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FDA Adverse Event Data Release May Mean More Lawsuits

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Law360, New York (January 18, 2017, 11:47 AM EST) -- The recent release of a large cache of historical data on reported adverse events, along with government plans to make raw data available on an ongoing basis, may have ripple effects on consumer class actions and other types of lawsuits filed against cosmetic, food and supplement manufacturers and retailers.

This article will describe the newly publicized adverse event database and speculate on the implications of the increased public transparency on product liability and consumer protection litigation.

What Facts Have Changed?

The Food and Drug Administration announced in December that it is publicly releasing data received by the FDA's Center for Food Safety and Applied Nutrition (CFSAN) about adverse events related to cosmetics and foods, including both conventional foods and dietary supplements.

Adverse events captured by the system consist of any negative reaction or complaints related to a product, from a serious illness, severe allergic reactions or other major medical events, to more mundane issues like defective packaging or an off smell to a product.

For conventional foods and cosmetics, all the adverse event reports submitted to CFSAN are voluntary because there is no regulatory requirement for manufacturers or other entities to submit these reports. But CFSAN receives both voluntary and mandatory reports associated with dietary supplements, due to a legal requirement for manufacturers and distributors of those products to file "serious" adverse event reports with the agency within a specified time period.

The CFSAN Adverse Event Reporting System (CAERS) includes data from reports submitted by consumers, medical professionals and industry. The initial data file made public by the agency contains CAERS data from January 2004 through September 2016 — although the agency clarified on January 3rd that the initial data file did not include voluntary reports from industry, and that those reports will be made available as part of the first update to CAERS.

Subsequent data files will contain raw data extracted on a quarterly basis and will be posted to the online CAERS portal on FDA's website. The first quarterly update, covering the last three months of 2016, is expected to be released in February 2017.

In its December 6th announcement, the FDA noted that from Jan. 1, 2004, through Sept. 30, 2016, it received a total of 56,574 adverse event reports in CAERS. Breaking that total down: 26,840 reports were for conventional food products; 25,412 were for dietary supplements; and 4,322 were for cosmetic products.

This new increased transparency from CAERS will help the agency and other public health experts

monitor and further examine trends in adverse event reports that could signal a true safety problem with a product. But the data will also almost certainly be mined by other interested parties, who could use isolated reports to file lawsuits against manufacturers or retailers of certain products, as we discuss further below.

Does The Timing Matter At All?

The timing of the agency announcement about the newly public CAERS database is interesting considering the start of the 115th Congress this month and the pending nature of the Personal Care Products Safety Act (S.1014).

Under the proposed act, cosmetic manufacturers would be required to report adverse events to the agency within 15 business days of becoming aware of the event. The law would also give the FDA mandatory recall authority over cosmetics in the event of safety concerns.

The primary cosponsors of the reform bill, Senators Dianne Feinstein (D-CA) and Susan Collins (R-ME), have not made any formal remarks about the FDA's decision to release CAERS data, but supporters of the proposed legislation believe the regulatory development is a step forward. Senators Feinstein and Collins are expected to reintroduce the Personal Care Products Safety Act for consideration by the new Congress.

Despite some opposition, congressional aides say the proposed legislation is likely to see movement this year in light of the relatively high degree of support it has received from diverse stakeholder groups. The FDA, too, welcomes the opportunity to increase its regulatory power over cosmetics and personal care products.

Last year, citing recent adverse event reports about WEN hair products, the agency stressed the need to do away with the voluntary reporting system so that companies are required to report serious adverse events as they become aware of them. Many industry members also support the bipartisan compromise legislation, as do consumer protection groups who view some strengthening of the U.S. regulatory system as "better than nothing."

So, although purely speculative on our part, we think there is some possibility that the FDA is seeking to mobilize public support for its position that it is finally time for cosmetics reform by making its CAERS data more transparent and readily accessible. But fallout from that same ongoing investigation into WEN hair products also shouldn't be overlooked as another potential contributing factor to the FDA's decision to make CAERS data easily available to the public.

Indeed, Dr. Linda Katz, director of the FDA's Office of Cosmetics and Colors, recently explained that "the most frequently reported adverse events for cosmetic products go into the general categories of hair care (including shampoos, conditioners, hair smoothing products, and hair dyes) and skin care products."

Because the FDA does not have authority to require mandatory reporting of adverse events related to cosmetics, she added, the agency is "just seeing the tip of the iceberg in CAERS." Yet reporting of adverse events associated with this category of products has increased since 2014, when only 445 reports were submitted — by comparison, in 2016, the FDA received 3,576 adverse event reports for cosmetic products.

What Could Greater AER Transparency Mean For Litigation Risks?

Although the data now accessible via CAERS previously could be obtained from the agency through a Freedom of Information Act request (often resulting in a lengthy and painful wait), regulators are "hoping that this increased transparency will result in more detailed and complete reports that will help us to more rapidly identify red flags about a possible safety issue with products we regulate," as articulated in an FDA blog post published by two CFSAN leaders in conjunction with the official announcement.

Other stakeholders also have expressed similar hopes for the new database when applauding the FDA's decision to make these reports more transparent. Individually, Consumers Union (CU), the policy and mobilization arm of Consumer Reports that advocates on behalf of consumers, the

Grocery Manufacturers Association (GMA), and the Personal Care Products Council (PCPC) each welcomed the development and recognized the valuable role these data could play in advancing their own goals.

CU noted that "this additional transparency may help consumers learn about potentially dangerous food, supplements, and cosmetics faster than they would otherwise," while GMA and PCPC expressed their interest in exploring ways to possibly use the database information towards further enhancing the safety of their members' food, cosmetic and personal care products.

Critically, however, CAERS data only reflect the information as it was reported to the agency — so the inclusion of a report in the system does not represent any determination by the FDA that a product is causally linked to the reported adverse event.

The system can also include duplicate reports for a given adverse event if, for example, both the consumer and her treating health care practitioner submitted the information to the FDA. Indeed, the webpage for entry into CAERS provides the prominent disclaimer: "The presence of an adverse event report in CAERS does not mean the FDA has determined that the product listed was the cause of the event. Information from the reports is included in its original form and reports not always contain sufficient information for FDA to determine whether there is a correlation between the reported event and use of the product."

Notwithstanding those limitations to the data extracts that are being made publicly available, there are certainly going to be instances in which a person or entity seeks to use information from CAERS to establish causation between an injury and a particular consumer product.

The release also raises concerns about whether those submitting the product complaints will demand some type of qui tam/whistleblower compensation from the government when a significant safety problem is identified.

Further, will the adverse event reports lead to the additional issuing of consumer notices of claims, such as those required under the California Consumer Legal Remedies Act (CLRA), or the filing of putative class actions that are based on thin allegations?

Such filings even today are often based on "information" that appears on the internet, so we question whether the impression of greater authority to information coming from a government-sponsored database will increase such lawsuits and CLRA-type demands.

A perfect storm could occur if the enforcement budgets of certain federal agencies (e.g., the FDA and the Federal Trade Commission) are cut back or restricted. In that case, it would not be surprising to see an increase in claims and class action filings increase by "citizen enforcers" or "private attorney generals" based on CAERS becoming part of the public domain with no restrictions on scientific veracity.

Additionally, we question how the FDA's mandatory recall authority for cosmetics, assuming it is obtained as part of a final Personal Care Products Safety Act, might interact with the CAERS database when there is no causation established as part of the adverse event reporting system.

Will a future recall threshold be based on the quantity of adverse event reports, rather than quality of the reports themselves? Some recent comments from the FDA, one of which is related above, make this concern on the part of industry a reality.

To stay ahead of these potential problems, it would be prudent for companies in this space to take their own actions to review the CAERS data extracts in order to determine whether complaints about their products are being sent to the FDA at a greater frequency or with different reactions than what might be typically reported directly to the company.

In the event that a company is seeing such trends, it should consider the possibility of taking certain actions, such as rebuttal or refutation reports that it could send to the agency. This type of affirmative interaction with the FDA may be beneficial to any company that may face a recall notice, consumer claim or class action complaint, so that it does not have to play defense before

the game starts.

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