

The Duty Dilemma: Regulatory and Legal Duties to Recall Food Products and Warn of Substantial Product Risks

For U.S. Food Laws & Regulations-Spring 2008

By Melanie Joy Neumann

May 4, 2008

INTRODUCTION

For years, the food industry has been riding the wave of Congress' seemingly age old debate of whether federal food agencies (for purposes of this paper, defined as the Food and Drug Administration and the United States Department of Agriculture) should be empowered with mandatory recall authority.¹ Despite myriad other enforcement powers, currently neither FDA nor USDA can mandate or otherwise require a food company to recall products.² Thus, most U.S. food recalls are technically voluntary actions taken by individual food companies to remove adulterated or misbranded product from commerce, with a few exceptions.³ Hence, whether or not fully understood, food companies do not have a per se regulatory *duty* to recall products under currently food agency regulations. End of story, right?

Wrong. The story has just begun. This paper purports that the story of a food manufacturer's quest to understand whether it has a "duty to recall" has only just begun at the agency regulation level, addressed in Part I herein. Part II will assert that in

¹ See e.g., "Congressional Leaders Call for Single Food Safety Agency", Progressive Grocer, February 15, 2007 . © 2007 VNU Business Media, Inc. See also Safe Food Act (cite legislation)

² 21CFR7.40

³ Certain statutory provisions authorize mandatory recalls of infant formula (21 USC § 350a(e)-(g)), medical devices (21 USC § 360h(e)), and human biological products (42 USC § 262).

addition to assessing agency regulations, food manufacturers must also consider common law legal doctrine, ranging from a common law duty of care to an often ignored and overlooked compilation of common laws known as the Restatement (Third) of Torts, *Product Liability* (specifically §10 and § 11). [The restatements are like treatises; they explain what the common law is, but are not law themselves.] Only until these common law provisions are also considered in conjunction with food agency regulations will food manufacturers fully understand their aggregate “duties” in a recall—both regulatory and legal.

I. FEDERAL REGULATORY AGENCIES AND FOOD RECALLS

Before embarking on an in-depth legal analysis of a company’s duty to recall, it is important to lay a proper foundation to ensure a common understanding of the U.S. food regulatory agencies’ jurisdiction and recall authority.

A. Federal Regulatory Agencies

The following four major U.S. federal agencies are involved in food regulation and safety in some manner: the US Food and Drug Administration (“FDA”), the US Department of Agriculture (“USDA”), the Centers for Disease Control and Prevention (“CDC”) and the Environmental Protection Agency (“EPA”). Notwithstanding, only FDA and USDA will be discussed in detail herein as these two agencies possess the jurisdiction and specific guidance / directives pertaining to food recalls.

U.S. Food and Drug Administration (“FDA”): FDA safeguards the nation's food supply by making sure that all ingredients used in foods are safe, and that food is free of contaminants -- like disease-causing organisms, chemicals, or other harmful substances.

FDA is an operating division of the U.S. Department of Health and Human Services (DHHS). The FDA was established after the passage of the Pure Food and Drugs Act of 1906. This act was the first nationwide consumer protection law, and it made the distribution of misbranded or adulterated foods, drinks, and drugs across state lines illegal. Today, the FDA is mandated by federal law to protect public health by ensuring the safety of the production, processing, packaging, storing, and holding of all domestic and imported foods, except for those products that are under the jurisdiction of the U.S. Department of Agriculture. FDA is also responsible for safeguarding all ingredients used in food products, approving new food additives, monitoring ingredients and foods to see that they are contaminant free, and monitoring dietary supplements, infant formulas, and medical foods for safety. The FDA oversees food labeling and requires that food product labels be informative, truthful, and useful to the consumer.⁴

In essence, FDA regulates all processed products containing 3% or less raw meat and less than 2% cooked meat. USDA regulates products with greater amounts of meat and poultry (*See* USDA section immediately below). However, FDA regulates game meats, such as venison, ostrich and snake and egg containing products (e.g. cake mixes) not covered by USDA.⁵

⁴ See Federal Food Drug & Cosmetic Act, 21 U.S.C. 301 and <http://www.fda.org/nutrition/Pre-Sma/Regulatory-Agencies.html>. Copyright © 2007 - Advameg

⁵ 21 USC 392(b)

FDA enforces several laws relating to the various products under its jurisdiction.

With respect to food, FDA enforces the Federal Food Drug and Cosmetic Act (“FDCA”)

⁶. “Food” is defined under Section 201 of the Act as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.⁷ Thus, pet food, food additives and other ancillary food products may would not think of as “food” generally fall under this agency’s purview.

Under the FDCA, the FDA does not have the authority to mandate or require a food manufacturer/processor to recall products. However, the agency may request a firm to recall products if it is not willing to remove dangerous products from the market. If the firm does not recall the product, then FDA can seek legal action under the FDCA including seizure and detention of available product, and/or injunction of the firm, including a court request for recall of the product.⁸

U.S. Department of Agriculture (“USDA”): The U.S. Department of Agriculture’s Food Safety and Inspection Service (“FSIS”) is responsible for the safety and labeling of traditional meat, poultry and egg products. USDA is the oldest federal agency that monitors the food supply in the United States. It was established in 1862 by President Abraham Lincoln. Today, the mission of the USDA includes a goal that ensures people a safe, affordable, nutritious, and accessible food supply.⁹

⁶ 21 U.S.C. 301

⁷ 21 U.S.C. 321 ; FDCA Section 201(f)

⁸ U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition; *FDA Recall Policies*, Industry Affairs Staff Brochure, June 2002

⁹ <http://www.faqs.org/nutrition/Pre-Sma/Regulatory-Agencies.html>. Copyright © 2007 - Advameg Inc.

The following three pieces of legislation vests USDA with this authority are as follows:

- The Federal Meat Inspection Act (FMIA): USDA/FSIS provides inspection for all meat products sold in interstate commerce, and reinspects imported products to ensure that they meet U.S. food safety standards.¹⁰
- The Poultry Products Inspection Act (PPIA): FSIS provides inspection for all poultry products sold in interstate commerce, and reinspects imported products to ensure that they meet U.S. food safety standards.¹¹
- The Egg Products Inspection Act (EPIA): FSIS inspects egg products sold in interstate commerce, and reinspects imported products to ensure that they meet U.S. food safety standards.¹²

With respect to recalls, USDA has issued FSIS Directive 8080.1 Rev. 4. According to Section I, Purpose, this Directive provides definitions, procedures and public notice protocols for the *voluntary* recall of FSIS-inspected meat and poultry products.¹³ Note the repeated use of the term “voluntary” in the Purpose statement and in the definition of recall set forth below, which illustrate the agency’s recognition that recalls are voluntary actions.

B. What is A Recall?

Although FDA and USDA define the term “recall” using different terminology, in essence, their respective descriptions mean the same thing.

¹⁰ 21 U.S.C. §601

¹¹ 21 CFR § 451

¹² 9 CFR §590.5

¹³ USDA FSIS Directive 8080.1 Rev. 4

FDA defines “recall” as “a firm’s removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (e.g. seizure)”¹⁴

In comparison, USDA defines “recall” as “a firm’s voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act or the Poultry Products Inspection Act.”¹⁵

Regardless of agency jurisdiction, a recall can be collectively defined as a firm’s voluntary removal of product from interstate commerce to protect the public from consuming products that may cause them physical (e.g. contamination resulting in illness/injury) or economic (e.g. false or misleading labeling) harm.

C. Purpose of a Recall

The most important purpose of any product recall is the protection of consumer health and safety. FDA and USDA/FSIS are charged with this overarching mission. For example, FDA’s mission is: 1) to promote and protect the public health by helping safe and effective products reach the market in a timely way, 2) to monitor products for continued safety after they are in use, and 3) to help the public get the accurate, science-based information needed to improve health.¹⁶

Notwithstanding this obvious primary objective, there exists a host of secondary reasons to recall suspect product. Whether for labeling errors, packaging errors,

¹⁴ 21 CFR 7.3 (g)

¹⁵ FSIS Directive 8080.1 Rev. 4

¹⁶ See FDA Internet Site at <http://www.fda.gov/oc/opacom/fda101/sld001.html>

substandard product, suspected or confirmed adulteration or misbranding, a company may choose to recall, or conduct a stock recovery or market withdrawal, in order to:

- Protect brand image
- Protect corporate reputation
- Minimize legal liability exposure
- Minimize disruption to sales

Many companies exercise an extremely “risk averse” approach to recall management. These companies will err on the side of recalling product if the decision is at all vague in order to mitigate legal liability for not exercising due care and/or to prevent loss of customer loyalty in the brand / corporate name resulting in potential lost sales. On the other hand, other companies are very reluctant to recall, delay significantly in issuing a recall announcement, and even waiting for the agencies to issue public non-consumption warnings before it will initiate a recall.¹⁷

Companies who choose not to recall are best served to do so with caution and great diligence in recording all investigative steps, findings and ultimate reason why they believe a recall was not warranted. Not only will this aide against later second guessing by the applicable regulatory agency, this real-time memo of reasonable investigative steps supporting a decision not to recall may assist in the event of subsequent litigation. That said, all it takes is one illness caused by a company’s product that was defective before leaving its control for liability to attach.¹⁸ Hence, companies tend to, and should,

¹⁷ See e.g. BJ’s Wholesale Club E. coli Litigation at http://www.marlerclark.com/case_news/detail/advocates-attack-food-recall-policy

¹⁸ See Section 402(A) Restatement (Second) Torts

err on the side of recalling based on its actual and perceived legal duties, discussed below, even if the regulations do not impose such a duty to recall.

II. LEGAL DUTIES IN FOOD RECALLS

As Part I illustrates, there is no express statutory duty to recall for manufacturers, sellers or distributors of food products imposed by regulations governed by the two main federal food regulatory agencies. However, the story doesn't end here. In addition to assessing agency regulations, manufacturers, sellers and distributors of food must also appreciate that the term "duty" has other legal meanings that may indeed impose a duty, albeit not expressed in statute, to recall products.

A. Common Law Duties and Implied Warranties:

Product liability law is the umbrella legal doctrine governing food illness/injury claims. This body of law is state based. A plaintiff in each state must bring an action within a certain period of time prescribed in the state's statute of limitations.¹⁹

Past precedent in product liability cases have recognized certain legal duties product sellers owe to their buyers. A duty may be express or implied. Express duties are those that are specifically spelled out in statute, regulations or other laws, ordinances, etc. Implied duties are those that are implied through some but not all contractual relationships—such as a duty of good faith and fair dealings such as that between an insured and his or her insurance carrier.²⁰ However, there are some instances where a contractual relationship is not required for implied duties to attach—such in the case of food products.

¹⁹ *Time Limits for Filing Product Liability Cases: State-by-State*, Copyright © 2008 FindLaw. See Internet at <http://injury.findlaw.com/defective-dangerous-products/defective-dangerous-products-law/state-time-limits-for-filing-product-liability-cases.html>

²⁰ *City of Midland et al v. O'Bryant et al*, 18 S.W.3d. 209 (Tex. 2000)

Many implied duties take the form of a warranty. Manufacturers of products provide express and implied warranties simply by way of doing business. In its broadest sense, a warranty is a type of guarantee that a seller gives regarding the quality of a product. A warranty may be express, meaning that the seller makes certain representations regarding the quality of a product. Yet some warranties may also be implied due to the nature of the sale.²¹

The Uniform Commercial Code (U.C.C.), which has been adopted in part by every state, provides the basis for warranties in the United States. The U.C.C. recognizes express warranties and two types of implied warranties:

- the implied warranty of merchantability: a promise that a product sold is in good working condition and will do what it is intended to do²²
- the implied warranty of fitness for a particular purpose: a promise that a seller's instructions on how to use a product will be accurate and safe²³

To illustrate, the intermediate appellate courts of Missouri have held that in cases involving food and beverages for immediate consumption, there is an implied warranty of fitness of such food and drink for human consumption.²⁴ “When products of food or drink have been prepared under the exclusive supervision of the manufacturer and the consumer must take them as they are supplied, the representations constitute an implied

²¹ *Legal Basis for Liability in Product Cases*, Copyright © 2008 FindLaw. See Internet at <http://injury.findlaw.com/defective-dangerous-products/defective-dangerous-products-law/legal-basis-for-liability-in-product-cases.html>

²² Uniform Commercial Code Article 2-314

²³ Uniform Commercial Code Article 2-315

²⁴ *McIntyre V. Kansas City Coca Cola Bottling Co.*, U.S. Dist. Ct (Western District Of Missouri); 85 F. Supp. 708; 1949

contract, or implied warranty, to the unknown and helpless consumer that the article is good and wholesome and fit for use.”²⁵

In sum, manufacturers/sellers of a product are under a duty to exercise reasonable care in its design so that it can be safely used as intended by its buyer/consumer, and that duty of care extends to all persons within the range of potential danger.²⁶ Thus, manufacturers/sellers must acknowledge the host of legal duties, both express and implied, they have in exchange for the privilege of participating in the sourcing of the nation’s, and the world’s, food supply. The next section contributes to the further understanding of such legal duties.

B. Restatement (Third) of Torts, Product Liability, §10 and § 11.

Companies should also consider an often ignored and overlooked common law legal doctrine explained in Restatement (Third) of Torts, *Product Liability*, specifically §10 and § 11.

The Restatement (Third) of Torts, *Product Liability* is part of a broader treatise called the Restatement of Law. The Restatement of Law is published by the American Law Institute as scholarly refinements and summaries of black-letter law, to "address uncertainty in the law through a restatement of basic legal subjects that would tell judges and lawyers what the law was."²⁷ While considered secondary authority (compare to primary authority), the authoritativeness of the Restatements of the Law is evidenced by their acceptance by courts throughout the United States.

The Restatement (Third) of Torts, *Product Liability* (1997) is the most recent summary of the current state of products liability law-- the law governing personal injury

²⁵ *Id.*

²⁶ See Pike v. Frank G. Hough Co., supra, 2 Cal.3d at p. 470; see also Rest.2d Torts, §§ 395, 398.

²⁷ See Internet at: http://en.wikipedia.org/wiki/Restatement_of_the_Law

claims, including food-related illness and injury claims.²⁸ This paper purports that an understanding of Sections 10 and 11 will provide food companies with a better understanding of some potential, hidden legal risks involved in its recall decision making and execution process. Whether these latent legal risks are considered a loaded gun or empty threat is ultimately left to the reader.

Restatement Duty to Recall

Restatement (Third) of Torts, *Product Liability 11* provides:

One engaged in the business of selling or otherwise distributing products is subject for liability for harm to persons or property caused by a seller's failure to recall a product after the time of sale or distribution if: (a)(1) a government directive issued pursuant to a statute or administrative regulation specifically requires the seller or distributor to recall the product; or (a)(2) the seller or distributor, in the absence of a recall requirement under Subsection (a)(1) undertakes to recall the product and . . . (b) the seller or distributor *fails to act as a reasonable man in recalling the product*. [emphasis added].

Thus, Section 11 imposes an affirmative duty to recall upon sellers and distributors *only* if such duty is expressly required by statute or regulation *or* if the seller or distributor initiates a voluntary recall and performs it in a negligent manner [emphasis added].

The express duty to recall found in subsection (a)(1) will apply in very rare situations as it relates to food per se. The only per se 'food' subject of a statutory recall requirement is infant formula²⁹. Other items under statute or regulation (pursuant to the Federal Food Drug and Cosmetic Act) that may be required by the agency to be recalled

²⁸ Id.

²⁹ 21 USC 250(a); 21 CFR Part 107 Subpart E

are certain biological products (such as blood) and medical devices.³⁰ As such, this so-called “duty to recall” is weak and rarely applied in the context of food.

However, subsection (a)(2) imposes in essence a “duty of care” upon a seller or distributor who voluntarily elects to recall products. If a recall is initiated, it must be executed reasonably in accordance with the well known negligence theory of the “reasonable person standard”. That is, what would a reasonable person with similar knowledge available at the time do under similar circumstances? Hence, sellers and distributors may not have a per se duty to recall, but they do have a duty of care if they recall product in a negligent manner.

So why impose this arguably, “after the fact” duty found in Subsection 11(a)(2)? *Product Liability Restatement §11* Comment c helps explain this question. In sum, the Reporter states that it was believed that a company would choose to recall in anticipation of being required to do so by a government regulator.³¹ An interesting conundrum is revealed—the legal world doesn’t impose a duty to recall because it presumes the regulatory world will. The regulatory world doesn’t impose a duty to recall because it cannot gain the legal backing it needs to pass such mandatory recall legislation in Congress. (Admittedly a sidebar to the major premise of this paper, the author could not resist pointing this out.) Author editorial aside, the real gist of Comment C is its conclusion, namely “. . .the seller should be under a common law duty to follow through on its commitment to recall.”³² Thus, manufacturers and distributors who conduct a voluntary recall should do so with great care, utilizing best in class recall execution

³⁰ 21 USC § 360h(e), and 42 USC § 262

³¹ Product Liability Restatement 11 comment c

³² *Id*

measures so as to ensure its recall will be deemed “reasonable” in the eyes of the regulatory agencies AND the court of law.

Restatement Duty to Warn:

Although there is no duty to initiate a recall under Section 11 or food regulations, is there a duty to warn consumers of contaminated or misbranded products? Restatement (Third) of Torts, *Product Liability* §10 sheds some light on this issue:

Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn:

- (a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller’s failure to provide a warning after the time of sale or distribution of a product when a reasonable person in the seller’s position would provide such a warning.
- (b) A reasonable person in the seller’s position would provide such a warning after the time of sale when:
 - (1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
 - (2) those to whom a warning might be provided can be identified and may reasonably be assumed to be unaware of the risk of harm; and
 - (3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
 - (4) the risk of harm is sufficiently great to justify the burden of the warning.

In short, Section 10 imposes an affirmative duty on sellers and distributors to warn customers/end users post-sale if they know or reasonably should know that their products may cause a substantial risk of harm. Over thirty (30) states have adopted some

form of a post-sale duty to warn provision in its state product liability rubric either by statute or common law.³³

Interestingly, there is a striking lack of case law that asserts a failure to warn claim against food companies who either fail to recall or allegedly wait too long to issue recall notification, resulting in subsequent harm. Conversely, most all case law asserting Section 10 involves consumer products regulated by the Consumer Product Safety Commission under the Consumer Product Safety Act³⁴ as in the *Comstock* case summarized below.

Michigan rendered the seminal, precedent-setting opinion confirming a post sale duty to warn. In 1959, the Michigan Supreme Court decided in *Comstock v. General Motors Corp.*,³⁵ that a car manufacturer had a duty to warn consumers of latent defects discovered “shortly after” the product was sold. In *Comstock*, the car manufacturer learned of a vehicle brake problem in several of the same model of vehicle a few weeks after releasing them for sale. However, the manufacturer took no action to warn buyers of the defect. After reaffirming that Michigan requires manufacturers to warn of defects known at the time of sale, the state supreme court extended this rule post-sale by holding that “a like duty to give prompt warning exists when a latent defect which makes the product hazardous to life becomes known to the manufacturer shortly after the product has been put on the market.”³⁶

The apparent lack of asserting this particular Restatement in food related product liability cases does not mean that it does not apply or that food companies are insulated

³³ Post Sale Duty to Warn: A Report of the Products Liability Committee, American Bar Association Section of Litigation (2004), page 39

³⁴ 15 U.S.C. 2051-2084)

³⁵ 358 Mich. 163, 177-78, 99 N.W.2d 627, 634-35 (1959)

³⁶ *Id.* at 177-78, 99 N.W.2d at 634-35

from this potential legal claim. However, contemplating how a plaintiff's lawyer may prove up a case based on Restatement Section 10 duty to warn against a food company who fails to recall product or unnecessarily delays in recalling product that results in serious adverse health consequences or death may prove useful to food sellers when making the recall decision. Given the dearth of food cases asserting Section 10, comparative analysis is necessary.

When comparing the criteria in Section 10 Subsection (b) that triggers this duty to warn with the definition of Class I food recalls, it becomes clear that Section 10 could indeed be more leveraged as a claim against food manufacturers who elect not to voluntarily recall product that could have been classified as a Class I recall. To revisit, a Class I recall is defined as a "recall involving a health hazard where a reasonable probability exists that consuming the product would cause serious, adverse health consequences or death."³⁷

Consider a hypothetical case similar in facts to the *Comstock vs. General Motors* case summarized above. However, for purposes of illustration, imagine that this case involved a manufacturer of ground beef. The manufacturer distributed numerous cases of one lot of ground beef product to various customers nationwide. A week later, the manufacturer receives two consumer complaints alleging illness after consuming the ground beef. One consumer has remaining product, which the manufacturer decides to retrieve and test. Three days later the test results reveal the presence of a food-borne pathogen, *Listeria monocytogenes*³⁸. The manufacturer does very limiting testing for

³⁷ See FSIS Directive 8080.1 Rev.4 and 21 CFR 7.3 (g)

³⁸ *Listeria monocytogenes* is a high risk pathogen that can cause severe health issues such as vomiting, diarrhea, nausea, fever and stillbirths in pregnant women

Listeria once a month, and exercises a questionable hold and release program of the product that it does test. One consumer suffers severe symptoms and develops *listeriosis*, a severe and potentially fatal illness. The consumer files a lawsuit for personal injury on the basis of strict liability and a failure to warn.

Setting aside the obvious primary claim the plaintiff would assert in strict product liability, does the manufacturer have a duty to warn in this case? When assessing these facts against Restatement (Third) of Torts, Product Liability 10, the answer is, as with most legal claims—gray. Some questions and responsive arguments that would likely surface in the court proceeding based on Section 10 are:

- Would a reasonable person in the seller's position provide such a warning?
(Considerations: Look at industry practices—what triggered other companies to recall similar products. Ask is the risk so great that a reasonable person would warn consumers not to eat the product?)
- Did the seller know or reasonably should have known that the product poses a substantial risk of harm to persons or property? (Considerations: Look at whether the manufacturer should have known that product contained *Listeria*. What it uses industry accepted practices consistent with USDA regulatory requirements? Or were its test and hold practices unreasonably lax?)
- Is the risk of harm to consumers sufficiently high to justify the burden of the warning? (Consideration: Would a reasonable person believe the risk to consumers could result in serious adverse health consequences or death?)

- Is there a way to adequately warn those consumers who may have purchased the suspect product? (Consideration: Ask whether a recall press release should be issued to notify the public not to consume the product?)

Notwithstanding the unique proclivities of different state laws and more importantly, judges, the ultimate outcome would likely echo the holding in *Comstock*: the manufacturer should have known that a food borne pathogen was in its product before it shipped it, and regardless, had actual notice of the defect upon receipt of the consumer complaints³⁹, thus triggering a duty to warn consumers of a substantial risk of injury.

Thus, the overlay of Section 10 to the Class I recall definition renders frighteningly clear that the food industry is not insulated from a duty to warn. This should be taken into consideration when recall teams and food industry legal counsel are making their respective recall decisions.

CONCLUSION

Manufacturers/sellers of food products must contend with numerous regulatory and legal concepts, guidance, regulations, and laws when deciding and executing a product recall. Although neither FDA nor USDA can require a company to initiate a recall, the agencies have other enforcement tools to use as leverage to incent companies to voluntarily recall products. As if the regulations aren't enough to understand, there is a whole body of legal doctrine imposing legal duties and obligations on manufacturers and sellers of food products. Thus, food companies should always ask their respective legal counsel to serve on the internal recall decision team to ensure that both regulatory

³⁹ “. . .defects become known or knowable by consumer complaints...” *Product Liability Restatement* 10 *comment b*, c 1997

agency regulations and expectations as well as the common law legal duties are being considered when making the recall decision.