

The ChemNutra Indictment: A Sign of Things to Come?

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In regulating our conduct, in everything from our daily lives to business activities, we assume that, unless accompanied by a culpable mental state, be it intentional, reckless or knowing, our actions should not be considered criminal. Based on this assumption, the shopper who leaves a store without paying for an item that was mistakenly left in the cart is not guilty of a crime. Likewise, the innocent purchaser of what is later determined to be stolen property should not be punished. Surprisingly, this is not always the case, at least with respect to the laws regulating the food industry. Under Federal Food, Drug and Cosmetic Act (FD&C) provisions, anyone who delivers or receives an adulterated or mislabeled food product across state lines, even unknowingly or unintentionally, is guilty of a crime.

On February 6, 2008, FDA announced the indictment of three business owners involved in producing, exporting and importing tainted Chinese wheat gluten thought to be at the root of the U.S. pet food recall in March and April 2007. The indictment, obtained by the Office of the U.S. Attorney for the Western District of Missouri, alleges violations of FD&C sections prohibiting "the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." Although the indictment claims that two owners of the American import company, ChemNutra, knew that the wheat gluten was incorrectly labeled to reflect that it had been subject to inspection upon leaving China, neither is charged with intentionally delivering the adulterated product, nor even with knowing that it was adulterated. Nevertheless, each count carries a punishment of up to a year in jail and a \$100,000 fine.

In an age when every week delivers news of a new recall or warning of a contaminated food product, is this indictment the harbinger of a new zero tolerance for FD&C violations? Will future recall notices be accompanied by announcements of criminal charges against corporations and individuals involved? Perhaps, most importantly, should the hapless individual whose company unwittingly and unknowingly ships a contaminated product fear jail, along with the civil fines, recall costs and lost profits that invariably accompany such incidents? Answers to these questions require taking a closer look at the FD&C, as well as FDA's role in its enforcement and the history of its application.

FD&C overview

The FD&C prohibits a wide range of conduct, including delivering a misbranded or adulterated product into interstate commerce (as charged in the ChemNutra indictment); misbranding or adulterating any regulated product; or receiving such a product in interstate commerce. The statute also prohibits "causing" any of these acts. As seen in the ChemNutra indictment, the FD&C is a strict liability statute. Simply engaging in forbidden conduct constitutes a criminal violation; one's mental state--intentional, reckless or knowing--is immaterial, although the statute provides enhanced penalties for violations committed "with the intent to defraud or mislead." (An individual acting with willful blindness, or consciously avoiding positive knowledge of the violation, will be deemed to have acted intentionally. The statute also authorizes enhanced penalties for repeat violations.)

Despite the wide scope of conduct prohibited by the FD&C and the strictness of its application, FDA has substantial discretion in recommending when and against whom criminal charges are to be brought. This discretion has been specifically recognized by the U.S. Supreme Court, which held that the FD&C is not a mandatory statute requiring FDA to seek prosecution for every alleged violation. Rather, FDA has complete discretion in deciding which alleged violations should be prosecuted. Instead of referring a suspected FD&C violation for investigation and prosecution, FDA has the option to apply a range of less serious remedies, including issuing a warning or untitled letter requesting voluntary correction of the violation or seeking civil sanctions, such as fines or product seizures.

When FDA does seek criminal prosecution of an FD&C violation, the matter is handled by that agency's investigative arm: the Office of Criminal Investigations (OCI). Established in 1991, OCI has primary responsibility for all FDA criminal investigations. It also has an active role in intelligence gathering, and serves as the primary point of contact for all intelligence issues relating to threats against FDA-regulated products, and as liaison between FDA and the law enforcement community for all criminal investigations pertaining to such threats. Operations are conducted by six field offices and six resident offices nationwide. According to the FDA website, OCI agents typically investigate approximately 1,000 criminal cases annually.

Aggressive enforcement

In June 2003, FDA announced an "aggressive enforcement strategy" for FD&C violations, striving for "dramatically increased enforcement, particularly in areas related to the most serious threats to public health." The largest increases in enforcement actions involved those related to criminal charges handled by the OCI. Between 1998 and 2002, annual OCI-recommended arrests increased from 250 to 286; annual convictions increased from 194 to 317.

This trend has continued since announcement of the aggressive enforcement strategy. FDA data indicates that between 2003 and 2006 (the last year for which statistics are available), convictions stemming from OCI investigations increased from 206 to 279. During this time, the number of FDA product recalls decreased from 4,627 to 4,266, while the number of FDA warning letters decreased from 582 to 528. These numbers suggests that, despite a decreasing number of potentially actionable FD&C violations, FDA chose to rely more often on criminal prosecutions than the other enforcement techniques available.

Despite these increases, a look at recent OCI-instituted prosecutions indicates FDA reserves criminal prosecutions for the most egregious or high-profile FD&C violations, including the most serious threats to public health; incidents with the potential to affect a large number of citizens; or violations accompanied by some evidence of culpable intent. For example, in 2006, FD&C prosecuted the supplier of a non-FDA approved flu vaccine during the 2004 flu vaccine shortage; Internet vendors of the drug DXM whose products lead to five purchasers' deaths; and an individual who tampered with infant formula by removing the product and filling the empty packages with common wheat flour.

The ChemNutra indictment fits this model of FD&C violations chosen for prosecution by FDA and OCI. Like those listed above, the violations leading to this indictment involved a highly-publicized and wide-ranging recall, as well as claims of widespread injury and death among affected pets. Moreover, although ChemNutra owners were not alleged to have intended or been aware of the purported adulteration of the wheat gluten, they both claimed to have been knowledgeable that the product had not been inspected upon export and to have not revealed this fact.

It is a simple reality that FDA and OCI do not have the resources to investigate for prosecution each one of the thousands of FD&C violations alleged each year, nor does the Department of Justice have the tools necessary to prosecute each one. Although the FD&C is broad in scope and strict in its application, FDA enjoys significant discretion in deciding which violations should be prosecuted. Examination of a handful of recent prosecutions suggests that FDA and OCI will concentrate their efforts where they are likely to have the most effect: high-profile violations leading to death or widespread injury, or involving particularly egregious conduct. By doing so, FDA and OCI can uphold the mantle of "aggressive enforcement" by sending a message of toughness and publicly demonstrating their commitment to prosecuting violations.

Although the indictment of ChemNutra and its owners may be surprising because it does not involve allegations of an intentional or knowing violation, it fits within the category of cases usually chosen by FDA for prosecution. While this situation should not be seen as a sign of an even more aggressive zero-tolerance policy, it is an important reminder of the high cost that can result from even unintentional violations of the FD&C.

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Web resources

[Federal Food, Drug & Cosmetic Act](#)

[FDA Indictment Announcement](#)

[Office of Criminal Investigations](#)

Other Resources

[Consumer Services, Product Recall, Retrieval, and Withdrawal](#)