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FDA's Present Authority To Require Post-Market Corrective Action

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Currently, FDA has several statutorily-based authorities to require companies to undertake post-market corrective action, and each one of them is designed to give the manufacturer an opportunity to present its perspective and any evidence supporting the approach the company proposes to take.

Here are the five varieties of US FDA authorities to compel post-market actions, along with due-process considerations. (See lead story, "*CDRH's New Post-Market Paradigm: Why The Public Should Be Worried*.")

1. Voluntary Recalls

FDA's regulations encourage manufacturers to recall marketed product that FDA "considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." (21 CFR § 7.3[g]) These requirements are "voluntary," but the manufacturer is under the duress of knowing that the failure to meet FDA expectations may lead to FDA enforcement action. There is no due process specifically at the voluntary recall level because the due process enters in if FDA decides to pursue an enforcement action such as seizure or an injunction.

2. FDA-Requested Voluntary Recalls

FDA can also request "a firm to initiate a recall when a product that has been distributed presents a risk of illness or injury or gross consumer deception, and agency action is necessary to protect the public health and welfare." (21 CFR § 7.45[a].)

3. Mandatory Recalls

In a rarely used provision, if a manufacturer or importer fails to voluntarily recall a device that is a risk to health, FDA may issue a recall order to the manufacturer under 21 CFR § 810. Authorized by Section 518(e) of the federal Food, Drug, and Cosmetic Act, these regulations kick in if, after providing the appropriate person with an opportunity to consult with the agency, FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death.

Initially, FDA is limited to issuing a cease distribution and notification order; this requires the person named in the order to cease distribution of the device, notify health professionals and device user facilities of the order, and instruct these professionals and device user facilities to cease use of the device. The person named in the order has an opportunity for a regulatory hearing or to provide a written request to FDA asking that the order be modified. FDA may later amend the order to require a recall of the device.

4. Order To Notify Or Refund Or Repair

Sec. 518 of the Act offers FDA a way of assuring that hazardous products in the hands of consumers and other users are repaired, replaced or refunded:

- Notification procedures:
  Under Sec. 518, FDA may require manufacturers or other appropriate individuals to notify all health professionals who prescribe or use the device and any other person of a health risk resulting from the use of the violative device. FDA can order notification if a device presents an unreasonable risk of substantial harm to public health; notification is necessary to eliminate the risk; and no more practicable means are available under the act to eliminate the risk. The procedures require prior consultation with the persons who are to provide the notification.

- Repair, replace or refund procedures:
  Section 518(b) authorizes FDA, after offering an opportunity for an informal hearing, to order manufacturers to repair, replace or refund the purchase price of devices that present unreasonable health risks. FDA can order these remedies if, after opportunity for an informal hearing, it determines that the device represents an unreasonable risk of substantial harm to the public health; the device was not designed and manufactured in accordance with the then prevailing state of the art; the risk is not due to negligent installation, maintenance, repair or use of the device by persons other than a manufacturer, importer, distributor or retailer; and notification alone is insufficient, and repair, replacement or refund is necessary.

  The procedures for ordering repair, replacement or refund are involved. The agency must consider available alternatives. Before ordering notification, FDA must determine that no

more practical means are available under the Act to eliminate the risk. Before FDA orders repair, replacement or refund, FDA must determine that notification alone is insufficient.

5. Adverse Publicity

Section 705(b) of the Act authorizes FDA to disseminate information regarding devices in situations involving, in the opinion of FDA, "imminent danger to health or gross deception of the consumer." FDA is obliged to follow procedural rules set up by the US Department of Health and Human Services at 45 CFR Part 17. Those regulations, in very broad terms, require that FDA only disseminate accurate, factual information. In practice, these requirements offer manufacturers virtually no due process protection and have been roundly criticized over the last nearly 50 years. But the lack of due process is what seems to make this FDA's option of choice.