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Has the Time Come for "Total Recall" of Medical Products?

By Peter Reichertz

On July 14, 2010, Congressman Edolphus Towns introduced legislation to provide for the mandatory recall of adulterated or misbranded drugs. The legislation, H.R. 5740, has been referred to the Committee on Energy Commerce. Congressman Towns was the chair of the subcommittee that held hearings about Johnson & Johnson/McNeil and its handling of adulterated children's drug products (including Tylenol® and Motrin®) this past Spring. Johnson & Johnson was scrutinized for delaying the recall of the products and allegedly covering up the recall of some of the products. As a result, there has been increased publicity over the authority of the U.S. Food and Drug Administration ("FDA") to require the recall of drug products.

While the existence of numerous drug recalls may lead many to believe that FDA has the legal authority to require a recall of drug products, at present the Federal Food and Drug and Cosmetic Act ("FFDCA") does not grant FDA this power. FDA does have the power to recall products approved as medical devices[1] and those approved as biological products.[2] The recall authority for medical devices is part of the Medical Device Amendments to the FFDCA; the recall authority for biological products is part of the Public Health Service Act. Similarly, FDA has no recall authority for foods or cosmetics; that possible grant of authority is subject to other pending legislation.[3]

As the situation now exists, recalls of drug products are a voluntary action undertaken by pharmaceutical companies when they become aware of the possibility that one of their products may be adulterated or misbranded. If the product is subject to a New Drug Application ("NDA"), there is a requirement that the NDA applicant notify FDA within three (3) working days of the receipt of:

> (i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it in the application.

Such a filing is called an NDA Field Alert Report.[4]

Most companies have a recall procedure in place whereby such information is reviewed, and a decision is made by an interdisciplinary group of employees as to whether a recall should be undertaken, and, if so, to what level of trade (consumers – class 1; retailers – class 2; or wholesalers – class 3) the recall should extend, based on an evaluation of the safety risk involved. The company notifies the FDA of the decision and keeps FDA aware of its actions, including its notifications to the trade and, if necessary, consumers, in accordance with FDA regulations on recalls found in 21 C.F.R. § 7, Subpart C.

How would H.R. 5740 change this practice if enacted? Under the proposed legislation, a drug company would be required to notify FDA "as soon as practicable" of the identity and location of any drug products "reasonably believed" to be adulterated or misbranded, which products could with reasonable probability "cause a threat of serious adverse health consequences or death to humans or animals". The Agency would have the power to request a voluntary recall or could issue an order requiring that the company immediately cease distribution of the drug product, and to provide notice to "persons who may be affected by such cessation of distribution". A company could appeal the order within twenty four (24) hours, by requesting an informal hearing that FDA has to provide in five (5) calendar days. Following the hearing, the Agency can decide to order a recall of the drug product in question or it can vacate the distribution cessation order. A recall order, if issued, would be required to:

(i) specify a timetable in which the recall will occur;

(ii) require periodic reports to the Secretary describing the progress of the recall; and

(iii) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

There is, under the draft legislation, in addition, the possibility of an "emergency recall order", where the FDA finds that there is an "imminent" threat of serious adverse health consequences or death to humans and animals. In such cases, the recall order becomes effective immediately. There is the same provision for an appeal if filed within twenty four (24) hours of issuance of the recall order and an informal hearing within five (5) calendar days. The recall is to continue, regardless of any appeal of the emergency recall order.

The bill would also provide that failure of a company to provide a required notice or for the company to comply with an order (recall/cessation of distribution) is a criminal violation under the FFDCA. There are specific provisions as to what Agency officials are authorized to issue the orders. It also is made clear it does not affect recall authority currently in place for devices and biologics.

The legislation, as drafted, seems only to require the notification, recall and notice to affected customer in situations traditionally considered Class 1 recalls, since it is limited to situations involving serious adverse health consequences or death.[5] The legislation would not require recalls in Class 2 or Class 3 situations. In addition it would require a recall only where the risk of serious adverse health consequences is "imminent" or "reasonably believed" to be probable, which is interesting as it would not rectify the problem that occurred with Johnson & Johnson children's products. In that case, the risk of serious adverse health consequences was deemed "remote". In addition, the legislation does not distinguish between "imminent" and "reasonable probability".[6]

The legislation appears to be based on similar wording found in Section 518(e) of the FFDCA providing recall authority for medical devices, although there are some differences. The medical device provision does not include an "emergency recall order". In addition, the informal hearing, in case of an appeal, would need to take place in ten (10) days, not five (5) days.

In the past, the FDA has sought to require recalls under its general enforcement powers, but has largely been rebuffed by the courts as "an additional arrow" not needed given its "already well equipped bow".[7] As far back as 1975, commentators have suggested that FDA needed drug recall authority.[8] While FDA has never vigorously sought such authority, the time for "total recall" authority for medical products may be near.

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[1] Section 518(e) of the FFDCA, 21 U.S.C. § 360h(e). See regulations at 21 C.F.R. § 810.

[2] Section 351(d)(1) of the Public Health Service Act , 42 U.S.C. § 262(d)(1).

[3] See H.R. 759, 815, 875, 999 and 2749 and S.510.

[4] See 21 C.F.R. § 314.81(b)(1).

[5] See 21 C.F.R. § 7.3(m)(1).

[6] The biologics recall provision in Section 351(d)(1) of the PHSA is triggered when "a product presents an imminent or substantial hazard to the public health". Arguably HR 5740 would, if enacted, encompass more situations where FDA could order the recall of a drug product.

[7] U.S. v. C.E.B. Products, Inc., 380 F. Supp. 664 (N.D. Ill. 1974); Cf. U.S. v. K-N Enterprises, Inc., 461 F. Supp. 998 (N D. Ill. 1978).

[8] Note, The Food and Drug Administration's Recall Power After United States v. C.E.B. Products. The Need to Amend the Food, Drug, and Cosmetic Act, 69 N.W. U.L. Rev. 936 (1975).