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PCA: Product Recall Dos And Don'ts

Law360, New York (February 27, 2009) -- On Jan. 30, 2009, the U.S. Food and Drug Administration announced that its criminal division and the U.S. Department of Justice were pursuing a criminal investigation of Peanut Corporation of America (PCA). This investigation comes on the heels of one of the largest food poisoning outbreaks in recent history.

According to U.S. Center for Disease Control statistics, 654 people across 44 states have been infected with Salmonella Typhimurium from ingesting peanut-based products originating from PCA's Blakely, Ga., facility.

An amended report of an FDA inspection of the Georgia facility noted 12 occasions between June 2007 and September 2008 where the company's own testing revealed that its products were contaminated by salmonella, but PCA shipped the products nonetheless.

Based upon statements allegedly made by PCA's management, the FDA initially reported that the company had re-tested products after it had obtained positive results for salmonella and had only shipped the goods after subsequent tests came back negative.

This information, however, was apparently belied by PCA's own internal documents. The FDA now reports that PCA distributed peanut butter, chopped peanuts and peanut meal that tested positive for salmonella even before it received negative findings from the follow-up tests.

Additionally, the FDA now says the company shipped products before it received the results of microbiological testing and then did not recall the products after such testing returned positive results.

Adding fuel to the fire, a recent Texas Department of State Health Services' (DSHS) inspection of PCA's Plainview, Texas, plant discovered dead rodents, rodent excrement and bird feathers in a crawl space above a production area.

The inspection also found that the plant's air handling system was not completely sealed and was pulling debris from the infested crawl space into production areas of the plant, resulting in the adulteration of

exposed food products. As a result, DSHS ordered PCA to recall all products ever shipped from its Plainview plant.

As egregious as PCA's conduct may appear, we must not rush to judgment. It is, after all, a fundamental tenet of our Constitution that we are all innocent until proven otherwise. All that exists right now are allegations based upon inspections conducted by the FDA and the DSHS. PCA has not admitted to any wrongdoing.

Given the nature of the allegations asserted against them, however, how likely is it that the company and its executives will be criminally prosecuted for their alleged conduct? Perhaps more important, what can other corporations and executives do to protect themselves from the specter of criminal prosecution?

The answer to these questions begins with a review of (1) the statute governmental authorities most often rely upon when pursuing criminal prosecutions arising from the introduction of allegedly adulterated products into the stream of commerce, (2) the government's history of enforcement and (3) a sampling of recent criminal prosecutions the government has pursued.

Federal Food, Drug and Cosmetic Act Overview

The Federal Food, Drug and Cosmetic Act (FDCA) under 21 U.S.C. §331(a) prohibits "the introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded."

In addition, 21 U.S.C. §331(c) prohibits "the receipt in interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise."

Significantly, the FDCA is a strict liability statute. This means that merely engaging in prohibited conduct is sufficient to constitute a violation — one's mental state is immaterial. The punishment for violation of §331 is imprisonment for not more than one year, a fine of not more than $1,000, or both.[1]

The statute does, however, provide enhanced penalties for violations committed "with the intent to defraud or mislead," or for repeat violations.[2]

The FDA enjoys substantial discretion in recommending whether and against whom criminal charges should be brought. Typically, however, charges are recommended against the highest level corporate executive and other employees who may have participated in the alleged criminal activity.

In June 2003, the FDA announced its objective to implement an "aggressive enforcement strategy" for

violations of the FDCA, particularly in areas related to the most serious threats to public health.

It appears that the FDA has accomplished its objective. While the number of product recalls actually decreased between 2003 and 2006, prosecutions instituted by the Office of Criminal Investigations (OCI), the investigative arm of the FDA, rose from 206 to 279.

Notwithstanding this increase, a review of recent OCI-instituted prosecutions reveals that the FDA reserves prosecution for high profile cases causing large-scale injury, or for those involving egregious conduct or violations accompanied by some form of intent.

History of Enforcement

One of the most recent OCI-initiated indictments is of three businesses and their executives in connection with the sale of wheat gluten allegedly adulterated with melamine that was at the epicenter of the highly publicized pet food recalls in March and April 2007.

Notably, the FDA has never publicly asserted that ChemNutra, the company that imported the wheat gluten, or its owners, Sallie and Stephen Miller, knew or tried to conceal the fact that the wheat gluten was adulterated or that they caused the product to become contaminated in any way.

Rather, the FDA merely contends that they knew the wheat gluten was mislabeled in order to avoid mandatory inspection upon leaving China.

Nonetheless, the Office of the U.S. Attorney for the Western District of Missouri obtained a 26-count indictment of ChemNutra and its owners. Each of the counts alleged against ChemNutra and its owners is punishable by imprisonment up to one year and/or a fine of not more than $1,000.

Compared to the alleged conduct of ChemNutra, the actions of PCA, as purported by the FDA, in shipping products it knew to be contaminated and in causing large-scale injury to humans, appear particularly egregious and fit squarely within the paradigm of those cases typically prosecuted by the government.

Indeed, PCA's alleged conduct is analogous to other OCI-instituted criminal prosecutions that resulted in convictions and, in some cases, enhanced penalties.

Examples of other convictions: Two men were sentenced in the Southern District of Indiana Federal Court to 77 months in prison after pleading guilty to introducing a misbranded drug into interstate commerce, resulting in the death of five youths; and, in 2005, an executive of a cold storage distribution company was convicted and sentenced to one year of federal incarceration for reboxing and relabeling ammonia-tainted food that was delivered to an Illinois elementary school, triggering the hospitalization of 43 students and

staff. The company was also required to pay hundreds of thousands of dollars in restitution.

Conduct in Question

The Justice Department's "Principles of Federal Prosecution of Business Organizations" also provides insight into the likelihood of criminal prosecution of PCA. These principles were written to provide guidance to prosecutors in determining whether to criminally charge a company.

According to these principles, four of the nine enumerated key factors for a prosecutor to consider are: (1) the nature and seriousness of the offense, including the risk of harm to the public; (2) the company's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation; (3) the pervasiveness of the wrongdoing within the company; and, (4) the existence and adequacy of the company's compliance program.

It is alleged that PCA's purported conduct may have led to the illness of hundreds of individuals and the death of nine.

Moreover, the alleged contradiction between the company's assertion that it shipped products testing positive for salmonella only after re-tests yielded negative results, and its internal records that show otherwise, does not evince a willingness to cooperate with investigators.

Stewart Parnell, PCA's president and owner, recently further demonstrated this refusal to cooperate by invoking his Fifth Amendment right against self incrimination when he appeared before a subcommittee of the House Committee on Oversight and Government Reform.

Finally, the alleged conditions observed at PCA's Plainview, Texas, facility may be viewed by some as a systemic disregard for public safety within the organization and the lack of any company-wide quality and sanitary compliance programs.

Minimizing Criminal Prosecution Risk

Based upon prior FDA-instituted prosecutions, the nature of PCA's alleged conduct and the extent of the harm allegedly caused by such conduct, the likelihood of PCA's criminal prosecution is rather high.

While it may be too late for PCA and its executives to change their fate, their experience offers valuable lessons to other companies in how to avoid criminal prosecution when confronted with violations or product recalls.

The obvious first step in preventing criminal prosecution is to avoid conduct that could lead to a violation or recall. There are times, however, when this is not possible.

Thus, when disaster strikes, it is important to take decisive action, including the retention of criminal defense counsel experienced in alleged FDCA violations and the immediate recall of all adulterated products if such products constitute a public health threat.

The recall process will proceed much more efficiently if an established crisis management plan is in place. Part of this plan should include regularly engaging in mock recalls.

Companies concerned that a recall may constitute an admission of wrongdoing should take solace in the fact that negative publicity surrounding a recall will almost always be eclipsed by the government and public perception that the company and its executives acted responsibly.

The company must also undertake a detailed and exhaustive investigation into the cause of the events leading to the recall or violation and implement an effective corporate compliance program, or improve upon an existing one, to ensure that these events never happen again.

The discipline or termination of wrongdoers within the company must also be considered, and the company must openly and fully cooperate with the relevant government agencies and promptly pay all civil penalties imposed.

Finally, the company must successfully demonstrate to relevant governmental authorities that the events leading to the recall or violation are not a reoccurring problem within the organization, are not condoned by management and are not part of an overall indifference to company policy and governmental regulations.

The whirlwind of events surrounding a violation or recall can rattle the most seasoned executives and most established business entities.

And while what has happened in the past can never be changed, acting swiftly to minimize harm to the public and openly working with governmental authorities are necessary elements to minimizing the potential for criminal prosecution.

--By Richard Fama, Cozen O'Connor

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[1] 21 U.S.C. §333(a)(1)

[2] 21 U.S.C. §333(a)(2)