

Product Regulation & Liability - USA

Launch of openFDA increases accessibility to adverse drug event reports

Contributed by **Morrison & Foerster LLP**

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On June 2 2014 the Food and Drug Administration (FDA) launched openFDA (<https://open.fda.gov>), a programme designed to improve access to publicly available data, beginning with adverse event reports. While greater accessibility to adverse event reports has industry benefits, it may also put drug manufacturers at greater litigation risk. This potential exposure highlights the need to prepare adverse event reports with an eye towards avoiding admissions on causality or making other statements in the absence of complete information.

openFDA

At present, the openFDA website contains a searchable database of more than 3 million adverse drug event reports submitted by drug companies, consumers and healthcare professionals from 2004 to 2013. These reports were previously available only through difficult-to-use reports or Freedom of Information Act requests.⁽¹⁾

While the first phase of openFDA includes only data on adverse drug event reports, it will soon include datasets on product recalls and structured product labelling data. The FDA also plans to expand openFDA beyond drugs to include data on devices and foods.

OpenFDA is a search-based application programming interface (API). openFDA users may submit a query to the API using a number of variables, including brand name, generic name, pharmacologic class, route of administration and active ingredients. Although the data available through openFDA is undoubtedly useful, the API requires users to write code to obtain search results. This process may be time consuming and impractical for everyday consumers who wish to obtain information on a particular drug.

However, the FDA stated that the API will allow developers to build their own applications on top of openFDA.⁽²⁾ One such application already exists. ResearchAE.com is a web-based application that allows the public to search the FDA's data in a more streamlined fashion, without having to write code.⁽³⁾ The application allows users to search openFDA data by entering search parameters into fields, much like an advanced search engine. It also provides manufacturer information based on a Google search of the new drug application or abbreviated new drug application number associated with a particular adverse event report. Other user-friendly applications will likely use openFDA's API to provide additional access to the FDA's data.

Using openFDA

Increased access to this data will be especially useful to academic researchers and pharmaceutical companies. The ability to avoid submitting Freedom of Information Act requests or analysing difficult-to-use reports will save researchers and pharmaceutical companies time and money. Having the data in one place in a simplified form will allow these groups to analyse adverse event reports and statistics in order to understand better the limitations and benefits of various drugs.

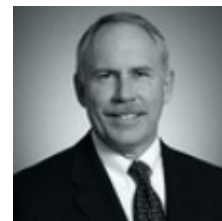
Impact on litigation

openFDA could increase litigation risk for pharmaceutical companies. Easier access to a decade's worth of adverse event reports will allow the plaintiffs' bar to mine adverse drug event data for potential claims and may lead to increased litigation filings. For pending litigation, openFDA will provide plaintiffs with access to more adverse event reports than they would be able to obtain in discovery, creating larger sample sizes on which experts can base their opinions.

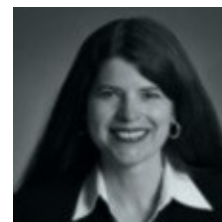
OpenFDA users – and potential plaintiffs – may overlook FDA warnings about lack of established causality and draw unwarranted inferences about a causal link between the drug and the adverse event. Additionally, the public may not realise that the raw number of adverse event reports for a

Authors

James W Huston



Erin M Bosman



Julie Y Park



particular drug is not indicative of the rate or prevalence of adverse events, as adverse event data do not convey the total number of people who have taken the drug. For these reasons, increased access to adverse event report data is likely to create a perception of more risk than actually exists, which could in turn lead to more lawsuits.

How manufacturers can protect themselves

The potential for plaintiffs to use openFDA data to generate or support litigation with widely accessible information highlights the need for drug manufacturers to take great care in preparing adverse event report submissions. Manufacturers must keep in mind the limitations announced on openFDA: that adverse event reports "do not undergo extensive validation or verification" and that a causal link between the drug and adverse events cannot be established through an adverse event report.

With regard to validation and verification, manufacturers often submit adverse event reports based solely on information provided by the reporter, without review or analysis of underlying medical records. Accordingly, the report should clearly refer to what was 'reported' rather than statements of what 'occurred' based on second-hand knowledge.

Manufacturers should also be mindful that product identification may not be accurate and that the FDA does not require statements regarding causation in adverse event report submissions.⁽⁴⁾ Therefore, admissions of product identification, liability and causation should be avoided.

While the FDA has heralded openFDA's launch as the latest tool in "promoting and protecting the public health", the increased accessibility to massive amounts of adverse event data is not all good news for the pharmaceutical industry. Instead, it should serve as a reminder that pharmaceutical companies must carefully conduct adverse event reporting in a manner that is consistent with FDA requirements while also protecting the company from unnecessary liability.

For further information on this topic please contact [James W Huston](mailto:jhuston@mofocom), [Erin M Bosman](mailto:ebosman@mofocom) or [Julie Y Park](mailto:juliepark@mofocom) at Morrison & Foerster LLP by telephone (+1 858 720 5100), fax (+1 858 720 5125) or email (jhuston@mofocom, ebosman@mofocom or juliepark@mofocom). The Morrison & Foerster website can be accessed at www.mofocom.com.

Endnotes

(1) See www.fda.gov/newsevents/newsroom/pressannouncements/ucm399335.htm.

(2) See www.fda.gov/newsevents/newsroom/pressannouncements/ucm399335.htm.

(3) See www.researchae.com.

(4) 21 CFR § 314.80(k): "An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the drug caused or contributed to an adverse effect."

Brittany L Rosentrater, summer associate at Morrison & Foerster and student at University of San Diego School of Law, helped to prepare this update.

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