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The Federal Prosecutor As Regulator

Good Manufacturing Practices and The False Claims Act

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The Department of Justice (DOJ) proclaimed 2012 as yet another health care fraud record-breaker. Of $4.9 billion in total False Claims Act (FCA) recoveries, over $3 billion was recovered in health care fraud actions. DOJ also opened 885 new civil, and over 1,100 new criminal, health care fraud investigations, and convicted 826 defendants of health care fraud-related crimes.

In the heavily regulated health care sector, the line between human error and a knowing "false claim" can be indistinct, aided and abetted by prosecutors' reliance on the FCA-defined concepts of "reckless disregard" and "deliberate ignorance" as proxies for proof of actual knowledge. See 31 U.S.C. § 3729(b)(1). Nowhere is this line more blurry than in the area of current Good Manufacturing Practices (cGMP) for pharmaceutical and medical device manufacturers.

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Background: cGMPs for Pharma and Med Device Manufacturers

Acting to ensure supply chain integrity for prescription and over-the-counter (OTC) drugs, and for medical devices is a well-understood and desirable goal. To help accomplish this, the FDA established cGMP regulations. These regulations are meant to set minimum standards for the facilities and the controls to be used for the design, manufacture, processing, packaging, storage and testing of drugs and devices, all in order to ensure efficacy and, of course, patient safety. 21 C.F.R. § 211 et seq. (drugs); 21 C.F.R. § 820 et seq. (devices).v

Failure to comply with a cGMP regulation "shall render such drug [or device] to be adulterated" and persons who are responsible for the failure to comply "shall be subject to regulatory action." 21 C.F.R. §§ 210.1(b), 820.1(c); 21 U.S.C. §§ 351(a)(1)(B), (a)(2)(B) (emphasis added). Of course, distributing an adulterated drug or device is also a prohibited act subject to criminal prosecution. 21 U.S.C. §§ 331(a)(1) (strict liability misdemeanor), 331(b) (felony requiring intent to defraud or a prior conviction).

But over and above FDA "regulatory action" and short of a DOJ criminal prosecution, the DOJ has taken the position that violations of cGMP — which render products "adulterated" — can create civil FCA exposure to treble damages and per-claim penalties of up to $11,000. The government's legal theory is that, in violating cGMP, the manufacturer knowingly causes false claims to be submitted to, or causes purchases of adulterated product by, federal health care programs. This theory was last on display in the DOJ's 2010 settlement with GlaxoSmithKline (GSK), although other cGMP investigations are said to be underway.

The GSK Matter

The GSK matter started as a qui tam action by a former GSK quality assurance manager whose complaints regarding operations at a particular plant allegedly were ignored, and who later was fired. The settlement included a $150 million criminal fine; a $600 million civil FCA and state settlement and a Corporate Integrity Agreement (CIA). The whistleblower got $96 million. See United States ex rel. Eckard v. SmithKline Beecham, CA No. 04-10375 (third amended complaint) (D.Ma. filed Oct. 17, 2008); United States v. SB Pharmco Puerto Rico, Inc., Crim. No. 1:10-CR-10355 (D.Ma. filed Oct. 26, 2010) (criminal information); Settlement Agreement executed Oct. 26, 2010 available at http://tinyurl.com/bwm5nrn; Corporate Integrity Agreement executed June 28, 2012 available at http://goo.gl/0vu0E.

Troubling Issues with the Application of the FCA to cGMP Cases

This may seem straightforward, but there are two potential problems with the government's approach in this area. First, there is a well-established FDA regulatory regime to catch, cor-

rect and, if necessary, sanction cGMP deficiencies. It includes periodic FDA audit-like inspections of manufacturing facilities, FDA reports of observed deficiencies on "FDA Form 483" and the manufacturer's written responses to those observations, including promised corrective action and preventive action plans (CAPAs). If the FDA is dissatisfied with a manufacturer's response, or if the FDA inspectors find conditions that deviate sufficiently from cGMP, the agency may issue a "Warning Letter." Indeed, in August 2009, FDA Commissioner Margaret Hamburg said that the FDA would significantly increase its cGMP enforcement activity; it has. In 2010-11, the number of FDA warning letters increased 156% — up to 1,720 letters.

Moreover, if the manufacturer ignores the Warning Letter, that failure to act may lead to more aggressive FDA enforcement action, including injunctions, product seizures, plant shut downs, consent decrees and/or monetary remedies in the form of restitution, disgorgement or liquidated damages. See, e.g., United States v. Ranbaxy Laboratories, Ltd., CA No. 1:12-cv-00250 (D.Md. filed Jan. 25, 2012) (Consent Decree for Permanent Injunction re cGMP and data integrity violations). Finally, and importantly, per the FDA:

[A cGMP violation] does not mean that there is necessarily something wrong with the drug … . The impact of cGMP violations depends on the nature of those violations and on the specific drugs involved. A drug manufactured in violation of cGMP may still meet its labeled specifications, and the risk that the drug is unsafe or ineffective could be minimal.

See http://goo.gl/3UWk3. The point is that the FDA has long engaged manufacturers in this interactive quality verification process, with a continuum of sanctions available, all of which are geared to the particular manufacturer, process and product. The need for federal prosecutors to become quasi-regulators enforcing cGMP under the rubric of the FCA is highly questionable.

Second, and perhaps more troubling, the cGMPs themselves are purposefully written in broad and largely undefined terms in order to allow manufacturers that are of different sizes, creating different products and employing different processes each to decide how to best implement and update the necessary controls. For example, consider drug manufacturer cGMPs. Micro-organism control must have "appropriate written procedures" and "appropriate testing"; sampling and lab controls must be "based on rational criteria" with "appropriate specifications and procedures"; equipment must be of "appropriate design"; storage must be in a "manner designed to prevent contamination"; etc. 21 C.F.R. §§ 211.113, 211.165(b), 210.3(21), 211.160(b), 211.63, 211.80(b) (emphasis added). See United States v. Utah Medical Products, Inc., 404 F.Supp. 2d 1315 (D.Utah 2005) (cGMP regulations "have the virtue of generality and the vice of imprecision").

But the question becomes, what exactly do these cGMPs require in a given manufacturer and product-specific instance? When exactly is a cGMP regulation violated, and how serious must a cGMP violation be in order to trigger FDA regulatory actions like the issuance of a Warning Letter?

These questions lack bright-line answers. Yet they must be answered before the FDA even acts administratively. All the more caution is warranted before the further step is taken of predicating an FCA action on an alleged cGMP violation. In other words, there can be real fairness and fair notice issues implicated by invoking the FCA to enforce broad cGMP regulations. The measured exercise of prosecutorial discretion is of paramount importance. Absent evidence of gross dereliction in the quality area that results in a product entering the stream of commerce that is both adulterated *and worthless*, resulting in serious risk to the public, targeting alleged cGMP violations for FCA recovery arguably is bad public policy, and unfair.

The New 'New' Thing?

Hopefully, there is ongoing debate within the DOJ and FDA about the legal and policy implications of quasi-criminalizing, under the FCA, alleged violations of broad and loosely defined cGMP regulations. Perhaps the GSK case should be viewed as an outlier triggered by a combination of alleged "plus factors" in that matter: prescription, as opposed to OTC, drugs were at issue; vulnerable cancer, pediatric and psychiatric patient populations were exposed; adulterated end-product apparently went out the door; serious health risks were possible; prior FDA warning letters had been issued; and there were allegations of deceit.

However, recall that the application of the "responsible corporate officer doctrine" (RCOD) in the Purdue Pharma case was once seen by some as an outlier due to the egregious abuse of and overdose deaths associated with Oxycontin. Yet the threshold for that doctrine's application evidently has lowered over time, as demonstrated by subsequent RCOD prosecutions brought by other U.S. Attorneys' Offices.

Recommendations Going Forward

Outlier or not, potentially heightened cGMP exposures under the FCA should drive manufacturers' attitudes and resource allocations concerning quality systems and personnel. Quality must have a "seat at the table" of management. A robust internal audit system to "preview" FDA inspections should be considered. CAPAs not only must be implemented but tracked to completion. Of course, FDA Form 483 observations should be taken seriously by management, and corporate officers should strive to foster a culture that does not accept such observations as a "cost of doing business." Finally, FDA Warning Letters should be treated as anything but routine communications, given the lurking threat of an FCA action, initiated either by a whistleblower or by a direct referral from FDA to DOJ.