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Increased FDA Regulatory Action: The Current Landscape and Its Impact on Drug and Medical Device Litigation

The Food and Drug Administration (FDA) has a number of tools to enforce its laws and regulations. From warning and untitled letters to seizures, recalls, injunctions, monetary penalties and criminal prosecutions, its options are quite varied. Over the last few years, however, FDA has significantly increased its use of these regulatory tools, reemphasizing its commitment to "prevent harm to the American people" through effective enforcement of FDA regulations.

Every indication suggests this pattern will only continue to increase in the future. This renewed emphasis on enforcement will invariably impact all industries regulated by FDA. As a result, it is important for drug and medical device companies to be aware of this refocused regulatory landscape and understand how these changes may impact them.

Specifically, since August 2009, FDA has enhanced its regulatory efforts by, among other things:

- Expediting the issuance of warning letters to companies by limiting the FDA chief counsel's review to circumstances where "significant legal issues" are present;
- Accelerating enforcement actions by eliminating the need to issue multiple warning letters to noncompliant firms before taking action;
- Increasing the funding necessary for additional inspection and compliance activities;
- Setting post-inspection deadlines of, in general, no more than 15 working days for a company to respond before moving forward with a warning letter or enforcement action;
- Emphasizing its intention to increase the use of misdemeanor prosecutions to hold corporate officials personally accountable for corporate actions; and
- Implementing the "Bad Ad" program to help healthcare providers recognize misleading prescription drug promotions and provide them with an easy way to report this activity to the Agency.

The tangible results of FDA's renewed focus are evidenced by the increased number of regulatory actions instituted over the last few years. By way of example, in 2008, 21 warning and untitled letters were issued to pharmaceutical companies by the Division of Drug Marketing, Advertising and Communication (DDMAC). In 2009, the number of warning and untitled letters issued to pharmaceutical companies jumped to 41, and more than 50 were issued to pharmaceutical companies in 2010. In addition, FDA only just issued its first warning letter stemming from its newly implemented "Bad Ad" program in December 2010 – a number that will certainly rise as we move into 2011. Similarly, FDA increased the number of inspections it conducted in 2009 – boasting an approximate 12 percent increase from fiscal year 2008 to fiscal year 2009, with inspections related to human drug products increasing from 2,221 in 2008 to 2,491 in 2009. The number of inspections increased again in 2010 to 2,798. Similarly, there was a 19 percent increase in the issuance of domestic Form 483 reports from fiscal year 2008 (748 reports) to fiscal year 2009 (892 reports) related to human drug products.

What Does This Mean for You?

Many perceive FDA's additional oversight as a positive development, but drug and medical device companies must be cognizant of this new regulatory landscape and its potential impact on them. The increase in FDA regulatory and enforcement actions invariably correlates with an increase in parallel investigations by multiple governmental agencies, and also private civil and/or shareholder litigation. Even though concurrent actions often involve similar factual questions, they raise a number of complex issues that go well beyond those addressed in a single litigation prosecuted in a single forum. Companies need to prepare for this eventuality and have a game plan ready to address the unique issues raised by concurrent actions.

Given FDA's recent pronouncements, a few issues seem likely to garner more attention in the coming year. Below is a brief overview of some of the more relevant considerations.

Fifth Amendment Considerations

FDA has broad authority to seek the criminal prosecution of persons who violate the Federal Food, Drug and Cosmetic Act (FDCA or the Act). FDA can seek the felony prosecution of any person who

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commits a prohibited act under the FDCA – such as the adulteration or misbranding of any drug or medical device – "with the intent to defraud." 21 U.S.C. 333(a)(2). If a company violates the Act, FDA can also seek the misdemeanor prosecution of any corporate official if that official held a position of authority such that he or she could have prevented the violation. *See U.S. v. Park*, 421 U.S. 658 (1975). Unlike a felony conviction, however, proof of fraudulent intent is not necessary for a misdemeanor conviction. *Id.*

The misdemeanor prosecution of corporate officials appears to be an especially relevant topic to drug and medical device companies today given recent statements about FDA's intent to increase use of this enforcement tool, and the recent issuance of criteria for prosecuting corporate officials under the "Park Doctrine." Specifically, in March of 2010, FDA Commissioner Margaret Hamburg, M.D., in a letter to Sen. Charles E. Grassley (R-Iowa), advised that FDA was considering increasing "the appropriate use of misdemeanor prosecutions" to hold corporate officials accountable for company activities. More recently, at an October 2010 conference in Washington, D.C., several FDA officials predicted an increase in the number of criminal prosecutions for those individuals violating the FDCA. Eric Blumberg, FDA's deputy chief for litigation, stated that he expected these investigations to be focused on the distribution of unapproved new drugs, failure to report unexpected adverse events caused by medical products and "flagrant" off-label promotion. This increased use of misdemeanor prosecutions, as well as the FDA's use of other regulatory enforcement tools such as felony prosecutions, raises Fifth Amendment issues of which companies must be aware.

The Fifth Amendment permits a person to refuse to testify under oath in a court of law (or tribunal) on the grounds that the answers could be used against that witness to convict him or her of a criminal offense. U.S. CONST. amend. V. This is commonly known as the privilege against self-incrimination. Where a corporate official refuses to testify before a court or tribunal based on this Fifth Amendment privilege, however, it can create issues for those defending claims in parallel proceedings. In criminal prosecutions, if a person refuses to testify, the prosecution may not comment on, nor may the jury draw an adverse inference from, the refusal to testify. *Griffin v. California*, 380 U.S. 609 (1965). Conversely, if a party declines to answer a question based on the Fifth Amendment in civil litigation, an adverse inference, under certain circumstances, may be drawn from the refusal to testify. *Baxter v. Palmigiano*, 425 U.S. 308 (1976). An adverse inference allows the fact-finder to draw a presumption that the response to a refused question would have been adverse to the individual's - and quite possibly the company's - position in the litigation. *Id.*

When preparing for civil litigation, pharmaceutical companies and their defense counsel must consider whether there is a realistic possibility that a related criminal investigation has already begun or could be commenced. If this possibility exists, the company should implement a coordinated civil and criminal defense strategy because any statement made by a person in civil litigation is admissible against that person or entity in any subsequent criminal proceeding. *See Fed. R. Evid.* 801(d). At the same time, if criminal prosecution has already commenced, a company must consider the impact of an adverse inference in civil litigations should a person decline to testify. Companies should consider who they intend to identify as a corporate witness during litigation and evaluate the potential implications, both civil and criminal, should that person be called to testify during trial. Absent knowledge of the specific facts and circumstances involved, there is no way to predict how a pharmaceutical company should handle potential Fifth Amendment issues, but one thing is certain: based on FDA's recent focus, pharmaceutical companies must consider whether criminal prosecution is possible, and, if so, implement a defense strategy that addresses that possibility.

First Amendment Considerations

Over the years, FDA has promulgated regulations that prohibit nearly all manufacturer speech – including truthful and non-misleading scientific or medical speech – regarding the off-label use of prescription drug products. This prohibition on truthful, non-misleading speech, coupled with FDA's stated intent to hold corporate representatives accountable for off-label promotion through, among other things, criminal prosecutions, raises a number of First Amendment issues.

The FDCA provides the statutory framework under which FDA regulates prescription drug products. While the FDCA does not directly address the use of off-label communications, the FDA, in interpreting a series of the FDCA's

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statutory provisions, has prohibited off-label communications, including truthful scientific communications. For example, the FDCA bars pharmaceutical manufacturers from introducing a "new drug" into interstate commerce without first securing FDA approval of the product and its labeling. 21 U.S.C. 331(d), 355(a). Once approved, that new drug's labeling may not later suggest it be used for a condition not first approved by FDA. 21 U.S.C. 321, 355. FDA, however, has expanded the definition of "labeling" to include almost all communications companies use to promote their products such as brochures, booklets, mailing pieces, detailing pieces, letters and more. *See* 21 C.F.R. 201.1(l)(2). As a result, an approved drug promoted through one of these methods for a use not included in the approved labeling, an off-label use, is considered a "new drug," the distribution of which is unlawful without first obtaining FDA approval of the product or labeling.

The FDCA also prohibits manufacturers from introducing "misbranded" products into interstate commerce. 21 U.S.C. 331(a), 333(a), 352. A drug is considered "misbranded" when its label is false or misleading or fails to include adequate directions for use. 21 U.S.C. § 352(a), (f). If, however, a drug is promoted for an "intended use" not approved by FDA, and therefore, not identified on the product label, FDA deems that product misbranded because the manufacturer is unable to provide adequate directions for that use. Despite the lack of specific provisions restricting off-label promotion of prescription drug products, FDA has interpreted its provisions as containing such a restriction. Absent from FDA's interpretation, however, is any distinction between truthful, non-misleading speech, and inaccurate or misleading speech.

There has always been tension between FDA's position on the truthful off-label promotion of prescription drug products and the First Amendment's prohibition of restrictions to free speech. The First Amendment provides that "Congress shall make no law…abridging the freedom of speech." U.S. CONST. amend. I. FDA regulations, however, restrict a pharmaceutical company's communications regarding the off-label use of a product, including fully supported, well established truthful statements pertaining to the risks and benefits of a product. The question arises, therefore, whether FDA's prohibition of the dissemination of truthful information related to an off-label use violates pharmaceutical companies' First Amendment rights.

Few cases have sought to challenge FDA's proscription of truthful off-label promotion of prescription drug products. In a series of cases, the Washington Legal Foundation (WLF) sought to challenge FDA's ability to control the dissemination of truthful, non-misleading scientific and medical information in the form of peer-reviewed journal articles, and sponsorship of continuing medical education programs. *See WLF v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998); *WLF v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). The policies at issue were expressed through the use of guidance documents. The WLF was initially successful; the District Court for the District of Columbia, applying the Supreme Court's test for commercial free speech articulated in *Central Hudson v. Public Service Commission of New York*, determined that the guidance documents violated the First Amendment because they were more extensive than necessary to serve the asserted governmental interest, and that they unduly burdened important speech. *WLF v. Frieidman*, 13 F. Supp. 2d at 74. On appeal, however, FDA clarified its position by asserting that the guidance documents did not provide FDA with independent authority to regulate manufacturer speech. Specifically, it stated that guidance documents did not "grant the FDA authority to prosecute those who transgress the restrictions" but instead created "a 'safe harbor' for manufacturers who follow" the provisions of the guidance. *WLF v. Henney*, 128 F. Supp. 3d at 13. As a result, the WLF's challenge to the guidance documents was rendered moot because FDA no longer claimed it had the authority to restrict this type of speech.

In October 2009, Allergan, Inc., filed a preemptive First Amendment suit requesting that the District Court for the District of Columbia invalidate as unconstitutional certain FDA regulations prohibiting truthful distribution of accurate off-label scientific information. Allergan's lawsuit sought to definitively determine whether a pharmaceutical company could share truthful scientific and medical information with the medical community to assist physicians in evaluating the risks and benefits of off-label use. Before Allergen could resolve its First Amendment lawsuit, however, it accepted a settlement with the Department of Justice (DOJ) regarding the DOJ's investigation into Allergan's sales and marketing practices – and as part

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of the settlement – Allergan dismissed its First Amendment lawsuit.

FDA's prohibition on the truthful promotion of off-label uses still raises a number of important First Amendment issues that pharmaceutical companies must consider. Those issues become even more significant when considering the FDA's ability to seek criminal prosecution of those violating the FDCA through off-label promotion, including corporate officials. A manufacturer must evaluate whether it is more important to provide truthful, non-misleading information to medical professionals to assist them in making appropriate prescribing decisions, or withhold such information to avoid possible investigations or criminal prosecution by FDA. Should a pharmaceutical company find itself the subject of an FDA regulatory or enforcement action, that company should carefully evaluate whether FDA's action violates its First Amendment rights, and then determine whether to challenge that action. Ultimately, until a pharmaceutical company challenges FDA's prohibition on truthful, non-misleading off-label communications, members of the pharmaceutical industry must continue to balance the opposing considerations of providing important medical and scientific information to qualified medical professionals versus the risks of being subjected to FDA action that could then spur private civil or shareholder litigation.

Privilege Considerations

The attorney-client privilege is designed to encourage full disclosure without fear that the information will be revealed to others. In that respect, the privilege ensures that clients receive the best and most competent legal advice and representation. The attorney-client privilege can, however, be intentionally or even unintentionally waived by either the client or the attorney. Often times, corporations voluntarily produce documents during a government investigation that would otherwise be protected by the attorney-client privilege. The implications of a waiver of the attorney-client privilege during FDA regulatory/enforcement actions, or governmental investigations by the DOJ or Securities and Exchange Commission (SEC) is an issue that warrants consideration.

Drug and medical device companies now frequently face the decision of whether to waive a claim of privilege and turn over documents otherwise protected by the attorney-client privilege during a governmental investigation to keep the company in good stead with the government – or fight the process with the fear that this conduct may only delay or harm the company in the investigation. Given the increase in regulatory investigations/enforcement actions and civil litigations, it is important for companies to evaluate the waiver of privilege, and its potential impact in any parallel or subsequent investigation or litigation. Some jurisdictions have determined that once a claim of privilege has been waived, a party loses the right to thereafter assert that a communication is protected, *see In re Quest Communications International, Inc.*, 450 F3d 1179, (10th Cir. 2006) (noting that a number of circuits have rejected the selective waiver doctrine), whereas others have determined that disclosing privileged documents in a separate and non-public investigation constitutes only a limited waiver of the privilege. *Diversified Industries, Inc. v. Meredith*, 572 F.2d 596 (8th Cir. 1978).

Prior to producing privileged documents during a government investigation (FDA, DOJ or SEC), companies and their counsel should discuss the potential implications of producing those documents – and the inherent risks associated with the production should additional or parallel actions be initiated. If the potential for additional litigation or regulatory action exists, companies must carefully weigh the perceived benefit of voluntarily producing those privileged documents in the setting of a government investigation versus the risk of those documents being used during any concurrent or future litigation. If the privilege has been waived in the context of a government investigation, counsel for the drug or medical device company must look to develop strategies to either protect the privilege in related civil or shareholder actions, despite the limited waiver, or limit the scope of discovery and/or use of these documents in any concurrent or subsequent action.

Evidentiary Considerations

The admissibility of FDA advisory or enforcement actions – and any remedial measures taken as a result of those actions – is frequently litigated in civil matters involving drug and medical device companies. Each time FDA acts, it creates a potential evidentiary issue for current or future civil actions. Given FDA's recent pronouncements – and the already evident increase in advisory and enforcement actions – it is important

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for drug and medical device companies to be aware that an FDA action, as well as any communications regarding that action, may ultimately become the focus of civil litigation.

When evaluating the admissibility of FDA advisory or enforcement actions, companies must consider the applicable rules of evidence, the relevant case law, the nature of the FDA action and the specific issues presented in the legal proceeding before conceding the admissibility of any FDA document or finding. By way of example, one of FDA's primary regulatory tools is the use of warning letters. Warning letters are FDA's "principal means of achieving prompt voluntary compliance" with the FDCA. *Regulatory Procedures Manual March 2010*, Chapter 4. They are informal and advisory, and communicate FDA's position on a matter. *Id.* Often times, these letters focus on promotional materials for a particular product, or adverse event reporting for that product. Plaintiffs frequently attempt to use this type of action as support for claimed wrongdoing or liability, and seek to admit these letters, and any related information about these actions, into evidence during trial. In many instances, however, this information will not be admissible. Companies and counsel should first consider the specific issues raised in the litigation and the purpose for which this information is being offered. If the information sought to be admitted is either irrelevant under FRE 401, or its probative value is substantially outweighed by the risk of prejudice, confusion of issues, or has the potential to mislead the jury under FRE 403, then the information should not be admitted at trial. Companies and counsel should also consider whether the letters may be excluded as inadmissible hearsay under FRE 801. In addition, they should also consider the relevant laws of the states within which they are litigating – such as whether the jurisdiction follows the learned intermediary doctrine – to assist in developing their defense strategy.

As another example, parties also frequently seek to introduce evidence of subsequent remedial measures such as labeling changes, the addition of a black box warning or a product recall during trial. Depending on the specific factual circumstances of a case, however, evidence of this type of action may not be admissible. Under FRE 407, evidence of subsequent remedial measure is generally "not admissible to prove negligence, culpable conduct, a defect in a product, or a defect in a product's design, or a need for a warning." Moreover, as noted above, under FRE 403, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence. Both of these Rules of Evidence have been used as a basis for excluding evidence of subsequent labeling changes in pharmaceutical product liability litigation. *See Werner v. Upjohn Co., Inc.*, 628 F.2d 848 (4th Cir. 1980) (holding that the district court erred in admitting a subsequent warning into evidence); *Giles v. Wyeth, Inc.*, 556 F.3d 596 (7th Cir. 2009) (affirming district courts determination to exclude evidence of a subsequent warnings and black box warning pursuant to FRE 403).

Pharmaceutical companies should also take into consideration their constitutionally protected rights when determining the extent to which certain FDA actions may be admissible. The case of the *State of West Virginia, et al v. Johnson & Johnson, et al.*, best exemplifies this consideration. In the West Virginia case, defendants received warning letters from DDMAC alleging that certain statements in two promotional pieces were "false or misleading." Thereafter, West Virginia filed a Consumer Credit Protection Act (CCPA) lawsuit against defendants using the language contained in the warning letters as support for the suit. At the close of discovery, the state filed a motion for partial summary judgment asserting that, as a matter of law, the promotional pieces should be deemed "false and misleading" in violation of the CCPA. The trial judge agreed determining that the DDMAC letters constituted an official FDA finding that the statements were false or misleading, and that it would "give deference to the FDA's findings and actions." Defendants appealed this decision alleging, among other things, that the trial court violated its due process and First Amendment rights. Fortunately, in November of 2010, the Supreme Court of Appeals in West Virginia reversed, holding that "the FDA's *belief*, as expressed in the warning letters and subsequent corrective letters, that [the defendants] violated the FDCA" was not sufficient to establish, as a matter of law, that the communications were actually false and misleading in violation of the CCPA and the matter was remanded to the trial court for further proceedings consistent with this finding.

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As described above, the admissibility of FDA advisory or enforcement actions is an important consideration for pharmaceutical companies. Drug and medical device companies should therefore initially evaluate whether an FDA action could become the subject of future litigation (civil or criminal) and, if so, implement a coordinated response that takes this possibility into account. Once litigation commences, companies and their counsel must then determine what role these actions may play in the litigation and develop a strategy to either exclude or limit the use of this information during discovery or at trial. To what extent evidence of an advisory or enforcement action by FDA will be admissible, however, ultimately will depend on the specific circumstances presented.

Conclusion

While these are just a few examples of the issues created by FDA's increased emphasis on regulatory enforcement action, they depict the often times serious subjects a company must consider when confronted with the possibility of defending parallel actions in multiple forums. Unfortunately, there is no way to predict where and when these issues will arise – or how an unknown court may ultimately address them. But one thing is certain: drug and medical device companies must be aware that these issues exist and develop a game plan, in advance, for addressing them in a thoughtful and effective manner.

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