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PRODUCT RECALL INSURANCE AND THE NEW FDA FOOD SAFETY MODERNIZATION ACT

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The increased recall authority of the FDA created by the FDA Food Safety Modernization Act ("FSMA") has important implications for policyholders. The FSMA was enacted on January 4, 2011. 21 U.S.C. § 2201 et seq., Pub. L. No. 111-353, 124 Stat. 2885 (2011), amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (1938). While some provisions of the FSMA were not designed to take effect immediately, the "FDA's new authority to order [mandatory] recalls" was effective as of January 4, 2011. Deborah M. Strauss, *An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business*, 66 FOOD & DRUG L.J. 353, 359 (2011).

"Prior to passage of FSMA, [the] FDA . . . [did not have] explicit authority to mandate a recall of most adulterated foods, or to impose penalties if recall requirements are violated." Renee Johnson, *Food Safety in the 111th Congress*, p. 20 (available at http://www.nationalaglawcenter.org/assets/crs/R40443.pdf). The FDA previously only had authority to recall "four types of products: infant formula, medical devices, human tissue products, and tobacco products." *Id.* at 20 n.65. However, while the FDA did not have the power to mandate a recall of a product, the FDA had the ability to request a voluntary recall of FDA-regulated products. *Id.* at 20.

The new law now provides for both voluntary and mandatory recall procedures. While the new statutory scheme does grant the FDA more power in the form of this mandatory recall procedure, it is clear that the voluntary recall procedure is still preferred and encouraged. If the HHS Secretary has information that an article of food is adulterated or misbranded and would cause harm or death to humans or animals, the Secretary must first "provide the responsible party (as defined in section 350f of this title) with an opportunity to cease distribution and recall such article." 21 U.S.C. § 350l(a). Second, if the responsible party refuses to institute a voluntary recall within the time allotted by the Secretary, the Secretary may order the responsible party to cease distribution of the article and notify all persons manufacturing, selling, or distributing the article to cease all sales and distributions of the article. *Id.* at 350l(b)(1). If the Secretary orders a mandatory recall, the FSMA provides the responsible party with the right of "an informal hearing, to be held as soon as possible, but not later than 2 days after the issuance of the order." *Id.* at 350l(c). During both voluntary and mandatory recalls, the Secretary must provide public notifications of recall orders and ensure coordinated communications with the responsible party, manufacturers and distributors, and the public. Johnson, *Food Safety in the 111th Congress*, p. 21.

To minimize confusion over the interplay between voluntary and mandatory recalls, the FDA website provides guidance. The FDA makes clear that the "FDA is required to first give a responsible party the opportunity to cease distribution and conduct a voluntary recall of an article of food. If the responsible party refuses to or does not voluntarily cease distribution or recall such food within the time and in the manner prescribed by FDA, FDA may proceed under the mandatory recall authority." FDA, Food Safety Modernization Act (FSMA), Frequently Asked Questions, http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm#IC. Therefore, there should not be any conflict between the voluntary and mandatory recall provisions. The Secretary must first give the responsible party the opportunity to adequately, promptly, and voluntarily recall the product before instituting a mandatory recall order.

If the Secretary mandates a recall of the harmful product and the responsible party refuses or fails to comply with the Secretary's order, the Secretary has the power to impose civil or criminal penalties on the responsible party. "The law provides for the assessment of civil penalties as well as criminal penalties for failure to comply with or

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follow a recall order. [However, t]he assessment of civil penalties for failure to comply with a recall order may preclude the assessment of criminal penalties." Johnson, *Food Safety in the 111th Congress*, p. 21. Thus, the FDA's strengthened authority to order and enforce mandatory recalls of products provides a strong incentive for responsible parties to cooperate initially and conduct a voluntary recall of harmful products.

A recall of a harmful product may result in significant expenses, business interruption costs, and potential third-party liabilities for the responsible party. Even before the passage of the FSMA, an insurance market existed to protect companies from these potential exposures. However, many general liability policies contain recall exclusions, which bar coverage for all expenses related to the recall of the named insured's own product. *See Cytosol Laboratories, Inc. v. Federal Ins. Co.*, 536 F.Supp.2d 80, 92 (D. Mass. 2008); *see also Thomas J. Lipton, Inc. v. Liberty Mut. Ins. Co.*, 34 N.Y.2d 356 (1974). Thus, policyholders bought product recall endorsements or separately purchased product recall insurance to protect against this "gap" in coverage.

Now, over a year after the FSMA was passed, it is clear that the FSMA has important insurance consequences for companies in FDA-regulated industries. The increased authority of the FDA to mandate recalls may lead to a corresponding increase in the number of product recalls conducted in a given year. Companies should analyze their current insurance coverage and ensure that they are properly protected against the expenses and potential liabilities associated with a product recall. Initially, any existing or potential new policy or endorsement should provide coverage for *both* voluntary and mandatory product recalls to account for the expanded authority of the FDA. Moreover, companies should seek product recall coverage that includes both first-party recall coverage for the costs of collecting and destroying the harmful product, as well as third-party recall coverage for damages claims by downstream customers and distributors of the product.

As the FDA and affected industries adjust to the FDA's broadened recall authority, it is important for policyholders to protect themselves against the huge potential expenses and liabilities associated with a product recall.

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