

### FDA Promises Guidance on Lawful Off-Label Promotion

Earlier this month, the U.S. Food and Drug Administration (the "FDA") announced that by the end of the year, the agency would issue a draft guidance document addressing the contours of lawful and unlawful off-label promotion.<sup>1</sup> The healthcare industry has heralded this announcement as a positive step in a regulatory environment that, many believe, provides unclear direction regarding the provision of truthful information to healthcare providers, leaving industry players vulnerable to FDA regulatory enforcement, criminal prosecution, and civil suits under the False Claims Act ("FCA").

While the FDA's announcement was welcomed by many after years of uncertainty and after recent events raised new questions about the constitutionality of the ban on off-label promotion, questions remain about the ultimate effect of the FDA's decision. First, will the agency provide clear statements regarding the scope of lawful and unlawful off-label promotion, or merely restate existing policy? Other agencies, including the Federal Trade Commission ("FTC") and the Securities and Exchange Commission ("SEC") have been criticized for issuing "new" guidance documents that simply restate the same ambiguous advice that prompted the industry to request their issuance.<sup>2</sup> The FDA has not provided any indication of what its draft guidance will say, and in the absence of an accompanying revision to applicable regulations, it is difficult to predict whether the FDA's guidance will provide clear advice to the pharmaceutical and medical device industries.

Second, what effect will this guidance have on criminal prosecution and FCA actions based on off-label promotion? While modified guidance could redirect enforcement actions from the FDA itself, the laws that enable the Department of Justice ("DOJ") to pursue criminal and civil suits for selling a "misbranded" product or causing the submission of a "false claim" under the FCA may be unaffected by a guidance document from the FDA unless other laws and regulations are also amended.

This Alert provides an overview of the events prompting the FDA's announcement and addresses the questions left open by the FDA's decision.

#### I. Recent Events Leading to the FDA's Announcement

In July 2011 and September 2013, several companies submitted Citizen Petitions to the FDA requesting greater clarity for drug and device manufacturers to provide "truthful and non-misleading scientific information" regarding uses for drugs and devices beyond those that were approved by the FDA.<sup>3</sup> The 2011 Petition requested clarity regarding several topics, including unsolicited requests for information from healthcare providers. The 2013 Petition built on the same areas addressed in the 2011 Petition and incorporated an additional discussion regarding the constitutionality of the FDA's effective ban on off-label promotion in light of the Second Circuit's decision in *United States v. Caronia*, 703 F.2d 149 (2d Cir. 2012), which held that the FDA's ban on truthful off-label promotion violated the First Amendment.<sup>4</sup>

<sup>1</sup> See Letter from L. Kux, Assistant Commissioner for Policy at the Food & Drug Administration to A. Bennett, J. McPhee et al., dated Jun. 6, 2014.

<sup>2</sup> See Marlissee Silver Sweeney, *Corporate Counsel*, "Define 'Reasonable' When it Comes to Data Security" (June 11, 2014) (discussing the FTC's guidance that dictates that companies should employ a "reasonableness" standard for data security and the challenges faced by companies attempting to apply this standard); Criminal Division of the Department of Justice and the Enforcement Division of the U.S. Securities and Exchange Commission, "A Resource Guide to the U.S. Foreign Corrupt Practices Act" (Nov. 14, 2012); *Law360*, "How Companies Should Use New FCPA Guidance" (Nov. 15, 2012) (noting that the FCPA Resource Guide "does not announce new policies or provide guidance that could not otherwise be gleaned from existing cases, settlements and opinion letters").

<sup>3</sup> See Citizen Petition from A. Bennett, P. Kalb et al. to the Division of Dockets Management of the Food and Drug Administration, dated July 5, 2011 (the "2011 Petition"); Citizen Petition from A. Bennett, C. Klasmeier et al. to the Division of Dockets Management of the Food and Drug Administration, dated Sept. 3, 2013 (the "2013 Petition").

<sup>4</sup> 2013 Petition at 2. We issued an alert detailing that decision and addressing its potential effect on False Claims Act Defendants. Patterson Belknap Alert, "Second Circuit Declares Off-Label Promotion Ban Unconstitutional: Implications for False Claims Act

The FDA responded, in part, to both Petitions in two Guidance documents issued in December 2011<sup>5</sup> and February 2014.<sup>6</sup> Both Guidance documents provided some additional information about the appropriate distribution of scientific information regarding off-label uses, but left several questions unanswered. The FDA also notably reminded manufacturers that a manufacturer's "intended use" of a product may be established by circumstantial evidence,<sup>7</sup> and that a drug "that is accompanied by written, printed, or graphic matter that suggests an unapproved use . . . would be considered misbranded."<sup>8</sup>

## II. FDA's Response

Although the FDA has partially responded to the 2011 and 2013 Petitions, the FDA acknowledged in its announcement that several issues raised in the petitions remain unresolved, including unsolicited requests from healthcare providers about off-label use, manufacturers' ability to distribute scientific and medical information on unapproved new uses, manufacturer discussions regarding scientific information "more generally," and the dissemination of healthcare economic information.<sup>9</sup>

The letter also contains references to some of the same ambiguous guidance contained in prior Agency announcements, indicating that the FDA's upcoming guidance may not answer many of the questions that plague the current regulatory environment. The letter notes that the Federal Food, Drug, and Cosmetic Act (the "FDCA") operates to ensure the use of medical products is based on "sound evidence"<sup>10</sup> and that distributing scientific information regarding off-label use may qualify in "appropriate circumstances."<sup>11</sup> These ambiguous terms may leave the industry in the same constitutional and regulatory quandary that has effectively foreclosed the distribution of truthful scientific information regarding off-label use.

## III. The Potential Effect on Criminal and Civil Actions Based on Off-Label Promotion

While clearer Guidance from the FDA regarding off-label promotion will be welcomed by the industry, the precise effects of this Guidance on criminal and civil suits are unknown. The DOJ has repeatedly taken the position that off-label promotion reflects a manufacturer's intent to sell a "misbranded" product, a position that is supported by FDA Guidance documents.<sup>12</sup> Until Congress revises the FDCA, drug and device manufacturers may find the FDA's Guidance fails to provide sufficient assurance that changes to marketing practices will not result in criminal exposure. This is especially true in light of the extraordinarily severe consequences for manufacturers convicted of selling a "misbranded" product, which can include debarment and exclusion from government healthcare programs.<sup>13</sup>

Second, even if the FDA's upcoming Guidance provides the industry with a clearer regulatory framework to provide truthful information regarding off-label uses, it is open to question whether promotion expressly permitted by the

Defendants" (January 2013), available at <http://www.pbwt.com/alert-second-circuit-declares-off-label-promotional-ban-unconstitutional/>.

<sup>5</sup> See FDA Draft Guidance, "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices" (Dec. 2011), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf> (the "December 2011 Draft Guidance"). The FDA also published a request for information and comments on "scientific exchange" to assist the Agency's evaluation of its policies on communications regarding off-label use. See 76 Fed. Reg. 81,508 (Dec. 28, 2011).

<sup>6</sup> See FDA Draft Guidance, "Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices" (Feb. 2014), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf> (the "February 2014 Revised Draft Guidance").

<sup>7</sup> *Id.* at 3–4.

<sup>8</sup> *Id.* at 4.

<sup>9</sup> Letter from L. Kux, Assistant Commissioner for Policy at the Food & Drug Administration to A. Bennett, J. McPhee et al., dated Jun. 6, 2014, at 9.

<sup>10</sup> *Id.* at 7.

<sup>11</sup> *Id.*

<sup>12</sup> February 2014 Revised Draft Guidance at 4 ("[A]n approved new drug that is accompanied by written, printed, or graphic matter that suggests an unapproved new drug with respect to that use . . . would be considered misbranded, because the drug does not meet the regulatory exemptions from the requirement that its labeling bear 'adequate instructions for use.'").

<sup>13</sup> See 21 U.S.C. § 335a.

FDA may still subject a manufacturer to liability under the FCA. As we previously discussed in our Alert regarding the *Caronia* decision, the law permits physicians to use their medical judgment to prescribe drugs for any indication regardless of FDA approval. Medicare and Medicaid, however, may only reimburse a prescription for a “medically accepted indication”—defined as a use approved by the FDA or supported by one of three compendia—and some courts have held that a request for reimbursement for such a prescription constitutes a “false claim” for payment under the FCA.<sup>14</sup> The DOJ and the whistleblowers awarded standing in FCA cases—known as *qui tam* relators—have used this premise many times to allege that off-label promotion “causes” a false claim for payment by encouraging off-label prescriptions, a subset of which may be submitted to Medicare or Medicaid under 31 U.S.C. § 3729(a)(1)(A).

In FCA cases based on off-label promotion, an underlying premise has been that the manufacturer engaged in unlawful activity, which caused the “false claim” for government payment (a non-reimbursable, off-label prescription). Indeed, government actions for off-label promotion typically combine both criminal suits—for selling a “misbranded” product—and civil suits—for causing the submission of a “false claim”—based on the same underlying activity.<sup>15</sup> If the FDA provides clear guidance delineating the scenarios in which manufacturers may provide truthful information regarding off-label use of a drug or device, it is open to question whether activities expressly permitted by the FDA could still give rise to FCA liability.

#### IV. Conclusion

The FDA’s promise to release more guidance for manufacturers that want to distribute truthful information regarding their products was welcome news in a regulatory environment that has been characterized by uncertainty. Patterson Belknap will continue to monitor developments in this area, and will provide further information when the FDA releases its guidance later this year.

<sup>14</sup> Patterson Belknap Alert, “Second Circuit Declares Off-Label Promotion Ban Unconstitutional: Implications for False Claims Act Defendants” (January 2013), available at <http://www.pbwt.com/alert-second-circuit-declares-off-label-promotional-ban-unconstitutional/>.

<sup>15</sup> See, e.g. Department of Justice Press Release, “Par Pharmaceuticals Pleads Guilty and Agrees to Pay \$45 Million to Resolve Civil and Criminal Allegations Related to Off-Label Marketing” (Mar. 5, 2013), available at <http://www.justice.gov/opa/pr/2013/March/13-civ-270.html> (discussing combined settlement for criminal suit based on selling a “misbranded” product and a civil suit for causing submissions of “false claims” for off-label prescriptions in violation of the FCA).

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