and statements were held to be truthful and nonmisleading, and thus protected.

*Amarin* reflects the current state of commercial speech doctrine as a force to be reckoned with. The court's affirmation of *Caronia* cemented a weighty commercial speech protection that the FDA had hoped would not take root. This move left only one step of the *Central Hudson* test — whether the speech in question is truthful and nonmisleading — as a gatekeeper to finding commercial speech protected. Given the FDA's relative expertise in assessing misleadingness, the court should have adopted a deferential posture on the *Central Hudson* misleadingness inquiry. There is precedent for such an approach: the D.C. Circuit and the District Court for the District of Columbia have done so in a pertinent line of cases. Instead, the court rejected the FDA's assessments and, further, edited the contested materials to resolve potential misleadingness — a role the D.C. courts identify as squarely within the purview of the FDA.

As the *Amarin* court noted, the 1962 Amendments establishing the FDA's drug approval regime predated the development of modern commercial speech doctrine.<sup>39</sup> Prior to the mid-1970s, commercial speech received no First Amendment protection.<sup>40</sup> Indeed, courts eschewed such protections as reminiscent of the earlier *Lochner* era, in which courts aggressively struck down government regulations to preserve the freedom of commercial actors.<sup>41</sup> In the last quarter of the twentieth century, however, the Supreme Court reversed its deferential approach to economic regulation where commercial speech is implicated, eventually developing the intermediate scrutiny *Central Hudson* test.<sup>42</sup> In *Sorrell v. IMS Health Inc.*,<sup>43</sup> decided five months prior to *Caronia*, the Court gestured toward an expansion of its protection of commercial speech,<sup>44</sup> indicating that as with other free speech claims, heightened scrutiny will be applied where restrictions on commercial speech are speaker- and content-based.<sup>45</sup>

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<sup>38</sup> *Id.* at 235–36.

<sup>39</sup> *Id.* at 226–27.

<sup>40</sup> *See, e.g.,* *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942) (“[T]he Constitution imposes no such restraint on government as respects purely commercial advertising.”).

<sup>41</sup> *See* *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 589–90 (1980) (Rehnquist, J., dissenting) (quoting *Nebbia v. New York*, 291 U.S. 502, 537 (1934); *Ferguson v. Skrupa*, 372 U.S. 726, 730 (1963)).

<sup>42</sup> *See id.* at 566 (majority opinion).

<sup>43</sup> 131 S. Ct. 2653 (2011).

<sup>44</sup> *Id.* at 2659.

<sup>45</sup> *Id.* at 2667; *see also id.* at 2677 (Breyer, J., dissenting). Both *Sorrell* and *Caronia* found that a stricter form of scrutiny was warranted but also applied the *Central Hudson* test. *Sorrell*, 131 S. Ct. at 2667–68; *United States v. Caronia*, 703 F.3d 149, 165–66 (2d Cir. 2012).

The *Caronia* majority applied post-*Sorrell* commercial speech doctrine and found that the regulation as interpreted by the FDA unduly restricted drug manufacturers' commercial speech rights.<sup>46</sup> In *Amarin*, the FDA clearly hoped that a second application of the *Central Hudson* test would yield a different result, arguing that the *Caronia* court's proposed less-restrictive alternatives were in fact "impractical, ineffective, unrealistic, or based on inaccurate assumptions."<sup>47</sup> An alternative application of the *Central Hudson* test might have preserved the agency's authority to monitor off-label drug promotion — Judge Livingston's *Caronia* dissent demonstrated as much,<sup>48</sup> and it also cogently argued that the FDA's regulatory regime is undermined by courts' protection of advertising as a form of commercial speech.<sup>49</sup> Indeed, much of the commentary surrounding the case pushed for a similar reconsideration of *Caronia*.<sup>50</sup> But the *Amarin* court rejected this line of argument, asserting that the *Caronia* court had already applied the *Central Hudson* test to the misbranding provision, and had done so properly.<sup>51</sup>

Given the muscular nature of commercial speech protections, the *Central Hudson* test's proviso that First Amendment commercial speech protections apply only to truthful and nonmisleading speech can serve an important gatekeeping function in granting such protection in cases like *Amarin*. However, the misleadingness standard provided by the Court is less than clear, referring obliquely to "forms of communication more likely to deceive . . . than to inform."<sup>52</sup> Further, the inquiry may vary depending on the legal context,<sup>53</sup> and although closer to a question of fact,<sup>54</sup> misleadingness has also been addressed as a matter of law.<sup>55</sup> Perhaps most importantly, when an agency has been

<sup>46</sup> *Caronia*, 703 F.3d at 168–69.

<sup>47</sup> Declaration of Janet Woodcock, M.D. at 25, *Amarin*, 119 F. Supp. 3d 196 (No. 15-CV-3588); see also *id.* at 15, 18, 25–26.

<sup>48</sup> *Caronia*, 703 F.3d at 177–81 (Livingston, J., dissenting).

<sup>49</sup> *Id.* at 169, 178–79.

<sup>50</sup> See, e.g., Kesselheim & Mello, *supra* note 4, at 193–97 (discussing a *Central Hudson* application that would uphold the provision).

<sup>51</sup> *Amarin*, 119 F. Supp. 3d at 225–26. The court quipped that if the FDA was unsatisfied with *Caronia*'s result, it should have appealed that decision. *Id.* at 227.

<sup>52</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563 (1980). The Court has also provided that the burden of proof is on the government, see *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 658–59 (1985), and that the government cannot rely on "rote invocation" of misleadingness to meet that burden, *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146 (1994).

<sup>53</sup> See, e.g., *Beneficial Corp. v. FTC*, 542 F.2d 611 (3d Cir. 1976) (referring to language in the Federal Trade Commission Act and describing precedent on the FTC misleadingness assessments).

<sup>54</sup> *Id.* at 617 ("Whether particular advertising has a tendency to . . . mislead is obviously an impressionistic determination more closely akin to a finding of fact than to a conclusion of law.").

<sup>55</sup> See, e.g., *Pearson v. Shalala (Pearson II)*, 130 F. Supp. 2d 105, 114 (D.D.C. 2001).

delegated authority to issue a determination on misleadingness, as in *Amarin*,<sup>56</sup> it is unclear what standard of review a court should adopt in assessing that determination. First Amendment challenges to agency actions generally receive de novo review, as another affirmation of the courts' commitment to protecting individual rights.<sup>57</sup> But where the agency is empowered to issue a relevant determination that relies on "scientific or technical data within its area of expertise,"<sup>58</sup> some courts have adopted a deferential approach to "reasoned" scientific determinations — in practice, leaning on agency assessment for the misleadingness prong.<sup>59</sup>

The D.C. courts took such an approach in the *Pearson* cases,<sup>60</sup> a line of decisions that similarly concerned FDA misleadingness determinations on off-label promotion in the context of a First Amendment challenge, albeit for dietary supplements, products facing a lower approval standard.<sup>61</sup> Without directly contradicting the FDA's assessment, the court distinguished between language that was inherently misleading, and thus could be banned, and language that was only potentially misleading.<sup>62</sup> The FDA could ban misleading claims where it provided empirical evidence that disclaimers would not fix their misleadingness;<sup>63</sup> otherwise, the FDA could not ban the language but was required to rely upon disclaimers to address their potentially misleading characteristics.<sup>64</sup> These courts took a "hard look" at the FDA determinations on misleadingness, rebuking the FDA for restricting

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<sup>56</sup> The FDCA misbranding provision authorizes the FDA to pursue criminal sanctions for statements that are false and misleading. See 21 U.S.C. § 352(a)–(n) (2012).

<sup>57</sup> See, e.g., *All. for Nat. Health US v. Sebelius (Alliance I)*, 714 F. Supp. 2d 48, 59 (D.D.C. 2010).

<sup>58</sup> *Alliance II*, 786 F. Supp. 2d 1, 12 (D.D.C. 2011).

<sup>59</sup> *Id.* (quoting *Alliance I*, 714 F. Supp. 2d at 60). The jurisprudence is spotty on the question of whether deference on constitutional matters is permissible. Although the "constitutional fact" doctrine theoretically precludes deference for constitutional inquiries concerning questions of fact, see Henry P. Monaghan, *Constitutional Fact Review*, 85 COLUM. L. REV. 229, 253 (1985), the Court has on occasion deferred to superior agency expertise in constitutional fact assessments, see, e.g., *Webster v. Doe*, 486 U.S. 592 (1988); *NLRB v. Gissel Packing Co.*, 395 U.S. 575 (1969). Matters of law are a thornier question, but see Adrian Vermeule, Essay, *Deference and Due Process*, 129 HARV. L. REV. 1890 (2016), for relevant discussion of deference to agency assessments on due process.

<sup>60</sup> *Pearson v. Shalala (Pearson I)*, 164 F.3d 650 (D.C. Cir. 1999); *Pearson v. Thompson (Pearson III)*, 141 F. Supp. 2d 105 (D.D.C. 2001); *Pearson II*, 130 F. Supp. 2d 105.

<sup>61</sup> See, e.g., *Alliance II*, 786 F. Supp. 2d at 5–8; see also *Pearson I*, 164 F.3d 650; *Pearson III*, 141 F. Supp. 2d 105; *Pearson II*, 130 F. Supp. 2d 105. For dietary supplements, the FDA promulgated a regulation based on its standard ("significant scientific agreement") for assessing food health claims under the Nutrition Labeling and Education Act of 1990. See Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

<sup>62</sup> *Alliance II*, 786 F. Supp. 2d at 6 n.4 (citing *Pearson I*, 164 F.3d at 659; *Pearson II*, 130 F. Supp. 2d at 110).

<sup>63</sup> *Id.* at 15.

<sup>64</sup> *Id.*

speech without explanation<sup>65</sup> and assessing whether the FDA's evaluation was inconsistent with its own standards.<sup>66</sup> Yet the courts sustained the deferential framework, and where they found that potentially misleading language required disclaimers, they remanded the case to the FDA to draft such disclaimers.<sup>67</sup>

While not explicitly stating its standard of review for the FDA's misleadingness assessment, the *Amarin* court clearly took a different tack from the D.C. courts. Even the order in which the court considered the materials at issue indicated that something different was happening here — under the *Pearson* cases, the court would have considered disclosures only *after* determining whether Amarin's promotional statement was misleading. Proceeding instead from disclaimers to the promotional statement, the court found nonmisleadingness in all contested language, in contradiction of the FDA's assessment that such language was at least potentially misleading. The court's greatest departure from the *Pearson* cases was the treatment of Amarin's disclaimers. The D.C. courts did not “presume to draft precise disclaimers,” but rather remanded the case to the FDA to draft the appropriate language<sup>68</sup> — a deferential approach reflecting separation of powers concerns and recognition of the relative strengths of courts and agencies. In *Amarin*, the court instead relied on its own assessment of the merits of language presented by both sides to generate disclaimers that it held to be truthful and nonmisleading. Rather than seeking to improve the FDA's ability to do its job, the *Amarin* court did the agency's job for it.

In its current form, commercial speech doctrine can be a powerful tool — yet this is all the more reason for courts to adopt a deferential approach to the misleadingness assessment. As Justice Breyer pointed out in his *Sorrell* dissent, when applied too fervently, the doctrine threatens a return to the *Lochner* era in which economic regulations were frequently struck down by overzealous courts.<sup>69</sup> The current state of the doctrine leaves vulnerable to First Amendment claims a significant proportion of government regulations developed in the last century to protect public health and welfare. Thus, at the very least, the *Central Hudson* misleadingness inquiry should operate to preserve agency authority over an assessment that the agency is most qualified to make.

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<sup>65</sup> *Pearson I*, 164 F.3d at 660.

<sup>66</sup> *Alliance II*, 786 F. Supp. 2d at 15.

<sup>67</sup> *See, e.g., Pearson I*, 164 F.3d at 659 (“We do not presume to draft precise disclaimers . . . ; we leave that task to the agency in the first instance.”).

<sup>68</sup> *See id.*

<sup>69</sup> *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2675 (2011) (Breyer, J., dissenting).