Counsel's Advisory

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DOJ USES FALSE CLAIMS ACT TO ENFORCE FDA MANUFACTURING RULES

by
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On January 12, 2017, the US Department of Justice announced it had reached a global settlement with Baxter Healthcare Corporation. The civil component of the settlement was atypical of other False Claims Act (FCA) matters. It was small by comparison—$2.158 million—and it was not based on off-label promotion or kickback activities. Instead, the Baxter settlement was based on an allegation that Baxter violated current good manufacturing practices (cGMP), a prohibited act under the Federal Food, Drug, and Cosmetic Act (FDCA). At any given time, a company is violating cGMP; by their very nature, "current" practices are constantly evolving. FDA has the statutory authority to enforce cGMP requirements, or to exercise its enforcement discretion—not DOJ.

Baxter manufactured large-volume sterile intravenous (IV) solutions in clean rooms outfitted with high-efficiency particulate absorption (HEPA) filters. Under its cGMP procedures, Baxter regularly scheduled inspection and testing of the HEPA filters and replaced any filters that failed testing. The subject five filters showed no "out of limits" test results, and the government agreed that "[t]here was no evidence of impact on the IV solutions manufactured at North Cove from the mold found on the HEPA filters above the Line 11 clean room."

Under the FDCA, a drug is adulterated if

> the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

21 U.S.C. § 351(a)(1)(B). The focus is not on an actual deviation from the product's quality and purity, but simply that the methods used to make the product are not cGMP compliant. Every year, FDA inspects hundreds of facilities and cites them for failing to follow cGMP in manufacturing FDA-regulated products. FDA has several enforcement tools to require compliance with cGMP, including Warning Letters, import bans, or injunctions.

Thus it is disturbing to see another governmental agency reviewing and imposing penalties for the same conduct. The only other major FCA settlements alleging cGMP violations involved situations

where alleged failure to follow cGMP resulted in contaminated or adulterated products. In the Baxter settlement, there was "no evidence of impact" on the products and no patient harm.

Counsel should be cognizant of DOJ's ever-creative theories to coerce an FCA settlement. The FDCA is appropriately enforced by the agency Congress entrusted to have the expertise to review cGMP requirements: FDA, not DOJ.

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