Show Me, Show Me, Show Me: FDA to Post Adverse Event Report Data Associated With Certain Products

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On December 7, 2016, the Food and Drug Administration announced that it would post on its website adverse event reports from January 2004 to the present for food (including food additives, color additives, and dietary supplements) and cosmetics.[1] These products are regulated by FDA's Center for Food Safety and Applied Nutrition. Depending on the type of product and adverse event, some reports are mandatory and others are voluntary. Previously, to obtain this information one had to submit a request under the Freedom of Information Act, which we know can take months, if not years. FDA hopes that the posting will provide transparency about adverse event reports and improving public health by identifying possible risks with a particular product.

Highlights

- FDA will post the data files on a quarterly basis here[2].
- The information will include that entered into FDA's CAERS [CFSAN Adverse Event Reporting System] database, such as:
  - demographic (e.g., age, gender) and administrative information regarding the adverse event
  - date of event
  - product role (suspect or concomitant)
  - reported brand/product name
  - industry code/name
  - reported symptom(s)
  - outcome information
- FDA notes:

  > Adverse event reports about a particular product and the total number of adverse event reports for a product in the CAERS database only reflect information reported and do not represent any conclusion by FDA about whether the product actually caused the adverse event(s).

- The agency acknowledges that some adverse events associated with any product may be underreported and yet, at times, duplicative.
- The agency intends to issue quarterly reports, but there will be a one-month lag. For example, the first quarterly report will be issued in February 2017 and cover CAERS data during October–December 2016. FDA intends to issue its second quarterly report in May 2017 for reports submitted in January-March 2017.
- We note that, while the agency's efforts to be more transparent are laudable and, perhaps, the posting of information will identify potential safety concerns for particular products,

1 81 Fed. Reg. 88244.
2 http://www.fda.gov/Food/ComplianceEnforcement/ucm494015.htm

thereby protecting consumers, companies should be aware of the potential liability exposure that posting may now present. While the agency makes clear that the reports do not represent an FDA conclusion or determination that a product may have actually caused the adverse event, it is possible, if not likely, that plaintiff's lawyers will review the posted information to evaluate possible claims or to support pending lawsuits. Therefore, companies should be made aware of this new initiative, carefully review whether a particular incident must be reported and, if so, be mindful of how they report the event. The report can, and may indeed, be used against a company in litigation.

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