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Client Alert

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Two New Developments in First Amendment Challenges to Off-Label Promotion: What's Next?

Following the Second Circuit's marquee First Amendment ruling in the *Caronia* case, two recent developments demonstrate a shift in the battleground for First Amendment challenges to the prohibition on off-label promotion under the federal Food, Drug and Cosmetic Act (FDCA). In December 2012, the U.S. Court of Appeals for the Second Circuit overturned the November 2009 conviction of Alfred Caronia for conspiracy to introduce a misbranded drug into interstate commerce, holding that Caronia's conviction based on promotion of off-label uses of an FDA-approved drug violated the First Amendment.[1] As we discussed in our December 20, 2012 client alert, "Second Circuit Vacates Off-Label Promotion Conviction on First Amendment Grounds in *U.S. v. Caronia*," the court summarized its holding by stating "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."[2]

Last week, two important developments occurred that shed new light on the potential direction of future enforcement efforts. First, Par Pharmaceutical Companies Inc. (Par) withdrew its First Amendment challenge to FDA's off-label promotion regulatory scheme as part of a global off-label promotion settlement with the Department of Justice. This dismissal follows the settlement of a similar First Amendment challenge advanced by Allergan and litigated by our firm in 2009 and 2010.[3] Second, the Ninth Circuit affirmed the conviction of Scott Harkonen, former Chief Executive Officer of InterMune, Inc., for wire fraud based on the dissemination of allegedly misleading information in a press release about a clinical trial. While these two developments may seem to detract from the Second Circuit's important First Amendment ruling in *Caronia*, they actually point to a shift in the enforcement landscape, the heightened burden on the government in future prosecutions, and the continued role the First Amendment will play in defending such actions going forward.

For more information, contact:

Jeffrey S. Bucholtz
+1 202 626 2907
jbucholtz@kslaw.com

Mark A. Jensen
+1 202 626 5526
mjensen@kslaw.com

Brandt Leibe
+1 713 751 3235
bleibe@kslaw.com

Nikki Reeves
+1 202 661 7850
nreeves@kslaw.com

Wick Sollers
+1 202 626 5612
wsollers@kslaw.com

Christopher A. Wray
+1 202 626 5570
cwray@kslaw.com

Elizabeth S. White
+1 202 626 2904
ewhite@kslaw.com

King & Spalding
Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

www.kslaw.com

Par Pleads Guilty, Drops First Amendment Challenge

On March 5, 2013, Par pleaded guilty to a criminal misdemeanor for misbranding Megace ES in violation of the FDCA[4] and agreed to pay $45 million to resolve its criminal and civil liability. Par also entered into a five-year Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the Department of Health and Human Services (OIG). This global resolution settled three whistleblower suits brought under the False Claims Act.[5]

Megace ES was approved by FDA for the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with AIDS. DOJ alleged that Par misbranded Megace ES by promoting it for use in elderly patients who did not have AIDS—an off-label use. According to DOJ's allegations in the Criminal Information, from July 2005 to 2009, Par distributed misbranded Megace ES without adequate directions for the off-label use of treating non-AIDS-related geriatric wasting.[6]

Also according to the Criminal Information, Par promoted Megace ES for off-label use in the elderly even though Par never conducted clinical studies of Megace ES in the geriatric population.[7] DOJ alleged that Par promoted Megace ES off-label by detailing physicians in long-term care facilities, including nursing homes, while knowing that few of these facilities housed AIDS patients.[8] The government also alleged that Par implemented a "conversion strategy" to convince doctors to prescribe Megace ES instead of competing drugs, without regard to whether the competing drugs had been prescribed to AIDS patients, and rewarded sales representatives for these conversions.[9]

In addition, according to the Criminal Information, Par made allegedly false and misleading claims that Megace ES was superior to a competing product even though Par did not have well-controlled clinical trial data supporting that claim.[10] The government also alleged that Par sales managers encouraged sales representatives to ask for patient identifying information covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[11]

Equally noteworthy, however, Par's plea agreement required it to dismiss with prejudice a declaratory judgment action it filed in October 2011 seeking to prevent the government from enforcing regulations that criminalize truthful and non-misleading speech to healthcare professionals under the First Amendment.[12] Following other First Amendment challenges to the off-label regulatory regime, Par sought to enjoin FDA not only from prohibiting truthful and non-misleading speech about *off-label* uses, but also from prohibiting truthful and non-misleading speech about *on-label* uses to physicians who may prescribe for unapproved uses.

Specifically, Par's pleadings argued that when manufacturers speak about on-label uses to physicians who prescribe off-label, the FDA regulatory scheme catches manufacturers "in a Catch-22" — they cannot unilaterally change the drug's label to address the off-label uses for which the physicians might prescribe the drug, but "based on the government's view of the FDA's 'intended use' regulations, *not* changing the labeling to add those directions violates the [FDCA's] criminal 'misbranding' rule."[13] By requiring the withdrawal of Par's First Amendment challenge as a condition of the global settlement, the government avoided having to litigate the merits of the First Amendment question in another jurisdiction outside the Second Circuit post-*Caronia*.[14]

Ninth Circuit Affirms Harkonen Conviction

In 2009, a jury convicted Scott Harkonen, the former Chief Executive Officer of InterMune, Inc., of wire fraud based on a press release that contained allegedly false and misleading statements. In the 2002 press release, which Harkonen drafted, InterMune claimed that a study demonstrated a treatment effect for an off-label use of one of InterMune's products, even though the outcomes touted in the press release were not endpoints for the study. In his defense, Harkonen argued that the press release "expressed a scientific view" protected by the First Amendment, while the government contended that false statements made with an intent to defraud the public were not protected by the First Amendment. The District Court in the Northern District of California sentenced Harkonen to three years probation, six months of home confinement, 200 hours of community service, and a $20,000 fine.[15]

On March 4, 2013, the U.S. Court of Appeals for the Ninth Circuit upheld Harkonen's conviction.[16] In an unpublished opinion, the Ninth Circuit analyzed Harkonen's First Amendment challenge by asking two questions: "(1) deferring to the jury's finding on historical facts, credibility determinations, and the elements of statutory liability, . . . whether sufficient evidence supports the verdict; and (2) if it does, . . . whether the facts, as found by the jury, establish the core constitutional facts."[17] The court clearly stated that the First Amendment "does not protect fraudulent speech," and therefore it considered "the core constitutional issue . . . [to be] whether the facts the jury found establish that the Press Release was fraudulent."[18]

The court held that sufficient evidence supported the jury's finding that Harkonen knowingly participated in a scheme to defraud. The court cited testimony at trial that the Press Release misrepresented the clinical study's results, testimony that Harkonen was "very apologetic" about the Press Release, evidence that Harkonen prevented clinical personnel from reviewing the Press Release prior to publication and attempted to shield his post-hoc analyses from FDA, and evidence that the Press Release was "capable" of influencing doctors to prescribe the product.[19] Second, the court also concluded that sufficient evidence supported the jury's finding that Harkonen had a specific intent to defraud, citing circumstantial evidence establishing "a clear financial incentive to find a positive result in the face of" the failed clinical study.[20] Because the jury's findings were supported by the evidence, the court deferred to the jury's determination that "the Press Release was misleading, that Harkonen knew it was misleading, and that Harkonen had the specific intent to defraud."[21]

The court declined to adopt Harkonen's argument that his speech was "genuine debate[] over whether a given treatment caused a particular effect" that should be "outside the scope of the mail and wire fraud statutes" because the jury "found beyond a reasonable doubt, that Harkonen issued the Press Release with the specific intent to defraud."[22] However, the court plainly stated that "genuine debates of any sort are, by definition, not fraudulent." The jury finding—that Harkonen's speech was fraudulent—put Harkonen's speech outside the realm of genuine scientific debate.

Implications of these Recent Developments

In light of the *Par* settlement and Harkonen's affirmed conviction, what is next for First Amendment challenges to the FDA's off-label promotion regulatory scheme? First, DOJ's insistence that Par dismiss its declaratory judgment action shows the government's continued interest in avoiding First Amendment litigation regarding the misbranding regime. DOJ's interest in avoiding more First Amendment precedent seems all the more acute after the *Caronia* decision, and in the context of the allegations in the *Par* case that appear to focus significantly on truthful off-label promotion. Second, although the government prevailed on the First Amendment issue in *Harkonen*, as the Ninth Circuit recognized, First Amendment arguments are at their weakest when the speech at issue is false or fraudulent. The jury's finding that Harkonen knowingly participated in a scheme to defraud sets the *Harkonen* case apart from many DOJ enforcement actions to date where there have not been formal findings or credible allegations of fraudulent off-label statements.

These recent developments also point to the emerging battleground in sales and marketing investigations in FDCA, mail and wire fraud, and False Claims Act cases—allegations of fraud and false and misleading statements. Expect enforcement authorities to pursue allegations that are more like those in *Harkonen—i.e.*, allegations of fraudulent or false and misleading statements beyond truthful off-label promotional claims—and less like those in *Par* and *Caronia—i.e.*, allegations of truthful off-label statements during promotional interactions. Shifting the enforcement focus in that way leaves less room for future First Amendment challenges to government enforcement, but also heightens the government's evidentiary burdens. As the government increasingly hones in on arguably fraudulent or false statements, it will scrutinize all communications. The *Harkonen* case demonstrates that statements in any context—even in a press release intended for investors—can present a significant risk that companies should consider addressing through their compliance programs.

One definitive lesson learned from the *Par* and *Harkonen* cases is that only litigation before a neutral third party will provide objective, definitive answers to these challenging questions. Allegations of fraud or false and misleading conduct during an investigation and resolution discussions are not uncommon, but the government has rarely proved those serious allegations in court. *Harkonen* notwithstanding, acquittals of individuals who put the government to its burden of proof at trial in the cases involving TAP and Synthes executives show that those elements are meaningful and can be difficult for the government to prove to a jury. Corporate entities seldom litigate these cases in light of the risk that a loss at trial could result in administrative exclusion by HHS-OIG, so the next chapter in this First Amendment story will most likely come in the context of DOJ's discretionary enforcement decisions about individuals and the trials that ensue.

[1] *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).

[2] *Id.* at 169; *See also*, King & Spalding Client Alert, *Second Circuit Vacates Off-Label Promotion Conviction on First Amendment Grounds in U.S. v. Caronia* (December 20, 2012), *available at* http://www.kslaw.com/imageserver/KSPublic/library/publication/ca122012.pdf.

[3] *See* Complaint, *Allergan, Inc. v. United States*, No. 09-1879 (D.D.C. Oct. 1, 2009).

[4] 21 U.S.C. §§ 331(a), 333(a)(1), 352(f)(1). 21 U.S.C. § 331(a) prohibits the introduction or delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 333(a)(1) establishes that a person who violates § 331 shall be imprisoned for not more than one year or fined not more than $1,000, or both. 21 U.S.C. §352(f)(1) defines a drug as "misbranded" if it lacks adequate directions for use.

[5] Press Release, Department of Justice, 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.

[6] Information, *United States v. Par Pharmaceutical Companies, Inc.* (D.N.J. Mar. 5, 2013).

[7] *Id.* at ¶ 19-20.

[8] *Id.* at ¶28.

[9] *Id.* at ¶29.

[10] *Id.* at ¶30A-D.

[11] *Id.* at ¶30E.

[12] Complaint for Declaratory and Injunctive Relief, *Par Pharmaceutical, Inc. v. United States*, No. 11-1820 (D.D.C. Oct. 14, 2011).

[13] *Id.* at ¶37.

[14] This is not the first time the government has required the dismissal of a declaratory action seeking to prohibit the government from enforcing regulations that criminalize truthful and non-misleading speech to healthcare professionals as part of a global settlement—the government required Allergan to dismiss a similar declaratory action as part of its $600 million off-label settlement in 2010.

[15] Press Release, Department of Justice, Former InterMune CEO Sentenced for False & Misleading Statements Related to Pulmonary Fibrosis Drug's Clinical Tests (April 14, 2011), *available at* http://www.justice.gov/opa/pr/2011/April/11-civ-475.html.

[16] *United States v. Harkonen*, No. 11-10209 (9th Cir. Mar. 4, 2013), *available at* http://cdn.ca9.uscourts.gov/datastore/memoranda/2013/03/04/11-10209.pdf.

[17] *Id.* at *2.

[18] *Id.* at *3.

[19] *Id.* at *3-4.

[20] *Id.* at *4-5.

[21] *Id.* at *5.

[22] *Id.* at *6-7.