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White Collar and Government Enforcement Practice

White Collar Watch

The Newsletter of the White Collar and Government Enforcement Practice

Contents

Companies that Source Pharmaceutical and Food Ingredients in the People's Republic of China Should Take Heed of the Government's Response to Recent Chromium Contamination

By Christopher R. Hall and Andrea P. Brockway

China's State Food and Drug Administration (SFDA) detained 45 people and seized more than 77 million gelatin drug capsules tainted with chromium in April 2012. The SFDA found that 254 pharmaceutical companies, or 12.7 percent of the drug capsule producers in China, had made products with unsafe levels of this toxic heavy metal. In extreme cases, tainted capsules contained 90 times the national standard for chromium. The SFDA found that certain manufacturers knowingly obtained non-pharmaceutical grade gelatin from a number of uncontrolled sources, including leather manufacturers (leather manufacturers can produce industrial-grade gelatin from scrap leather). Working in tandem with the SFDA, China's Ministry of Public Security shut down 80 illegal production lines in the Zhejiang, Hebei and Jiangxi provinces. While there have been no immediate reports of deaths or illness caused by the tainted gel capsules, long-term chromium exposure has been linked to organ damage and the development of cancer and chronic illnesses.[1]

In a recent quarterly disclosure to the Securities and Exchange Commission, Biostar Pharmaceuticals, Inc., detailed the effect of the chromium investigation on drug companies operating in China. Biostar reported that the SFDA suspended the sale and distribution of thirteen drugs from nine pharmaceutical companies that used contaminated capsules. In addition to suspending drug sale, the SFDA also revoked production

1 Miranda Shek, SFDA Plans to Blacklist Drugmakers, Global Times, June 1, 2012.

licenses of two gel capsule manufacturers. In an official statement, the SFDA reported that it had ordered the Zhejiang provincial drug authority to revoke the licenses of plants in Huaxing and Zhuokang for "grave violations of laws and regulations," without specifying their wrongdoings. The SFDA stated that it would pursue criminal charges and harsh punishments where appropriate.

The SFDA is pursuing remedial measures. The SFDA promulgated regulations that require pharmaceutical companies to self-inspect and self-screen to ensure that moving forward they do not accept toxic products into their inventory. Biostar's disclosure cites a government mandate titled the "Notification of Strengthening Quality Control on Capsule Drug and Related Products and Announcement of Strict Implementation of Inspection of Every Batch of Official Gelatin Capsule and Capsule Drug." Pursuant to the mandate, all companies purchasing capsules must maintain quality inspection certificates from the manufacturing facilities. The capsules must also have passed quality inspections by the SFDA. In addition to the self-screening measures listed above, the SFDA dispatched an investigation group for onsite inspection and investigation of pharmacies and plants.[2]

The SFDA has also taken a page out of the US HHS-OIG exclusion manual and its List of Excluded Individuals and Entities (LEIE). In June 2012, the SFDA proposed to "blacklist" executives who oversee pharmaceutical companies found to produce substandard or counterfeit drugs. If approved, eight categories of individuals and companies would be subject to blacklisting, including those who produce or sell counterfeit drugs, produce medical instruments without a business license, and cause injuries with unlicensed products.

According to a draft of the blacklist proposal released by the agency, the list of offending executives would be made public and would detail their respective companies' violations. The proposed regulations would also exclude "serious" offenders from engaging in drug or medical device production or other related business activities for 10 years. The SFDA would also inspect blacklisted companies and their products more frequently. It will also require violators to file periodic reports on quality control changes and other manufacturing improvements, not unlike the Corporate Integrity Agreement process in the United States.[3]

The SFDA's response to the chromium contamination scandal is part of a larger effort by the Chinese government to modernize and increase the safety of its pharmaceutical and medical device industries. In December 2011, the Chinese government unveiled its 2011-2015 National Drug Safety Plan. The Plan requires the revision of laws and regulations governing the distribution of medicines, including a "severe crackdown" on counterfeit and other illegal medicines. The Plan seeks to achieve 100 percent adherence to China's new Good Manufacturing Practices (GMP) rules by 2015. The Plan also calls for strengthening the SFDA's enforcement powers. At the same time that the Plan was released, China's State Council identified an objective of more frequent and broader SFDA inspections of manufacturing and clinical facilities, especially in rural areas.[4]

These reforms in China have broad implications for U.S. companies conducting business there. Manufacturers who source food and drug supplies in China for production plants there must prepare for SFDA investigations. Best practices require these companies to adopt self-regulation procedures, such as inventory acceptance testing, third-party calibration of testing equipment, self-inspections and quality audits, rehearsals for SFDA inspections, and education within the quality function of the SFDA's expectations.

The SFDA's response to the chromium contamination scandal continues. The Saul Ewing White Collar and Government Enforcement practice group will keep you up-to-date on this story as it develops and will advise you on how it might affect your business.

2 Biostar Pharmaceuticals, Inc., Quarterly Report (Form 10-Q), at 16 (May 15, 2012).

3 *SFDA Proposes 'Blacklist' to Shame Drugmakers into Higher Standards*, Pharm. Corp. Compliance Rep., June 8, 2012, at 2012 WLNR 11973655.

4 Phil Taylor, *China unveils five-year drug safety plan,* Securing Pharma, December 7, 2011.

D.C. Circuit Affirms Exclusion from Federal Health Care Programs Under "Responsible Corporate Officer" Doctrine — with a Twist

By Christopher R. Hall and Gregory G. Schwab

On July 27, 2012, in the closely watched case of *Michael Friedman, et al. v. Kathleen Sebelius, et al.,* the United States Court of Appeals for the D.C. Circuit held that pharmaceutical corporate executives found guilty of misdemeanor "misbranding" under the "responsible corporate officer doctrine" ("RCO doctrine") had committed a "misdemeanor relating to fraud"—the standard for exclusion from federal health care programs pursuant to 42 U.S.C. § 1320a-7(b)(1).

We have written previously about this appeal by three Purdue executives. Please see http://www.saul.com/media/site_files/2623_White%20Collar%20101711_article1_v2.pdf and http://www.saul.com/media/site_files/3193_White%20Collar%20Fourth%20Article%20071911.pdf for more background. The executives had been excluded from Federal health care programs for 12 years. They had argued during their administrative and court appeals during the past several years that misdemeanor misbranding did not "relate to fraud" because they had been convicted under the RCO doctrine—a strict liability offense that does not require proof of intent. The Court rejected this argument, finding instead that 42 U.S.C. § 1320a-7(b)(1) "authorizes the [HHS-OIG] to exclude from participation in Federal health care programs an individual convicted of a misdemeanor if the conduct underlying that conviction is *factually related* to fraud" (emphasis added). This ruling, however, did not represent a complete victory for the government. The Court remanded the case to the HHS Departmental Appeals Board (DAB) for additional factual findings which may render the government's victory pyrrhic.

The D.C. Circuit's Analysis

The Appeals Court concluded that HHS may appropriately examine the circumstances underlying the RCO misdemeanor conviction to determine if it was "related to" fraud:

> [T]he text, structure, and purpose of the statute, viz. to protect Federal health care programs from financial harm wrought by untrustworthy providers, all indicate the Secretary's circumstance approach is proper; i.e., the statute authorizes exclusion of an individual whose conviction was for conduct factually related to fraud.

The Court went on to construe the meaning of "related to" expansively to encompass an executive's misdemeanor offense factually connected with a fraud committed by others employed by the corporation. The Court reasoned that the phrase was extremely broad and "[r]ather than referring only to generic misdemeanor offenses that share all the 'core elements' of fraud, the capacious phrase includes any criminal conduct that has a factual 'connection with' fraud." In light of the Court's broad construction of this language and its analysis of other aspects of the statute, the Court concluded that:

> Their convictions for misdemeanor misbranding were predicated upon the company they led having pleaded guilty to fraudulently misbranding a drug and they admitted having 'responsibility and authority either to prevent in the first instance or to promptly correct' that fraud; they did neither. Accordingly, section 1320a-7(b)(1)(A) authorized the Secretary to exclude them for a time from participation in Federal health care programs.

With respect to the length of the exclusion, however, the Court agreed with the executives that the 12-year exclusion was not adequately supported in the record, and was therefore "arbitrary and capricious." Specifically, HHS had not adequately explained why the Secretary had excluded these executives for as long as 12 years, while previous executives excluded on the basis of a misdemeanor had all received shorter exclusion periods. The D.C. Circuit ordered the district court to remand the issue to HHS for further fact finding consistent with its opinion.

A Victory for the Government, but with a Potentially Fatal Twist

The D.C. Circuit did not hand the government an absolute victory. On remand, HHS must explain the reasons supporting the length of the exclusion, which the executives argued was unprecedented. While HHS cited a number of cases where individuals had been excluded for more than 10 years, the Court pointed out that each of those cases involved a felony conviction or a conviction for Medicare fraud, with incarceration, mandatory exclusion, and a presumptive baseline exclusion of five years (unlike the misdemeanor conviction, with discretionary exclusion and presumptive baseline of three years for the three executives). The Court also noted that HHS had not excluded anyone for more than ten years under the particular section of the exclusion statute – section 1320a-7(b) – *ever*. The longest period of exclusion under that section was four years. HHS never acknowledged or explained the departure from precedent in ordering the Purdue executives' to a 12-year exclusion. This, the D.C. Circuit held, rendered HHS's decision arbitrary and capricious. "We do not suggest the [executives'] exclusion for 12 years based upon a conviction for misdemeanor misbranding might not be justifiable; we express no opinion on that question. Our concern here is that [HHS] did not justify it in the decision under review." On remand, HHS surely will marshal facts that justify some increase over the three-year presumptive period, but we will have to wait and see. The D.C. Circuit distinguished the Secretary's prior upward adjustments with care; HHS will have to explain how a 12-year exclusion period (or any lesser period it selects in the wake of this opinion) fits into the existing rubric of exclusion rulings.

Going Forward

The D.C. Circuit's decision makes clear that the HHS-OIG can exclude pharmaceutical, medical device, and other health care executives who fail to prevent the fraudulent misbranding or adulteration of their products even if they did not personally commit or condone the conduct.

The decision carries great importance because DOJ, together with the Food and Drug Administration ("FDA") and the OIG, recently increased prosecutions under the RCO doctrine. In light of the *Friedman* decision, this trend likely will continue and increase. Some of the more vocal members of Congress believe that prosecuting corporations alone does not sufficiently deter corporate crime and regulatory noncompliance. They have called for regulators and prosecutors to pursue senior executives more aggressively for corporate wrongdoing and to hold them personally liable. Perhaps now more than ever, pharmaceutical, medical device and other health care industry executives must take seriously their responsibility to ensure regulatory compliance and to respond immediately to information suggesting non-compliance.

Congress Considering Significant Increase in SEC Penalties

By Gregory G. Schwab

Last month Sens. Jack Reed (D-R.I.) and Charles Grassley (R-Iowa) introduced a bipartisan bill that would significantly enhance the penalties that the Securities and Exchange Commission can seek.

Among other measures, the Stronger Enforcement of Civil Penalties Act of 2012 would increase the cap for the most serious securities law violations to $1 million per violation for individuals and $10 million for companies. (The current cap is $150,000 per violation for individuals and $725,000 for entities.)

The bill also would allow the SEC to triple the monetary fines sought in both administrative and civil actions in certain cases where the penalties are tied to the defendant's illegal profits. Currently, the law allows the SEC to calculate penalties equal

to a defendant's "gross amount of pecuniary gain" only in federal court actions.

The bill would give the SEC new authority to impose sanctions equal to investor losses in cases involving "fraud, deceit, manipulation, or deliberate or reckless disregard of a regulatory requirement" where the loss or risk of loss is significant. Finally, the bill would increase the stakes for repeat offenders.

SEC Chair Mary Schapiro sought the enhanced enforcement powers in a letter to Sen. Reed, Chairman of the Subcommittee on Securities, Insurance, and Investment. Schapiro's November 28, 2011 letter was sent the same day that Judge Jed S. Rakoff of the U.S. District Court for the Southern District of New York rejected a proposed $285 million deal between the SEC and Citigroup Global Markets Inc. to settle alleged misrepresentations involving a collateralized debt obligation. Among other problems, Rakoff faulted the SEC for proposing only a $95 million fine for the firm, whereas it had imposed a $535 million penalty against Goldman Sachs & Co. in a similar case.

SEC Enforcement Director Robert Khuzami, responding to Judge Rakoff's decision, noted that "securities law generally limits the disgorgement amount the SEC can recover to Citigroup's ill-gotten gains, plus a penalty in an amount up to a defendant's gain."

With bipartisan support, it is likely that the bill will be enacted into law.

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