THE IMPACT OF MANDATORY RECALLS ON NEGLIGENCE AND PRODUCT LIABILITY LITIGATION UNDER THE FOOD SAFETY MODERNIZATION ACT

I. INTRODUCTION

Most Americans—at least once in their lives—will utter the words, "It must have been something I ate," hands pressed against their stomachs as they rush to the bathroom to disgorge their last meal. Many will never see a doctor, but instead, will climb into bed and wait for the illness to pass. Forty-eight million other Americans though, will seek medical help.[1] Three thousand of them will die annually of food-borne illnesses.[2] The federal government has attempted to decrease these numbers by passing the Food Safety Modernization Act ("FSMA"), which was signed into law by President Obama on January 4, 2011.[3] The overall goal of the FSMA is " . . . to improve the nation's food safety by empowering the [Food and Drug Administration ("FDA")] to effectively promulgate, oversee, and enforce food safety regulations."[4] To accomplish this goal, the FSMA shifts focus from responding to contamination to preventing it.[5]

Most experts support the new law, but not everyone is pleased.[6] Critics speculate the new provisions of the FSMA " . . . will likely create a

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[1] *See* CDC and Food Safety, CDC.GOV, http://www.cdc.gov/foodsafety/cdc-and-food-safety.html (last visited Jan. 2, 2013).

[2] *Id.*

[3] *The New Food Safety Modernization Act (FSMA),* FDA.GOV, http://www.fda.gov/Food/FoodSafety/FSMA/default.htm (last visited Jan. 2, 2013).

[4] Philip N. Yannella & Eliot J. Walker, *The Food Safety Modernization Act: A Review of the Act and Its Potential Impact on Private Litigation*, PRODUCT SAFETY & LIABILITY REPORTER, 30 PSLR 110, 2 (2011), *available at* http://www.dechert.com/files/Publication/6ca5625b-1d19-4c2f-9cf1-0ed1e5a33158/Presentation/PublicationAttachment/5f8640cc-4978-47d9-984d-20dd694afd19/The%20Food%20Safety%20Modernization%20Act.pdf.

[5] *See* The New Food Safety Modernization Act, supra note 3.

[6] *See* Debra M. Strauss, An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business, 66 FOOD & DRUG L.J. 353, 357 (2011).

whole host of litigation issues."[7] Section 206, which gives the FDA the authority to order a mandatory recall, is one such provision critics claim is "one of the most ominous and far-reaching provisions of the FSMA."[8] More specifically, critics argue the term "reasonable probability,"[9] as used in section 206, is not a stringent enough standard, and that when coupled with a mandatory recall will be seen as proof that a manufacturer was negligent.[10] This assertion is itself too broad. The FSMA will not increase litigation, nor make it easier for plaintiffs to succeed.[11] Rather, it is likely the courts will interpret the term "reasonable probability"[12] as it has been interpreted under the Food, Drug and Cosmetic Act ("FDCA"), with the result being little to no effect at all on litigation.[13]

Section II of this Comment will briefly discuss the history of federal food safety regulation and notable food-borne illness outbreaks that prompted the creation of the FSMA. Section III will focus on the role of negligence in food industry litigation prior to the passage of the FSMA, specifically plaintiffs' reliance on the res ipsa loquitur doctrine. Section IV will focus on the term "reasonable probability,"[14] including the probable interpretation of the term and how it will affect plaintiffs' lawsuits. Section V will focus on product liability theories and how there will likely be no change or increase in litigation caused by the FSMA. Finally, Section VI will examine preemption and limited immunity provisions for food manufacturers that might further calm food industry fears over litigation.

II. THE HISTORY OF FOOD SAFETY REGULATION IN THE UNITED STATES AND THE FOOD SAFETY MODERNIZATION ACT

Federal food safety regulation began in 1906 when Congress enacted the Meat Inspection Act ("MIA") and the Pure Food and Drug Act

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[7] Gary Wolensky, Anne Marie Ellis, & Kelly Regan, *The Food Safety Modernization Act: Another Law Of Unintended Consequences?*, ABA MASS TORTS LITIGATION, VOL. 10 NO. 1, 3 (2011), *available at* http://hewittwolensky.com/wp-content/uploads/2012/01/litigation-masstorts-fall2011.pdf.

[8] *Id.*

[9] *See* Food Safety Modernization Act § 206, 21 U.S.C. § 3501 (2011).

[10] *See* Wolensky, Ellis, & Regan, *supra* note 7, at 4; *See* Yanella & Walker, *supra* note 4, at 4 (stating that the FSMA " . . . leave[s] the courthouse doors open to plaintiffs' attorneys . . .").

[11] *See infra* Part IV, Subsection A.

[12] *See* Food Safety Modernization Act § 206.

[13] *See infra* Part IV.

[14] *See* Food Safety Modernization Act § 206.

("PFDA").[15] The MIA authorized federal inspections of meat processing facilities,[16] while the PFDA prohibited dangerous foods, drugs, and consumer deception.[17]

The next significant change in food safety law was the passage of the FDCA in 1938, which came about amidst public outrage over the government's inability to assure product safety.[18] The FDCA enlarged the " . . . FDA's food safety authority . . ." by authorizing the FDA " . . . to inspect factories, establish safety tolerances for unavoidable poisons, and create identity and quality standards."[19] The FDCA also required manufacturers " . . . to label food ingredients"[20] and increased penalties for violations.[21] Over the next seventy years, amendments to the FDCA further expanded food safety regulation under the Infant Formula Act of 1980,[22] the Nutrition Labeling and Education Act of 1990,[23] the Food Quality Protection Act of 1996,[24] the Food and Drug Administration and Modernization Act of 1997,[25] and the Food Allergen Labeling and Consumer Protection Act of 2004,[26] to name a few.

As society has changed and grown, so has the food industry, its manufacturing methods, and the resulting dangers.[27] The FSMA gives the FDA the tools to prevent[28] these widespread food-borne illness out-

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[15] Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 64 (2000-2001) (discussing regulation of food products by the federal government beginning in 1906).

[16] *Id.* at 79.

[17] Dennis R. Johnson, The History of the 1906 Pure Food and Drugs Act and the Meat Inspection Act, 37 FOOD DRUG COSM. L.J. 5, 8 (1982).

[18] Merrill & Francer, *supra* note 15, at 81.

[19] *Id.*

[20] *Id.* at 81-82.

[21] James Harvey Young, The Government and the Consumer: Evolution of Food and Drug Laws. The 1938 Food, Drug, and Cosmetic Act, 13 J. PUB. L. 197, 203 (1964).

[22] *See* Infant Formula Act of 1980, 21 U.S.C. § 350a (West 2013).

[23] *See* Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343 (West 2013).

[24] *See* Food Quality Protection Act of 1996, 7 U.S.C. § 136 (West 2013).

[25] *See* Food and Drug Administration and Modernization Act of 1997, 21 U.S.C. § 301 (West 2013).

[26] *See* Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (West 2013).

[27] Michael R. Taylor *Forward in* The Food Safety Modernization Act: A Comprehensive, Practical Guide to the Landmark Legislation, xvii (James William Woodlee, ed., FDLI 2010).

[28] *See The New Food Safety Modernization Act, supra* note 3 (prior law only allowed the FDA to respond after an outbreak occurred).

breaks.[29] For example, in 2008, more than one-thousand people in forty-three states became sick with *Salmonella* poisoning.[30] The outbreak was linked to tomatoes, jalapenos, and serrano peppers from Mexico and Florida.[31] In 2009, contaminated peanut butter was recalled after nine people died and more than twenty-thousand were sickened by *Salmonella*.[32] Finally, in 2010, Wright County Egg of Galt, Iowa recalled more than 380 million eggs after hundreds of people became sick with *Salmonella*.[33] The FSMA is designed to prevent outbreaks such as these and make sure the United States' food supply is safe.[34]

At first glance, the FSMA appears to be an extraordinary step in the right direction in the interests of consumer safety and industry accountability.[35] However, the FSMA is not without its critics.[36] One such criticism concerns section 206, which now gives the FDA authority to order mandatory recalls of food products if it determines "that there is a *reasonable probability* that an article of food is adulterated . . . or misbranded . . . and the use or exposure . . . will cause serious adverse health consequences or death to humans or animals."[37] The FDA must also provide current recall information on its website, including the current status of a recall.[38] Critics argue that "reasonable probability"[39] is not a stringent enough standard and that when combined with a mandatory recall will be seen as proof that a food is dangerous, encouraging the filing of successful lawsuits.[40] However, such an assertion ignores the legal requirements of proving negligence and product liability theories.[41]

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[29] *See* Susan A. Schneider, *Notes on Food Law: An Overview of the Food Safety Modernization Act*, 2011 ARK.L. NOTES 39, 46 (2011) (discussing the complexity of a global food system and the tools the FSMA gives the FDA to meet challenges).

[30] *13 Worst Foodborne Illness Outbreaks in U.S. History*, HEALTHLINE.COM, http://www.healthline.com/health-slideshow/worst-foodborne-illness-outbreaks#13 (last visited Jan. 4, 2013).

[31] *Id*.

[32] *Id*.

[33] William Neuman, *Egg Recall Expanded After Salmonella Outbreak*, NYTIMES.COM (August 18, 2010), http://www.nytimes.com/2010/08/19/business/19eggs.html (last visited Jan. 4, 2013).

[34] *See The New Food Safety Modernization Act, supra* note 3.

[35] *See Food Safety Modernization Act*, Frequently Asked Questions, FDA.GOV, http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm (last visited Jan. 4, 2013).

[36] *See* Wolensky, Ellis, & Regan, *supra* note 7; *See generally* Yanella & Walker, *supra* note 4, at 4.

[37] Food Safety Modernization Act § 206, 21 U.S.C.A. § 3501 (2011) (emphasis added).

[38] *Id*.

[39] *Id*.

[40] *See* Wolensky, Ellis, & Regan, *supra* note 7, at 4.

[41] *See infra* Part III.

III. LIABILITY FOR FOOD-BORNE ILLNESSES PRIOR TO THE FSMA

Prior to the passage of the FSMA, negligence claims that concerned adulterated food almost always failed because it is very difficult to prove a defendant's food caused illness.[42] Plaintiffs attempted to get around this hurdle by using the doctrine of res ipsa loquitur;[43] however, use of the doctrine presented difficulties.[44]

Negligence is a failure to show the same care towards another that a reasonable person would in the same situation.[45] Plaintiffs must prove four elements in order to establish a defendant's negligence: duty, breach, causation, and damages.[46] Where plaintiffs have only circumstantial evidence that the defendant was negligent, plaintiffs may resort to the doctrine of res ipsa loquitur to create a presumption of negligence.[47] To succeed, however, plaintiffs must prove that more likely than not the defendant's negligence caused their injury.[48]

Res ipsa loquitur is a state law doctrine; however, federal courts apply it according to the state in which they sit.[49] The requirements of the doctrine are set out in *Ford v. Miller Meat Company*, 28 Cal.App.4th 1196 (1994).[50] In that case, the plaintiff brought suit against a supermarket and meat supplier for negligence after she broke a tooth when she bit into a bone fragment in ground beef she had purchased.[51] The case was ultimately decided on appeal in favor of the defendant, and the appellate court provided a three-prong test for determining if res ipsa loquitur applies.[52] First, the incident " . . . must be caused by an agency or instrumentality under the exclusive control of the defendant."[53] Second, the incident " . . . must be of a type that ordinarily does not happen unless someone is negligent."[54] Third, " . . . it must not have been due to any voluntary act or contributory fault of the plaintiff."[55]

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[42] David Polin, *Proof of Liability for Food Poisoning*, *in* 47 Am.Jur. Proof of Facts 3d § 18 (1998).
[43] *See Id.* § 21.
[44] *See infra* Part III; *See infra* Part IV, Subsection B.
[45] *See* RESTATEMENT (SECOND) OF TORTS § 298 (1965).
[46] *See* RESTATEMENT (SECOND) OF TORTS § 328A (1965).
[47] *See generally* RESTATEMENT (SECOND) OF TORTS § 328D (1965).
[48] *See* Polin, *supra* note 42, § 21.
[49] Daniel A. Morris, *Evidentiary Matters—Res Ipsa Loquitur*, *in* Federal Tort Claims § 2:24 (June 2012).
[50] Ford v. Miller Meat Co., 28 Cal.App.4th 1196, 1202-03 (Ca. 1994).
[51] *Id.* at 1199.
[52] *Id.* at 1202-03.
[53] *Id.* at 1202.
[54] *Id.*
[55] *Id.* at 1202-03.

In determining if the first prong is met in food-borne illness cases, courts also look at whether plaintiffs have excluded all other possibilities for their illness.[56] In *Burnett v. Essex Insurance Company*, 773 So.2d 786 (La. 2000), the plaintiffs' physician testified that the illness was unrelated to one of the plaintiff's chronic abdominal problems because the other plaintiff in the case contracted the illness at the same time.[57] However, tests were not done to determine whether the illness was bacterial or viral, or from where it might have originated.[58] The court found the plaintiffs' proof was insufficient because their physician could not rule out other possible causes of illness, such as local drinking water, or the fact that one of the plaintiffs was prone to gastric disorders.[59] The burden has proven even more difficult to satisfy when a plaintiff has eaten previous meals, which was a factor in *Hairston v. Burger King Corporation*, 764 So.2d 176 (La. 2000). The *Hairston* court found the plaintiff's evidence insufficient because her medical expert testified the cause of illness could have been anything she had eaten an hour or even a week before eating defendant's food and becoming ill.[60]

As for the second prong, even where there is evidence the defendant was negligent, it does not automatically lead to the conclusion the illness occurred because of this negligence.[61] In the unpublished opinion of *Jones v. Varallo's Restaurant, Inc.*, No. 91C-1481, 1992 WL 301300 (Tenn. 1992), the court upheld a motion for summary judgment for the defendant.[62] The court's reasoning noted that the plaintiff had provided no evidence from which a jury could infer that contaminated food was the result of the defendant's negligence.[63] Also the court found that the contamination could have come from sources other than the defendant's operation.[64]

If these challenges were not already enough, res ipsa loquitur doctrine has been applied differently within some jurisdictions.[65] Georgia's appellate court serves as an example.[66] In *Stevenson v. Winn-Dixie Atlanta,*

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[56] *See* Burnett v. Essex Ins. Co., 773 So.2d 786, 790 (La. App. Ct. 2000).
[57] *Id.* at 788.
[58] *Id.*
[59] *Id.* at 790.
[60] Hairston v. Burger King Corp., 764 So.2d 176, 178 (La. App. Ct. 2000).
[61] Polin, *supra* note 42, § 21.
[62] Jones v. Varallo's Restaurant, Inc., No. 91C-1481, 1992 WL 301300, at 1 (Tenn. App. Ct. Oct. 23, 1992).
[63] *Id.*
[64] *Id*.
[65] Polin, *supra* note 42, § 21.
[66] *See* Stevenson v. Winn-Dixie Atlanta, Inc., 211 Ga.App. 572, 574, 440 S.E.2d 465 (1993).

Inc., 211 Ga. App. 572 (Ga. 1993), the plaintiff and her children consumed the defendant's ice cream and experienced fever, nausea, vomiting, and diarrhea.[67] The *Stevenson* court held that res ipsa loquitur was not applicable because the nature of the incident was not sufficient to indicate that it was caused by the defendant's negligence and the plaintiff had not excluded every other possible cause of her illness.[68] The court further found that the amount of ice cream consumed, the speed at which it was consumed, a virus, or some other unknown source could have reasonably caused the family's illness.[69] This case, similar to the cases previously referenced, was decided against the plaintiff, and further added to the list of factors plaintiffs had the burden of excluding.[70]

However, two dissenting judges in *Stevenson* believed res ipsa loquitur should have applied and the case should have been allowed to proceed to trial.[71] The dissent noted that if in the opinion of the jury the most *reasonable* cause of the plaintiff's illness was the ice cream, then the defendant was guilty of negligence.[72] In effect, the dissent would have relaxed evidentiary requirements under the doctrine to allow the case to proceed to trial, and left it to a jury to decide whether the defendant's negligence was the most reasonable cause of the plaintiff's illness.[73]

Following *Stevenson*, the dissent's view prevailed eight years later in *Worthy v. The Beautiful Restaurant, Inc. et al.*, 252 Ga.App. 479 (Ga. 2001).[74] In that case, the plaintiff was six months pregnant when she ate eggs in the defendant's restaurant and began experiencing abdominal pain, vomiting, and diarrhea.[75] Two weeks later, the plaintiff visited a physician and was diagnosed with a severe case of *Trichomoniasis*, which is a sexually transmitted disease, and a urinary tract infection.[76] The following day, she was admitted to the hospital, where it was discovered that her fetal membranes had ruptured prematurely.[77] Seven days later her son was born with several birth defects.[78]

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[67] *Id.* at 573.
[68] *Id.* at 574.
[69] *Id.*
[70] *See supra* Part III.
[71] *See Stevenson*, 211 Ga.App. at 575.
[72] *Id.* at 577 (emphasis added).
[73] *See id*.
[74] *See* Worthy v. Beautiful Restaurant, Inc., 252 Ga.App. 479, 481, 556 S.E.2d 185 (2001).
[75] *Id.* at 479-480.
[76] *Id.* at 480.
[77] *Id*.
[78] *Id.*

The *Worthy* court ruled that a genuine issue of material fact existed as to whether the eggs served by the defendant were the only reasonable source of the plaintiff's illness and the resulting birth defects of her son.[79] The court further held that a genuine issue of material fact existed as to whether the rupture of fetal membranes would be a foreseeable consequence of the plaintiff's illness.[80] Thus, as the dissent had proposed in *Stevenson*, the *Worthy* court left the decision as to whether the eggs were the cause of the plaintiff's injury to the jury.[81]

With the exception of *Worthy*, litigation appeared to favor defendants.[82] If we are to believe the critics, the FSMA will allow plaintiffs to point to the mandatory recall of a product and allege that the manufacturer more likely than not was negligent.[83] This would suggest that post-FSMA plaintiffs' burden would be less than the requirements of res ipsa loquitur.[84] However, prior federal laws interpret the term "reasonable probability,"[85] and it seems likely the standard will remain the same, making it difficult to win lawsuits.[86]

IV. DEFINING "REASONABLE PROBABILITY" UNDER THE FSMA

Post-FSMA, the standard of proof in a negligence claim is likely to remain as burdensome to plaintiffs as it was before the passage of the law.[87] Critics speculate such a broad term gives the FDA too much power and will allow plaintiffs to attempt to use such a finding by the FDA to infer that a food manufacturer's product is dangerous and file suit.[88] Determination of whether this will be the case depends on how "reasonable probability"[89] is interpreted under the FSMA's mandatory recall provision.[90] The FDA has not promulgated rules providing guidance on how it will interpret "reasonable probability."[91] Further, the

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[79] *See id.* at 481.
[80] *See id.*
[81] *See* Stevenson v. Winn-Dixie Atlanta, Inc., 211 Ga.App. 572, 577, 440 S.E.2d 465 (1993).
[82] *See supra* Part III.
[83] *See* Wolensky, Ellis, & Regan, *supra* note 7, at 4.
[84] *See infra* Part IV (analyzing the burden as not being less than current res ipsa loquitur requirements, but likely remaining the same).
[85] *See* 21 C.F.R. § 810.2(h) (West 2013); *See* Food Safety Modernization Act § 206, 21 U.S.C.A § 3501.
[86] *See infra* Part IV, Subsection A.
[87] *See infra* Part IV, Subsection A; *See infra* Part IV, Subsection B.
[88] *See* Wolensky, Ellis, & Regan, *supra* note 7, at 4.
[89] *See* Food Safety Modernization Act § 206, 21 U.S.C.A. § 3501 (2011).
[90] *See id.*
[91] *See id.*

FSMA is so new there is no case law that provides criteria. However, the FSMA is not the first federal law to use the term "reasonable probability."[92] The term is also used in FDCA regulations.[93]

There is support for the belief that "reasonable probability"[94] under the FSMA could be interpreted similar to the way in which it is under the FDCA.[95] In the past, the United States Supreme Court has looked to language interpretation in other statutes to interpret undefined terms.[96] For example, in *Oscar Mayer & Co. v. Evans*, 441 U.S. 750 (1979), the plaintiff sued for violation of the Age Discrimination and Employment Act ("ADEA").[97] One of the main issues in contention was the construction of a specific section of the law.[98] The Supreme Court ultimately relied on Title VII, an earlier statute, in constructing the ADEA because the statutes shared the same purpose, the language was almost verbatim, and the legislative history indicated that the contended section of the ADEA found its source from Title VII.[99]

When analyzing the FSMA and the FDCA, the similarities they share are starkly apparent.[100] Both share a similar purpose—protecting the public from products with a "reasonable probability"[101] of causing harm.[102] Both also share the same language.[103] The FDCA defines a Class I recall as " . . . a situation in which there is a *reasonable probability that* the use of, or exposure to, a . . . product *will cause serious adverse health consequences or death*."[104] Similarly, the requirement for a mandatory recall under the FSMA is " . . . that there is a *reasonable probability* that an article of food is adulterated . . . or misbranded . . . and the use or exposure . . . *will cause serious adverse health conse-*

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92 *See id.*
93 *See* 21 C.F.R. § 7.3(m)(1) (West 2013).
94 *See* Food Safety Modernization Act § 206.
95 *See* Oscar Mayer & Co. v. Evans, 441 U.S. 750, 756 (1979).
96 *See id.*
97 *See id.* at 754.
98 *See id.* at 756.
99 *Id.* at 756.
100 *See* 21 C.F.R. § 810.2(h) (West 2013) (defining reasonable probability as more likely than not an event will occur); *See* Food Safety Modernization Act § 206, 21 U.S.C.A § 3501.
101 *See* Food Safety Modernization Act § 206.
102 *See* Food Safety Modernization Act § 206; *See generally Background on the FDA Food Safety Modernization Act (FSMA)*, FDA.GOV, http://www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm (last visited Jan. 5, 2013) (discussing the background and purpose of the FSMA).
103 *See Background on the FDA Food Safety Modernization Act*, *supra* note 102.
104 *Supra* note 93 (emphasis added).

quences or death to humans or animals."[105] Lastly, since the FSMA generally expands or modifies existing FDA authority under the FDCA, and because its an amendment, and not a wholly separate statute, as was the case in *Evans*,[106] it can be argued Congress intended terms within the FSMA to be construed the same as the FDCA.[107]

The FDCA would also seem to be an appropriate standard for the FDA to rely on in making mandatory recall determinations.[108] First, the FSMA is an amendment to the FDCA, and both are closely linked in that they exist as a means of protecting the public.[109] Second, both employ very similar language in regard to recalls, including the term "reasonable probability,"[110] which the FDCA defines as "more likely than not an event will occur."[111] It is important to note that this definition is also the same as that of res ipsa loquitur.[112] Third, the FDA provides examples on its website that lump together adulterated foods and medical devices as the types of hazards that would trigger a Class I recall.[113] Finally, under the FDCA, the FDA can make a Class I recall mandatory.[114] Based on this reasoning, as well as the FDA's website, which places food and medical devices in the same category, it seems logical to conclude that "reasonable probability"[115] could be interpreted under section 206 of the FSMA similar to the way it is interpreted under the FDCA.

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[105] Food Safety Modernization Act § 206 (emphasis added).

[106] *See* Oscar Mayer & Co. v. Evans, 441 U.S. 750 (1979) (the United States Supreme Court interpreting language between two separate statutes).

[107] *See generally* Renee Johnson, The FDA Food Safety Modernization Act, at 7, *available at* http://www.nationalaglawcenter.org/assets/crs/R40443.pdf (last visited Oct. 27, 2012) (discussing the FSMA as modifying the FDCA).

[108] *See id.*; *See generally Background on the FDA Food Safety Modernization Act*, *supra* note 102.

[109] *See generally* Johnson, *supra* note 107; *See generally Background on the FDA Food Safety Modernization Act*, *supra* note 102.

[110] *See supra* note 85; *See* Food Safety Modernization Act § 206, 21 U.S.C.A § 3501.

[111] *Supra* note 85.

[112] *See* Polin, *supra* note 42, § 21; *See infra* Part III (stating that to succeed using res ipsa loquitur plaintiffs must prove that *more likely than not* the defendant's negligence was the cause of injury).

[113] *See FDA 101: Product Recalls—From First Alert to Effectiveness Checks*, FDA.GOV, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm (last visited Jan. 5, 2013).

[114] *See* 21 C.F.R. § 810.10 (West 2013); *See also id.*

[115] *See* Food Safety Modernization Act § 206.

A. Interpretation of the FDCA Applied to the FSMA and Negligence Suits

Analogous case law supports adoption of the FDCA's definition as a logical choice.[116] Such an adoption would mean plaintiffs would be prohibited from using a mandatory recall to support the use of res ipsa loquitur to allege that a food manufacturer must have caused their illness.[117] A mandatory recall would only show that the FDA found the food manufacturer had deviated from a regulation under the FSMA, rather than serve as evidence that the manufacturer had been negligent.[118] Thus, plaintiffs would only be operating on the assumption that a mandatory recall was a deviation from FSMA regulations, and would not be enough to satisfy res ipsa loquitur requirements.[119]

A similar approach was applied in *Gross v. Stryker Corporation*, 858 F.Supp.2d 466 (W.D. Penn. 2012), where the plaintiff's artificial hip failed.[120] After a year, a subsequent surgery revealed that the device had fractured.[121] Sometime after the plaintiff's surgery, the defendant manufacturer recalled the device.[122] The plaintiff claimed that by recalling the device, the defendant admitted its manufacture violated FDCA regulations and requirements and he brought a product liability and negligence claim asserting the res ipsa loquitur doctrine.[123] The court held that even if a plaintiff does properly plead facts demonstrating a defendant's failure to satisfy regulations, there is no private cause of action against a manufacturer under the FDCA.[124] The court also found that the recall was only evidence that the FDA purportedly acknowledged some deviation from current good manufacturing practices.[125] The court's reasoning was that the recall did not establish an applicable standard of care that supported a negligence claim, nor did it establish any duty that the defendant owed the plaintiff.[126]

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116 *See infra* Part IV, Subsection A.
117 *See* Gross v. Stryker Corp., 858 F.Supp.2d 466, 497 (W.D. Penn. 2012) (holding that a warning letter or voluntary recall did not establish a breach of duty on the part of the manufacturer).
118 *Id.*
119 *See Gross*, 858 F.Supp.2d at 497; *See Ford*, 28 Cal.App.4th at 1202-03. (stating res ipsa loquitur requirements).
120 *Gross*, 858 F.Supp.2d at 471-72 (2012).
121 *Id.* at 472.
122 *Id.* at 473.
123 *See id.* at 482-83.
124 *Id.* at 492.
125 *Id.* at 497.
126 *Gross*, 858 F.Supp.2d at 497.

An analogous case concerning a mandatory recall provides even stronger support for adopting the FDCA as the standard for interpreting the FSMA.[127] In *In re Medtronics, Inc. Sprint Fidelis Leads Products Liability Litigation*, 592 F.Supp.2d 466 (D. Minn. 2009), which involved an FDA order of a Class I recall,[128] the plaintiffs alleged the defendant violated the FDCA by failing to timely inform the FDA that the leads of its implantable cardiac defibrillator were defective.[129] The court held that the FDCA did not create private rights of action.[130] If the same reasoning were extended to the FSMA, which also does not provide a private right of action,[131] then plaintiffs might also be precluded from relying on the FSMA as the basis for a lawsuit.[132]

If the same rationales as those in the preceding two cases were extended to suits alleging violation of the FSMA, there would be no reason for food manufactures to fret over a mandatory recall because merely pointing to a mandatory recall and alleging the manufacturer must have been negligent is unsupported by case law.[133] Thus, a food manufacturer's mandatory recall would not be proof of a breach of duty to a consumer, but only that the manufacturer deviated from FSMA regulations.[134] Plaintiffs would likely be unable to successfully allege a cause of action under such a circumstance.[135]

1. Food Manufacturers' Possible Vulnerability Under the FSMA

There is an exception food manufacturers should be aware of that might expose them to liability; however, it is an exception within their ability to control.[136] In another case, *Bass v. Stryker Corporation*, 669 F.3d 501 (5th Cir. 2012), which involved the same defendant and medical device as *Gross*,[137] the *Bass* court held that if a plaintiff plead that a manufacturer failed to comply with its own specific processes or procedures approved by the FDA and the failure caused an injury, the claim

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[127] *See* In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F.Supp.2d 1147, 1161 (D. Minn. 2009); *See infra* Part IV.
[128] *Supra* note 93.
[129] *See In re Medtronic, Inc.*, 592 F.Supp.2d at 1159.
[130] *Id.* at 1161.
[131] *See generally* Food Safety Modernization Act, 21 U.S.C.A. § 3501 (West 2011) (no provisions in the act allow for a private right of action).
[132] *See In re Medtronic, Inc.*, 592 F.Supp.2d at 1161.
[133] *See* Gross v. Stryker Corp., 858 F.Supp.2d 466, 497 (W.D. Penn. 2012); *See In re Medtronic, Inc.*, 592 F.Supp.2d at 1161.
[134] *See Gross*, 858 F.Supp.2d at 497.
[135] *See id.*
[136] *See* Bass v. Stryker Corp., 669 F.3d 501, 512 (5th Cir. 2012).
[137] *See generally Gross*, 858 F.Supp.2d at 466.

could stand.[138] The difference between the two cases is that in *Gross* the plaintiff alleged his injury was a result of defendant's failure to adhere to FDA regulations; whereas in *Bass*, the plaintiff alleged his injury was a result of the defendant failing to adhere to its own manufacturing standards.[139]

Even as applied to the FSMA, the outcome would still be in favor of the manufacturer, even though it violated the FSMA and its product was recalled, unless the manufacturer deviated from its own manufacturing practices.[140] In a suit involving adulterated food, the burden would be on the plaintiff to show that the food manufacturer violated its own rules, not that it violated the FSMA.[141] Thus, there is an incentive for food manufacturers to remain in compliance with their own established standards.[142] Such standards must be reported to the FDA and updated every three years under the FSMA anyway;[143] therefore, it stands to reason it should be a much lighter burden for food manufactures to rebut any accusations made by plaintiffs.[144]

B. The Future of Litigation For Negligence Claims Relying on Res Ipsa Loquitur

Based on the above, it seems likely the res ipsa loquitur doctrine will be applied the same way post-FSMA, as it was pre-FSMA.[145] Considering the close relationship and language between the FDCA and FSMA, it is likely that courts could find that the FSMA does not provide a private right of action, nor that a mandatory recall is evidence of negligence.[146] Since res ipsa loquitur requires plaintiffs to prove *more likely than not* a food manufacturer caused their injury, and the FDCA defines "reasonable probability . . . "[147] as " . . . *more likely than not* an event will occur," the standard would likely remain the same since the FDCA and res ipsa loquitur doctrine use the same language.[148] Food manufacturers would

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138 *Bass*, 669 F.3d at 512.
139 *See Gross*, 858 F.Supp.2d at 497; *See Bass*, 669 F.3d at 513.
140 *See Bass*, 669 F.3d at 513.
141 *See id.*
142 *Id.*
143 *See* Food Safety Modernization Act § 103, 21 U.S.C. § 3501 (2011) (requiring hazard analysis and risk-based preventive controls to be established by food manufacturers).
144 *See id.*
145 *See supra* Part IV; *See supra* Part IV, Subsection A.
146 *See supra* Part IV.
147 *Supra* note 85.
148 *See id.* (emphasis added).

remain protected by the fact that the burden of proof under res ipsa loquitur is a heavy one.[149]

Applying the three-prong test in *Ford*,[150] the analysis would have similar outcomes as those previously examined.[151] Under the first prong, plaintiffs must properly identify the manufacturer and prove they became sick from the manufacturer's product.[152] It would not be adequate for a plaintiff to allege he became sick after eating the manufacturer's product, and as a result, the defendant must have been negligent in some way.[153] The plaintiff has the burden of proving that, more likely than not, the defendant, (or the defendant's employees or agents), caused the food to become adulterated while it was under the defendant's exclusive control.[154] This can be difficult to prove since the food industry is large and complex, and a product can pass through the hands of many different people or companies before reaching grocery stores or restaurants.[155]

Under *Burnett*, satisfying the burden of res ipsa loquitur would also still require the plaintiff to rule out other possible causes of their illness.[156] For example, a plaintiff with a history of stomach disorders would have to prove, possibly through the testimony of his doctor, that the illness that resulted after consuming the manufacturer's food product was completely independent of any existing intestinal or other medical illness.[157] To overcome such a burden, a plaintiff would have to prove the symptoms allegedly caused by the defendant's food product are significantly different or have little in common with any symptoms stemming from his existing medical condition.[158] Proof of such differences would have to be sufficient enough to leave little or no doubt that the manufacturer acted negligently to cause the plaintiff's illness.[159]

In addition, as shown in *Hairston*, this burden can be even more difficult when a plaintiff has eaten previous meals.[160] The application of this requirement to a negligence claim makes the burden on the plaintiff seem overwhelming.[161] Not only must a plaintiff still prove that more likely

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149 *See Supra* Part III; *See infra* Part IV, Subsection B.
150 Ford v. Miller Meat Co., 28 Cal.App.4th 1196, 1202-03 (Ca. App. Ct. 1994).
151 *See supra* Part III.
152 *Ford*, 28 Cal.App.4th at 1202.
153 *See* Polin, *supra* note 42, § 21.
154 *Ford*, 28 Cal.App.4th at 1202.
155 J.A. Beaman & A.J. Johnson, Food Distribution Channel Overview, at 1 (2006).
156 *See* Burnett v. Essex, Inc., 773 So.2d 786, 790 (La. App. Ct. 2000).
157 *See id*.
158 *See id.* at 788.
159 *See Ford*, 28 Cal.App.4th at 1202.
160 *See* Hairston v. Burger King Corp., 764 So.2d 176, 178 (La. App. Ct. 2000).
161 *See id.*

than not the defendant's negligence was the cause of his illness, but he must also prove that everything else he ate on the same day he consumed the manufacturer's product, or even the same week, did not cause his illness.[162] Accepting the assumption that an average person eats at least three times a day over a seven-day period, there could be at least twenty meals, not counting the manufacturer's product, which a plaintiff faces the challenge of disqualifying as the cause of his illness.[163]

Other variables compound the problem of proving a food manufacturer's negligence, such as whether there is any possibility another agent might have caused the contamination before the product reached the plaintiff, or whether the plaintiff caused the illness through his own negligent preparation or even storage of the product.[164] In addition, when the plaintiff goes to the hospital for treatment of the potential food-borne illness, tests are not likely going to be able to isolate the exact food that caused the plaintiff's illness.[165] Many different products can cause bacteria such as *Salmonella* and *E.coli*.[166] Both can also survive for days outside of the human body, and even once they are consumed, there can be a delay before any symptoms begin to appear.[167] If no symptoms appear for several days, the plaintiff could be faced with excluding a higher amount of possible foods that could have caused their illness in the span of time between ingesting the food and becoming physically ill.[168] Logically, it seems highly unlikely that a plaintiff would succeed under res ipsa loquitur doctrine in such circumstances, unless the only meal they had eaten in the period between ingestion and the onset of illness had been the manufacturer's product.

Returning to the second prong in *Ford*, the incident "must be of a type that ordinarily does not happen unless someone is negligent."[169] Based on the manner in which the court dealt with it in *Jones*,[170] plaintiffs face a significant challenge because the United States' food system is com-

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[162] *Id.*

[163] *See id.*

[164] *See Food Safety*, CDC.GOV, http://www.cdc.gov/foodsafety/facts.html#howcontamination (last visited Jan. 5, 2013); *See generally* Beaman & Johnson, *supra* note 155.

[165] *See Food Safety*, *supra* note 164.

[166] *See id.*

[167] *See Viruses, Bacteria, and Parasites in the Digestive Tract*, URMC.ROHESTER.EDU, http://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=90&ContentID=P02019 (last visited Jan. 5, 2013); *See Food Safety*, *supra* note 164.

[168] *See Hairston*, 764 So.2d at 178.

[169] Ford v. Miller Meat Co., 28 Cal.App.4th 1196, 1202 (Ca. 1994).

[170] Jones v. Varallo's Restaurant, Inc., No. 91C-1481, 1992 WL 301300, at 1 (Tenn. App. Ct. 1992) (finding that the contamination could have come from sources other than the defendant).

plex.[171] By the time a food product has reached the supermarket it has traveled countless miles and been handled by several players, from distributors to brokers.[172] Any one of these players might have acted negligently and caused the plaintiff's illness, rather than the manufacturer.[173] For example, products that are required to remain frozen might not have been kept frozen at the correct temperature during transit.[174] Alternatively, the plaintiff may not have prepared the product properly or may have stored it incorrectly.[175] Thus, while res ipsa loquitur may seem to be a viable tool for plaintiffs who would bring a claim against a food manufacturer whose product they suspect made them sick based on the fact it was mandatorily recalled, courts apply a very stringent set of rules that make it difficult for plaintiffs to succeed.[176]

As mentioned previously, courts have applied the doctrine inconsistently within some jurisdictions.[177] Such inconsistent applications can create uncertainty for plaintiffs and discourage them from pursuing litigation.[178] In the context of *Stevenson*, a plaintiff might also have to prove that his illness was not a result of overeating or eating too quickly.[179] However, these two standards ignore the fact that if the food was contaminated, then the amount consumed has no bearing, since other factors, such as age and physical condition better determine how prone someone is to becoming sick after eating adulterated food.[180] The *Stevenson* court also mentioned that the plaintiff failed to show that it was not a virus that caused her and her family to become ill.[181] This factor seems misplaced since viruses can also cause food-borne illnesses.[182] Requiring the plaintiff to exclude such a factor in order to succeed seems antithetic to the purpose of res ipsa loquitur since if she had been able to identify a virus

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171 Beaman & Johnson, *supra* note 155.
172 *Id*.
173 *See generally* Beaman & Johnson, *supra* note 155; *See generally Food Safety*, *supra* note 164.
174 *See generally Food Safety*, *supra* note 164.
175 *See id*.
176 *See supra* Part IV, Subsection B.
177 *See supra* Part III.
178 *See generally How Much Do Lawsuits Cost?*, CALABORLAW.COM, http://www.calaborlaw.com/2008/09/26/how-much-do-lawsuits-cost/ (last visited Jan. 5, 2013) (discussing average litigation costs for plaintiffs, and attorneys' reluctance to take a case on contingency if the case is frivolous).
179 *See* Stevenson v. Winn-Dixie Atlanta, Inc., 211 Ga.App. 572, 574, 440 S.E.2d 465 (1993).
180 *See Food Safety*, *supra* note 164.
181 *See Stevenson*, 211 Ga.App. at 575.
182 *See Food Safety*, *supra* note 164 (such viruses include *Norovirus*, which is highly contagious and causes inflammation of the stomach or intestines).

it would have strengthened her case and possibly eliminated her reliance on the doctrine.[183] What exactly the court meant by adding this factor is unclear, but one possible reason might have been to further reinforce the burden on plaintiffs in future, similar cases.[184]

If the dissent's view were adopted, and such a relaxed standard were the norm, any negligence action would have a much greater chance of surviving summary judgment and proceeding to trial because it disregards those burdens previously mentioned, which plaintiffs currently face.[185] If this were the case, then the concerns put forth by critics of the FSMA would be well founded. As critics assert, plaintiffs could sue, literally alleging a manufacturer's recalled product caused their illness, and then proceed to trial by virtue of the fact that they got sick after eating that product.[186] In such a case, the courthouse doors would be wide open to plaintiffs and their attorneys.[187] However, case law shows that such an outcome does not generally occur.[188]

Of course, there is always a rare exception, as seen in *Worthy*.[189] In its opinion, the Georgia appeals court distinguished *Stevenson* from *Worthy* by explaining that in the former case the plaintiff's expert admitted that things other than the ice cream which the plaintiff ingested could have caused the plaintiff's illness.[190] Whereas in the latter, "although it . . . strain[ed] credulity," the plaintiff's experts pointed to the eggs served by the restaurant as the only reasonable source of the plaintiff's illness.[191] This explanation disregards the fact that the court in *Stevenson* also gave consideration to the defendant's evidence, which the plaintiff failed to refute.[192]

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[183] *See Stevenson*, 211 Ga.App. at 574 (holding that a virus was just as reasonable a cause of plaintiff's illness as a food-borne illness; however, contrary to what the Court holds, some food-borne illnesses are caused by a virus).

[184] *See id.* (holding that illness alone is not sufficient to prove that a defendant was the cause of plaintiff's illness. The court states other factors, such as a virus, the amount consumed, or the speed at which it was consumed could also be the cause of illness. Therefore, plaintiffs have the burden of excluding these as possible causes).

[185] *See supra* Part III.

[186] *See* Wolensky, Ellis, & Regan, *supra* note 7, at 4.

[187] Yannella & Walker, *supra* note 4, at 4.

[188] *See supra* Part III; *See supra* Part IV, Subsection B.

[189] *See* Worthy v. Beautiful Restaurant, Inc., 252 Ga.App. 479, 481, 556 S.E.2d 185 (2001) (holding that plaintiff's assertion that defendant's eggs were the only reasonable cause of her food-borne illness, even though defendant's evidence and plaintiff's medical history showed otherwise, and would likely have satisfied *Stevenson*).

[190] *Id.*

[191] *Id.*

[192] *See Stevenson*, 211 Ga.App. at 573-74.

In *Worthy*, the court's opinion ignored the defendant's evidence, which is troublesome when viewed in light of the plaintiff's own medical history.[193] Also missing from the analysis, as well as the defendant's argument, was the plaintiff's severe *Trichomoniasis* infection, which is also known to cause premature delivery in pregnant women.[194] But perhaps the most troubling aspect of this opinion stems from four words in the opinion: "although it . . . strain[ed] credulity."[195] Res ipsa loquitur doctrine is meant to allow plaintiffs to remain in court using circumstantial evidence, but this language seems to suggest that the plaintiff's evidence in *Worthy* might not have reached even this level.[196] Unfortunately, much is left unaddressed in the *Worthy* opinion, perhaps so that the court could arrive at the result the dissent had wanted in *Stevenson*.[197] With the exception of *Worthy*, which is a rare anomaly amongst the case law, res ipsa loquitur already presented its share of challenges for plaintiffs.[198] With the passage of the FSMA, the same challenges will still exist.[199]

Case law and analysis favors food manufacturers over plaintiffs on negligence claims relying on res ipsa loquitur doctrine.[200] Plaintiffs shouldered a heavy burden prior to the FSMA, and with the passage of the FSMA, it is likely this burden will not change.[201] Whether it will even have a place in suits involving mandatory recalls ultimately remains to be seen since the FDA has yet to mandate one.[202] All of this, of course, is assuming a food manufacturer does not voluntarily recall the product on its own, which has always and continues to be, the norm in the industry.[203]

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193 *See Worthy*, 252 Ga.App. at 480.

194 *Trichomoniasis Fact Sheet*, CDC.GOV, http://www.cdc.gov/std/trichomonas/STD Fact-Trichomoniasis.htm (last visited Jam. 5, 2013).

195 *Worthy*, 252 Ga.App. at 481.

196 *Id.*

197 *See Stevenson*, 211 Ga.App. at 577.

198 *See supra* Part III; *See supra* Part IV, Subsection B.

199 *See supra* Part IV, Subsection A.

200 *See supra* Part III; *See supra* Part IV, Subsection B.

201 *See id.*

202 *See generally The New Food Safety Modernization Act, supra* note 3 (no mandatory recalls have yet been listed on the FDA's website).

203 Michael T. Roberts, Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety, 59 FOOD & DRUG L.J. 563, 583 (2004).

V. THE FSMA'S AFFECT ON OTHER PRODUCT LIABILITY THEORIES

Like negligence and res ipsa loquitur, similar outcomes would likely be seen in claims concerning theories of product liability.[204] Under these other theories, plaintiffs can file a lawsuit against a food manufacturer alleging they were injured by the manufacturer's product because it was designed or manufactured defectively,[205] or the food manufacturer failed to properly warn the consumer of a latent danger in the product.[206] Plaintiffs can also allege the manufacturer's product breached the implied warranty of merchantability, which is an unspoken guarantee from the seller to the buyer that the purchased product is fit for the ordinary purpose for which it is to be used.[207]

Before the passage of the FSMA, such suits were attempted against caffeinated alcoholic beverage manufacturers, following a press release from the FDA, which warned manufacturers that the caffeine added to their alcoholic beverages was an "unsafe food additive."[208] In one case, *Cook v. Millercoors, LLC, et al.*, 829 F.Supp.2d 1208 (M.D. Fla. 2011), the plaintiff was a passenger on a motorcycle in which the driver had consumed several caffeinated alcoholic beverages before having an accident.[209] The district court granted the defendant's motion to dismiss, holding the plaintiff's allegations were insufficient to support her claim.[210] In regard to the failure to warn, the court found that the defendant had no duty to warn of the dangers of consuming alcohol because of the universal recognition of the dangers associated with drinking and driving.[211] Lastly, as to the design defect, the court found that even though the FDA had not recognized stimulants as safe for use in alcoholic beverages, it did not constitute a design defect.[212]

Critics seem to be proposing that an FDA press release is similar to a mandatory recall under the FSMA;[213] however, this is not the case.[214] An

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[204] *See infra* Part V.
[205] *See* RESTATEMENT (THIRD) OF TORTS § 2 (1998).
[206] *See* RESTATEMENT (THIRD) OF TORTS § 10(a) (1998).
[207] *See* U.C.C. § 2-314(2)(c) (2011).
[208] Press Release, Food and Drug Administration, FDA Warning Letters Issued to Four Makers of Caffeinated Alcoholic Beverages (Nov. 17, 2010), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm234109.htm (last visited Jan. 5, 2013).
[209] Cook v. Millercoors, LLC, 829 F.Supp.2d 1208, 1211 (M.D. Fla. 2011).
[210] *See id.* at 1217-19.
[211] *See id.* at 1214.
[212] *See id.* at 1216.
[213] *See generally* Yannella & Walker, *supra* note 4, at 4 (discussing the occurrence of lawsuits following an FDA press release addressing the combination of caffeine and alcohol in products as making those products adulterated).

FDA press release is meant to provide information on a particular matter, while a mandatory recall forces a company to remove a product from the market.[215] If anything, an FDA press release is more like a voluntary recall, in that when a company recalls a product voluntarily, the FDA publishes this information on its website and includes it in its weekly enforcement report.[216] However, assuming for the sake of argument that a press release and a mandatory recall can be reconciled as being of the same nature, a product liability suit based on a mandatory recall would likely have a similar outcome as that of the *Cook* case.[217]

A suit alleging failure to warn based on a mandatory recall would likely be difficult to prove.[218] Under a failure to warn claim, the plaintiff would have to prove that a food product was made unsafe or dangerous because the food manufacturer failed to provide sufficient warnings, instructions, or labels with the product.[219] The plaintiff would have to prove that a reasonable person in the manufacturer's position would have provided a warning about the product.[220] However, food manufacturers are not likely to place a product on the market they believe will cause a food-borne illness, and products such as fruits, vegetables, and nuts do not easily lend themselves to the ready discovery of whether they are adulterated in the same way that alcohol is known to be dangerous.[221] In addition, food manufacturers are highly unlikely to put a warning label on such products because such a label would be off-putting to consumers.[222] Consumers want to feel confident when they bite into an apple that it is completely safe.[223] Consumers cannot do this with the thought

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[214] *See infra* Part V.

[215] *See* Food Safety Modernization Act § 206, 21 U.S.C.A. § 3501 (2011); *See generally Press Announcements*, FDA.GOV, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm (last visited Jan. 5, 2013) (the FSMA authorizes mandatory recalls, but press release only announces voluntary recalls).

[216] *See generally Enforcement Reports*, FDA.GOV, http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm (last visited Jan. 5, 2013) (providing information to consumers on all voluntary recalls).

[217] *See Cook*, 829 F.Supp.2d at 1216 (holding that the FDA's finding that the addition of stimulants to alcoholic beverages did not establish a correlation between the FDA's findings and the safety of the product).

[218] *See infra* Part V.

[219] *See* RESTATEMENT (THIRD) OF TORTS § 10(a) (1998).

[220] *Id.*

[221] See *Cook*, 829 F.Supp.2d at 1214.

[222] *See generally* 21 C.F.R. § 101.17 (West 2013) (not requiring labels on fruits and vegetables).

[223] *See Survey: Consumer Confidence About Produce Safety Improving—Consumers Expect Industry to Make Changes*, PMA.COM, http://www.pma.com/press-center/press-

of a warning label in the back of their mind that they might become sick later.[224] If this were the case, they would likely not buy the product.[225]

A claim for design defect appears to be the most difficult claim for plaintiffs to prove against a food manufacturer.[226] A product has a design defect when its design makes it unreasonably dangerous.[227] Like *Cook*, even if the FDA recognizes the use of an ingredient as not safe, it does not necessarily mean there is a design defect.[228] A food product is defective in design only when there is a foreseeable risk of harm, which could have been avoided by using an alternative design.[229] In the case of foods (excluding meat and poultry), there is only one way to grow them; i.e., farming. Further, because of section 103 of the FSMA, if there is an alternative design that is less dangerous to consumers, it will likely have already been in place and approved by the FDA.[230]

A claim for breach of implied warranty might provide a narrow condition in which plaintiffs might maintain a claim.[231] In *Cuevas v. United Brands Co., Inc*, No. 11cv991, 2012 WL 760403 (S.D. Ca. 2012), a plaintiff sued for breach of implied warranty, alleging the product's label failed to adequately disclose the amount of caffeine or the risks associated with caffeinated alcoholic beverages.[232] The court denied defendant's motion to dismiss, reasoning the plaintiff's claim was not based on the inherent dangers of alcohol but on the undisclosed effects of caffeine and alcohol combined.[233]

The problem with this, of course, is that an alcoholic beverage filled with caffeine is not the same as a fruit or vegetable contaminated with *E.coli* or *Salmonella* bacteria. Alcohol is universally recognized as dangerous,[234] but it is a product that consumers willingly ingest. Consumers do not buy fruits or vegetables because they want to ingest harmful bac-

releases/survey-consumer-confidence-about-produce-safety-improving-consumers-exp-2 (last visited Jan. 5, 2013).

[224] *See generally id.* (stating that consumers expect higher safety standards from the food industry).

[225] *See generally id.*

[226] *See infra* Part IV.

[227] *See* RESTATEMENT (THIRD) OF TORTS § 2 (1998).

[228] *See* Cook v. Millercoors, LLC, 829 F.Supp.2d 1208, 1216 (M.D. Fla. 2011).

[229] *See* RESTATEMENT (THIRD) OF TORTS § 2 (1998).

[230] *See generally* Food Safety Modernization Act § 103, 21 U.S.C. § 3501 (2011) (requiring hazard analysis and risk-based preventive controls to be established by food manufacturers).

[231] *See infra* Part V.

[232] Cuevas v. United Brands Co., Inc., No. 11cv991, 2012 WL 760403, at 1 (S.D. Ca. Mar. 8, 2012).

[233] *Id.* at 8-9.

[234] *See* Cook v. Millercoors, LLC, 829 F.Supp.2d 1208, 1214 (M.D. Fla. 2011).

teria that can lead to kidney failure or death, nor are food producers likely to place labels on fruits and vegetables regarding the possible presence of bacteria, so a case involving mandatorily recalled food would look different. Further, a company that refuses a mandatory recall may very well open themselves up to a product liability claim.[235] However, this will still require the company to have actually committed an act prohibited under product liability.[236] Greater regulation through the FSMA can actually help food manufacturers avoid such lawsuits by making sure they comply with the law's requirements.

The above assumes that a press release and a mandatory recall are equal; however, as already mentioned, both are quite different in their purpose.[237] To speculate in such a broad manner as critics have done seems presumptive in light of the analysis provided up to this point.[238] It seems likely the courts would be more inclined to adopt a position similar to that in which they have with the FDCA in regard to similar lawsuits.[239] However, the large question that seems to be looming over critics' speculation is why some food manufacturers are so against, or perhaps afraid, of the FSMA. The FSMA will not increase litigation or the chances a food manufacturer will be obligated to pay large judgments, as shown in the cases cited.[240] The speculation of these charges alleged by critics seems tainted with an element of fear mongering.[241] One might conclude food manufacturers are against it because they do not want consumers knowing when they are cutting corners and taking risks with safety for the sake of increasing profits.[242]

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[235] *See* Wolensky, Ellis, & Regan, *supra* note 7, at 4.
[236] *See supra* Part V.
[237] *See id.*
[238] *See supra* Part IV; *See supra* Part V.
[239] *See supra* Part V.
[240] *See* Cook v. Millercoors, LLC, 829 F.Supp.2d 1208, 1219 (M.D. Fla. 2011); *See* Cuevas v. United Brands Co., Inc., No. 11cv991, 2012 WL 760403, at 8 (S.D. Ca. Mar. 8, 2012); *See supra* Part V.
[241] *See generally* Matt Kibbe, *Overreaching Food "Safety" Modernization Act Would Destroy Family Farmers*, REDSTATE.COM, http://www.redstate.com/mattkibbe/2010/11/19/overreaching-food-safety-modernization-act-would-destroy-family-farmers/ (last visited Jan. 5, 2013) (misrepresenting provisions of the FSMA and the effects it would have on food manufacturers).
[242] *See generally How Food Manufacturers Turn Mouldy, Mislabeled or Outright Contaminated Foods into Edible—and Profitable—Goods*, DAILYMAIL.COM, http://www.dailymail.co.uk/news/article-2067330/How-food-manufacturers-turn-mouldy-mislabelled-outright-contaminated-foods-edible--profitable--goods.html (last visited Jan. 5, 2013) (discussing how manufacturers reuse moldy food products to create profits).

VI. RECOMMENDATIONS

The FSMA will likely have little or no impact on negligence and product liability litigation, but one way to calm concerns and fears in the food industry would be to limit the liability of food manufacturers in private litigation.[243] Providing food manufacturers with limited immunity from civil actions when they comply with an FDA request for a voluntary recall may provide a measure of reassurance for food manufacturers.[244] Often "when faced with the prospect of an unsafe product, companies have a conflict of interest: they want to remove the contaminated product from the stream of commerce, but they fear that too much adverse publicity generated by a recall may taint their . . . image."[245] Such a conflict "may cause a company to engage in a recall . . . that is smaller and slower than is necessary to protect public health."[246] With the FDA's mandatory recall power looming, combined with a measure of immunity for voluntarily recalling a product, it will lessen conflicts and prompt food manufacturers to act quickly.[247]

Another way to strengthen the law and calm concerns would be to amend the law to expressly preempt state regulations similar to the FDCA.[248] This would allow manufacturers to only concern themselves with complying with the FSMA, rather than the FSMA and state laws.[249] This would also bring the FSMA closer in line with the FDCA, which preempts state claims regarding medical devices where the state law adds or takes away from the FDCA.[250] The policy behind limiting the liability of medical device manufacturers was to spur innovation, even though individuals are sometimes injured when using medical devices.[251] Such a policy promotes medical advancement and economic interests.[252] Adopting a similar policy for the FSMA could promote economic interests by

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[243] *See* Roberts, *supra* note 203.
[244] *Id.*
[245] *Id.* at 582.
[246] *Id*.
[247] *Id*.
[248] *See* 21 U.S.C.A. § 360k (West 2013).
[249] *See generally* Food Safety Modernization Act, 21 U.S.C.A. § 3501 (several sections, such as 103, 105, 112, and 402 expressly prohibit preemption).
[250] *See* 21 U.S.C.A. § 360k (West 2013).
[251] In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F.Supp.2d 1147, 1166 (D. Minn. Jan. 5, 2009).
[252] *Id.*

keeping food manufacturing costs low and thereby allowing consumers to continue purchasing affordable food products.[253]

VII. CONCLUSION

"Much has been made of the FDA's new mandatory recall authority . . ." but the agency has yet to even " . . . exercise it."[254] In fact, the FDA might be hesitant to use its new power.[255] Based on the words of Michael Taylor, FDA Deputy Commissioner for Foods, who said, "a mandatory recall is a sign of failure. It means preventative controls were either not in place or not used effectively. It means a company has not accepted the responsibility for its actions,"[256] a mandatory recall may be used as only a very last resort.

No law is perfect, but the FSMA will turn out to be a step in the right direction for food safety in the long run. Voluntary recalls continue to be the norm, and in most cases the FDA and the food industry continue to work together to ensure adulterated food is removed quickly from the stream of commerce.[257] The new mandatory recall authority merely gives the FDA additional leverage if any case should arise in which a company refuses or is incapable of instituting a voluntary recall.[258]

With the heightened sense of concern for food safety among consumer advocacy groups, giving the FDA additional leverage to compel the recall of unsafe food products makes sense for the protection of consumers and for the well-being of the food industry.[259] There is nothing to suggest the FSMA has left food manufacturers open to increased lawsuits or

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[253] *See contra* Gary Wolensky, Anne Marie Ellis, & Kelly Regan, *The Food Safety Modernization Act: Another Law Of Unintended Consequences?*, American Bar Association, Mass Torts Litigation, Vol. 10 No. 1, 3, http://hewittwolensky.com/wp-content/uploads/2012/01/litigation-masstorts-fall2011.pdf (last visited Jan. 2, 2013).

[254] Food & Supplements Second Annual Workshop, Food Safety Modernization Act Update, 4 (June 12, 2012), *available at* http://www.americanbar.org/content/dam/aba/administrative/litigation/materials/2012_food_supplements_2nd_annual_cle_wrkshp/2012_aba_panel1_aba_food_safety_modernization_act_update.authcheckdam.pdf; *Cf.* Josh Hicks, *FDA Uses New Authority to Shut Down Peanut Butter Plant Linked to Outbreak*, WASHINGTON POST BLOG, (Nov. 28, 2012, 12:30 PM), http://www.washingtonpost.com/blogs/federal-eye/wp/2012/11/28/fda-uses-new-authority-to-shut-down-peanut-butter-plant-linked-to-outbreak/ (discussing the FDA's first exercise of its registration suspension authority under section 102 of the FSMA, giving it the power to close a food manufacturer's facility).

[255] *See* Food & Supplements Second Annual Workshop, *supra* note 254.

[256] *Id.*

[257] Roberts, *supra* note 203 (discussing the benefits of a mandatory recall system).

[258] *See id.*

[259] *See generally id.*

given plaintiffs the opportunity to win huge windfall judgments based on only a small amount of evidence.[260] If such an outcome is likely, then the possible alternative discussed above is possibly more likely, since there is supporting evidence.[261]

However, a law like the FSMA should not raise worries over how it will affect a company's pocketbook, but about whether it is strong enough to improve our society. Consumers put their trust in manufacturers who provide food. The government should create laws to make sure that trust is not misplaced. The FSMA gives the FDA the tools to do this. With such a heightened degree of trust placed upon food manufacturers they should be subject to broad regulation. Consumers should know exactly how these companies make sure their food is delivered to the supermarkets in a safe condition. Food manufacturers should want that too because greater consumer trust can help the bottom line just as easily as cutting corners.

DAVID BENTON[262]

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[260] *See* Wolensky, Ellis, & Regan, *supra* note 7, at 4; *See* Yannella & Walker, *supra* note 4, at 4.

[261] *See supra* Part IV; *See supra* Part V.

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