A NEW ERA IN FDA RECALL AUTHORITY

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What Medical Device Manufacturers Need to Learn From Baxter

On July 13, 2010, the FDA issued specific requirements for Baxter, a global medical products and services company, to use in recalling infusion pumps. These requirements follow a May 3, 2010, order by the FDA for Baxter to (i) recall and destroy 200,000 of its Colleague infusion pumps, (ii) to reimburse its customers, and (iii) to assist customers in finding replacement devices.

Baxter's recall is unusual and raises several questions about the scope and course of the FDA's enforcement authority. What is so distinctive about the FDA's actions in Baxter's recall is that (i) almost all recalls in the past had been voluntary; but in this rare instance, the FDA has come so close to exercising its mandatory recall authority; and (ii) the FDA barely ever in the past directly ordered a manufacturer to reimburse its customers for a defective device. Under the FDA's July requirements, Baxter will also provide a transition guide to assist customers affected by the recall. This transition guide will include a list of FDA-cleared or approved pump alternatives, suggestions to help minimize disruption and patient risk during the transition period, and detailed information on the refund, replacement, and lease-termination.

Existing Legal Authority

Under Section 518 of the Federal Food, Drug, and Cosmetic Act, the FDA is vested with the authority to order mandatory device recalls, repairs, replacements, and refunds. Although the FDA's order to Baxter to recall its Colleague infusion pumps is not technically an exercise of its mandatory recall authority, because it is pursuant to a 2006 consent decree between the FDA and Baxter, it has a stark resemblance to a mandatory recall order by the FDA. It is further debatable where the FDA draws its authority to order Baxter to refund its customers. Is it the exercise of its authority to order refunds, is it pursuant to the consent decree, or is the FDA arbitrarily giving itself an equitable remedy of "restitution" without recourse to the court to decide whether equity justifies restitution? Not only is the source of FDA's authority to order refunds ambiguous, the fact that the FDA provided no formula or guidance to calculate the refund to the customers is even more perplexing.

Through Baxter's recall, is the FDA setting a precedent for other device manufacturers to address device deficiencies promptly and thoroughly? Yes. Baxter's recall should be a lesson for all medical device manufacturers and their officers, directors, and managers, particularly those companies whose devices have longer life-spans.

Consequences

The effects of the FDA's actions in the Baxter case go far beyond the fines paid to the government as part of the consent decree settlement in 2006. The costs involved in both money and time spent on conversions to new products under the FDA's expansive recall requirements may outweigh the fines. Given the FDA's high-end estimate of 200,000 units in the field, Baxter may be facing an average cost of $2,000 to $3,000 per pump to meet the FDA's recall requirements.

Baxter's recall may be the first of its kind, but it won't be the last. The FDA's actions in Baxter's recall is part of a larger trend at the FDA to push the boundaries of existing law and require medical device manufacturers not just to meet legal standards but to meet high industry standards as well. Medical device manufacturers should review the FDA's requirements in this Baxter recall and evaluate whether additional recall, replacement and warranty language should be incorporated into a product's terms and conditions or existing sales/distribution agreements. Additionally, medical device companies should begin evaluation of products at risk for recall and take compliance steps to proactively avoid FDA involvement in a recall action.

Hodgson Russ's interdisciplinary Life Sciences Practice Group can assist medical device companies in the evaluation of their product risk, preparation of appropriate contractual protections, and evaluation of FDA compliance deficiencies to allow proactive corrective actions,