Guidehouse

Plaintiff Claims in Pharma and Device Product Liability Cases: Do They Create Adverse Event Reporting Obligations for Manufacturers?

Some Frequently Asked Questions

1. **The fda requires manufacturers of drugs and devices to submit reports of certain adverse events to the agency. What about information about the experiences of plaintiffs in product liability lawsuits? Is this adverse event information that needs to be submitted to the fda?**

   Information from plaintiffs in product liability litigation might qualify as reportable adverse events. Drug and device adverse event reporting regulations differ, but both require assessment of information from product liability litigation to determine whether it needs to be reported to the Food and Drug Administration (FDA).

   Drugs. Drug regulations require adverse event reports to the FDA for serious and unexpected adverse events (i.e. not listed in the current labeling).[1] The regulations also require manufacturers to review all adverse events received from any source to determine if the events are reportable.[2] The FDA has said specifically that adverse event information received by a drug manufacturer's legal department in the course of product litigation must be forwarded to the firm's drug safety organization for evaluation and possible reporting to the FDA.[3]

   Devices. Device regulations require manufacturers to evaluate all complaints received about a product to determine whether the complaint provides information about a reportable adverse event.[4] A complaint is defined by the FDA as "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution."[5] In a recent guidance document, FDA specified legal documents as one source of complaint information that should be reviewed to determine whether the information is reportable to the FDA.[6]

2. **Some product liability cases have thousands of plaintiffs. Does information about all of them need to be submitted to the fda?**

   Information about all plaintiffs should be reviewed to determine if the information is reportable to the FDA. In addition, as more information becomes available in the course of the litigation, any initial reports must be supplemented with additional relevant information.[7] This can be quite burdensome to manufacturers because of the number of plaintiffs and the amount of information that must be reviewed in a short period of time.

3. **How do you determine if information from a plaintiff must be submitted as an adverse event report? Some plaintiffs haven't even used the product or experienced any injury at all.**

   Drugs: Any adverse event "associated" with the use of the drug, whether considered drug-related,[8] must be submitted to the FDA if the adverse event is serious and unexpected.

   Devices: Information that "reasonably suggests" that a device caused or contributed to a death or serious injury must be reported to the FDA.[9] The FDA has stated that it needs to be aware of an association between the use of a device and death/serious injury, as well as instances where there is a causal connection.[10]

   In both drug and device litigation, some plaintiffs may have frivolous claims. It can be very time-consuming to separate the wheat from the chaff when conducting the required investigation and analysis necessary to evaluate each complaint. However, the FDA has shown little sympathy for manufacturers unilaterally deciding that some complaints are frivolous and burdensome. Adverse event reporting is simply the law.

4. **What happens if a manufacturer has already submitted a report to the fda about some of the litigation plaintiffs?**

   This is another challenge associated with adverse event reports arising out of litigation. We know the FDA doesn't want duplicate reports. (Manufacturers don't want duplicate reports either. It makes the product look bad.) It is time consuming and difficult to determine if information about any plaintiffs has already been provided to the FDA, but it really should be done to avoid duplication.

1. 21 CFR 314.80(c)(1)(i).
2. 21 CFR 314.80(b).
3. The Food and Drug Administration, Compliance Program 7353.001, Chapter 53, Postmarketing Surveillance and Epidemiology: Human Drug and Therapeutic Biological Products, Part III.M, https://www.fda.gov/media/84969/download. This compliance program also states that a drug company may petition the FDA for a waiver of the reporting requirements or alteration of the reporting time frames. The FDA may grant the waivers on a case-by-case basis, for good cause shown.
4. 21 CFR 820.198(a).
5. 21 CFR 820.3(b).
6. Guidance for Industry and Food and Drug Administration Staff, Medical Device Reporting for Manufacturers, November 2016, Section 2.11, https://www.fda.gov/media/86420/download.
7. See 21 CFR 314.80(c)(1)(ii), and 21 CFR 803.56.
8. 21 CFR 314.80(a).
9. 21 CFR 803.50(a).
10. The Federal Register of September 14, 1984, 49 FR 36326, 36331. See also, the Federal Register of December 11, 1995, 60 FR 63578, 63590.

5. **Wouldn't it be easier to submit information about all plaintiffs to the fda?**

   The device regulations make it clear that submitting an adverse event report is not an admission that the device caused or contributed to the adverse event. Guidehouse has seen manufacturers throw up their hands and submit information about all plaintiffs, duplicative or not, plaintiff injury or not, and whether or not the information reasonably suggests that the device caused or contributed to the adverse event. We don't recommend that approach. It might be easier, but it's not what the FDA wants, and it could distort product safety signals.[11]

6. **If the manufacturer wins the litigation, would that mean nothing would be reportable to fda? Could a manufacturer wait until the litigation is concluded to submit reports?**

   Unfortunately, no. In general, drug adverse event reports must be submitted within 15 days,[12] and device adverse event reports must be submitted within 30 days. These time frames apply to initial and supplemental reports.

   In addition, the standard for reporting an adverse event to the FDA is quite a bit lower than plaintiff's burden at trial. For example, a manufacturer may argue in litigation that the user was adequately warned based on the device label warnings and precautions. However, from an FDA regulation standpoint, even if the manufacturer provided adequate warnings about the possibility of the event occurring, the device adverse event may be reportable to the FDA.

7. **What happens if companies don't submit all these reports to the fda?**

   Failing to submit required adverse event reports to the FDA misbrands the product. Sometimes, the FDA will pursue criminal sanctions against a company executive whose company fails to submit required reports. For example, in December 2018, Olympus Medical Systems Corporation, including one executive, pleaded guilty to failing to submit required reports on the company's reusable duodenoscopes.[13] More frequently, the FDA issues a warning letter, followed by a seizure and injunction if the company does not comply with the FDA's requests.

8. **Under the regulations, the manufacturer's receipt of information about the event triggers the obligation to investigate and report events. Could a law firm help the manufacturer by shielding it from specific information about plaintiffs in litigation?**

   We know of a law firm not providing information about plaintiff complaints to its client, presumably to protect the client from having to submit adverse event reports. This left the client in a situation that took significant time and cost to remediate, as well as having to work closely with the FDA until the remediation was complete. The client fired the law firm.

9. **What's your advice for lawyers representing clients in this situation?**

   We recommend that lawyers representing drug or device clients in product liability litigation remind clients that the litigation will likely lead to additional complaint-handling obligations, including potential for increased adverse event reporting. In our experience, complaint handling obligations and related resource requirements sometimes get overlooked by the client. And sometimes the volume of complaints arising out of litigation simply overwhelms the client's adverse event reporting systems and processes. The client must continue its day-to-day activities while also handling the new litigation-related complaints and potential subsequent reporting activities.

   Guidehouse assists law firm clients in these situations by working with the client to evaluate the complaints and complete reporting requirements in a timely manner, including identification of plaintiffs for which adverse event reports have already been submitted and submitting supplemental reports, as needed.

For further information, please view the following video: Watch now

11. M.A. Munoz and G.J. Dal Pan, "The Impact of Litigation-Associated Reports on Signal Identification in the US FDA's Adverse Event Reporting System," PubMed.gov, May 16, 2019, https://www.ncbi.nlm.nih.gov/pubmed/31098918.
12. 21 CFR 314.80(c)(1)(i).
13. Department of Justice, "Olympus Medical Systems Corporation, Former Senior Executive, Plead Guilty to Distributing Endoscopes After Failing to File FDA-Required Adverse Event Reports of Serious Infections," Office of Public Affairs, December 10, 2018, https://www.justice.gov/opa/pr/olympus-medical-systems-corporation-former-senior-executive-plead-guilty-distributing.

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