

Maine Law Review

Volume 65
Number 2 *Colloquium: Local Food || Global Food:*
Do We Have What It Takes to Reinvent the U.S. Food System?

Article 17

January 2013

How Reliance on the Private Enforcement of Public Regulatory Programs Undermines Food Safety in the United States: The Case of Needed Meat

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Recommended Citation

Diana R. Winters, *How Reliance on the Private Enforcement of Public Regulatory Programs Undermines Food Safety in the United States: The Case of Needed Meat*, 65 Me. L. Rev. 719 (2013).
Available at: <https://digitalcommons.mainerlaw.maine.edu/mlr/vol65/iss2/17>

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HOW RELIANCE ON THE PRIVATE ENFORCEMENT OF PUBLIC REGULATORY PROGRAMS UNDERMINES FOOD SAFETY IN THE UNITED STATES: THE CASE OF NEEDLED MEAT

Diana R. H. Winters

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HOW RELIANCE ON THE PRIVATE ENFORCEMENT OF PUBLIC REGULATORY PROGRAMS UNDERMINES FOOD SAFETY IN THE UNITED STATES: THE CASE OF NEEDLED MEAT

*Diana R. H. Winters**

INTRODUCTION

Mechanically tenderized meat is a relatively small, although persistent, food-safety problem in terms of the number of individuals affected by foodborne illness. However, the regulatory history of mechanically tenderized meat is a window into a much larger issue, that of regulatory inertia and the inadequacy of existing mechanisms to counter this stasis. This regulatory inertia does not have a simple cause, nor is it amenable to a simple solution. It cannot be reduced to a problem of agency capture, or a problem with agency incompetence, and although I will propose a couple of fixes, all of them have flaws.

Telling the story of the ongoing conversation on mechanically tenderized meat among the United States Department of Agriculture (USDA), the meat production industry, and interest groups representing the consuming public is important for at least two reasons. First, the focus on a food safety problem that is not well known to the public illustrates the commonplace nature of regulatory inertia, demonstrating that such cases are not confined to high-profile issues with elusive solutions. It is striking that this story of delay and dysfunction takes place in the context of a politically uncontroversial issue that is amenable to a simple regulatory solution and that is particularly well suited to national regulation. Although regulatory inertia is not easily fixed, the problem with mechanically tenderized beef is.

Second, this story demonstrates the ineffectual nature of private enforcement. Private enforcement, in the form of agency-forcing suits, should act as a counterpoint to agency delay and dysfunction, by subjecting agency action to judicial review. We expect the judiciary to oversee the process of regulatory fermentation, and to ensure that an agency makes its decisions in a timely, appropriate manner. If an agency acts contrary to its statutory mandate, or bows excessively to political pressure, then oversight by the neutral judiciary should get it back on track. Here, however, government, industry, and advocacy groups representing the consuming public have been discussing this issue for a decade while individuals continue to get sick. Judicial review is, of course, unavailable until a party brings suit. No parties have done so here, although regulatory inaction has persisted for over a decade.

And, if a party does bring suit—for example, imagine that a consumer advocacy group sues the USDA for denying its petition requesting that

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mechanically tenderized meat be labeled—there are shortcomings with the judicial review process itself. These deficiencies include a lack of judicial expertise in the complex matters regulated by agencies, a piecemeal approach to solving regulatory problems, and difficulty and inconsistency in the implementation of judicial directives.

“Mechanical tenderization,” or “blade tenderization,” or “needling,” or “hammering,” is a process where tiny cuts are made in beef by needles or blades, which cut the connective tissue and immediately tenderize the meat.¹ Mechanical tenderization has been used for decades, and meat that has been mechanically tenderized is sold to restaurants, hotels, group homes, and, now more frequently to grocery stores.² Statistics about the amount of beef mechanically tenderized per year are unavailable, but “a 2008 USDA survey showed that more than 90 percent of beef producers are using it on some cuts,” and there is some evidence that the amount of beef being mechanically tenderized is increasing.³ Needled meat is usually indistinguishable from “intact” meat, and it is usually not labeled.⁴

When meat is mechanically tenderized, it becomes more susceptible to contamination by pathogens that cause foodborne illness because the needles can carry bacteria, such as *E. coli*, into the interior of the meat, where it is harder to kill by cooking.⁵ There have been at least six recalls of needled meat since 2000, five of which were associated with illnesses.⁶ Because of its increased susceptibility to contamination, the USDA recommends that mechanically tenderized meat be cooked to a higher temperature than intact cuts of meat.⁷

Several times over the last decade, consumer protection and food safety advocates have called on the USDA to require the labeling of mechanically tenderized meat, and to educate retailers and consumers about the process.⁸ For the most part, the USDA has not responded, although there is currently a proposed rule to require the labeling of mechanically tenderized beef in review with the Office of

1. Bill Marler, *My Steak Has Been Needle or Blade Penetrated or Hammered – Really? What About E. Coli?*, FOOD POISON JOURNAL (Dec. 26, 2009), <http://www.foodpoisonjournal.com/food-poisoning-information/my-steak-has-been-needle-or-blade-penetrated-or-hammered-really-what-about-e-coli/>.

2. Mike McGraw, *Beef's Raw Edges*, KANSAS CITY STAR.COM, (Dec. 6, 2012), <http://www.kansascity.com/2012/12/08/3951690/beefs-raw-edges.html>.

3. *Id.* (quoting David Theno, a beef industry consultant and food safety expert, who commented that cattle are coming to market sooner, and “may be less tender than animals that spend more time in feedlots”).

4. *See id.*

5. *See* Sarah Zhang, *Grosser Than Pink Slime: Poop-Contaminated, Mechanically Tenderized Beef*, MOTHER JONES (Dec. 11, 2011), <http://www.motherjones.com/environment/2012/12/e-coli-mechanically-tenderized-beef>; Author's own research (on file with author). In August 2009, another journalist found six *E. coli* O157:H7 outbreaks associated with mechanically tenderized beef between 2003 and 2009. *See* Gretchen Goetz, *Food Safety Advocates to USDA: Require Labeling for Tenderized Meat*, FOOD SAFETY NEWS (Aug. 27, 2012), <http://www.foodsafetynews.com/2012/08/advocates-call-on-usda-to-require-labeling-for-mechanically-tenderized-meat/>.

6. *Infra* Section I.B.

7. McGraw, *supra* note 2; Marler, *supra* note 1.

8. *See, e.g.*, Letter from Safe Food Coal., to the Honorable Tom Vilsack, Sec'y, U.S. DEPT. OF AGRIC. (June 12, 2009), available at [http://www.marlerblog.com/uploads/file/SFC_letter_to_Vilsack_Meat_Tenderization_6_12_09\[1\]\[1\].pdf](http://www.marlerblog.com/uploads/file/SFC_letter_to_Vilsack_Meat_Tenderization_6_12_09[1][1].pdf).

Management and Budget (OMB).⁹

Exact statistics are difficult to come by, but by most counts mechanically tenderized meat has been associated with approximately 100 illnesses, and a handful of deaths.¹⁰ When compared to other major foodborne illness outbreaks of the past decade—listeria-contaminated cantaloupe killed over thirty people in 2011,¹¹ more than a thousand people were sickened by eggs in 2010,¹² over four hundred people were hospitalized because of tainted peanut butter in 2009 and at least six people died,¹³ and in 2006, contaminated spinach sickened 131 people and hospitalized at least sixty¹⁴—these numbers seem insignificant. In fact, in August of 2012, Dr. Richard Raymond, Undersecretary for Food Safety at the USDA from 2005-2008, said that although the idea of regulating mechanically tenderized meat had been discussed at the Food Safety and Inspection Service's (FSIS) meetings, "the risk [of illness] was not significant enough to require a labeling process."¹⁵

This "small" problem, however, is particularly amenable to a regulatory solution for five reasons. First, it is extremely hard to bring private actions against wrongdoers.¹⁶ Second, the harm here is widely diffused. It is difficult to trace the source of foodborne illness to a particular food, much less a particular meat processor. Third, the food supply is a model of information asymmetry. It is difficult even for regulatory agencies to gather information about the treatment of meat,¹⁷ and even more so for the average consumer. Fourth, regulating needle-tenderized meat is politically unremarkable. It *is* potentially economically impactful, and for this reason, the USDA is subject to industry pressure not to regulate, but this is not an issue that is going to raise moral or ethical hackles.¹⁸ Fifth, the regulatory solution here is *easy*. Consumer advocates are calling for increased information disclosure, which can be implemented without large change to the current meat production and distribution system.

9. Goetz, *supra* note 5.

10. See Zhang, *supra* note 5; author's own research (on file with author). Both illnesses and deaths may be undercounted because of underreporting and difficulty in identifying and tracing mechanically tenderized meat.

11. *Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado*, CENTERS FOR DISEASE CONTROL & PREVENTION (Sept. 4, 2012), <http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html>.

12. Scott Hensley, *Salmonella Cases Rise as Recall of Contaminated Eggs Grows*, NPR (Jan. 7, 2011), <http://www.npr.org/blogs/health/2010/08/20/129321965/salmonella-recalled-egg-contamination>. Salmonellosis is an infection caused by the bacteria salmonella.

13. Associated Press, *More peanut butter products recalled*, MSNBC (Jan. 18, 2009), http://www.msnbc.msn.com/id/28695782/ns/health-food_safety/.

14. Drew Falkenstein, *Spinach recall among Huffington Post's worst product recalls of all time*, FOOD POISON J. (Feb. 24, 2010), <http://www.foodpoisonjournal.com/2010/02/articles/foodborne-illness-outbreaks/spinach-recall-among-huffington-posts-worst-product-recalls-of-all-time/>

15. Goetz, *supra* note 5.

16. Richard A. Epstein, Laurence A. Tisch Professor of Law, New York Univ. Law Sch., Speech at Hoover Institution: Environmental Law 101 (Oct. 27, 1998), in *HOOVER DIGEST*, Apr. 30, 1999, available at <http://www.hoover.org/publications/hoover-digest/article/7436> ("The governing principle is simply this: Wherever it's hard to organize private actions against admitted wrongdoers, then it is permissible to resort to direct governmental regulation . . .").

17. McGraw, *supra* note 2.

18. Think, for example, of the attempt to switch emergency contraception to over-the-counter status for women of all ages.

What has taken place over the last decade, however, belies the apparent simplicity of this regulatory solution. The ongoing discussion between the agency, industry, and the consuming public (through advocacy groups) has resulted only in unfulfilled promises, and regulatory inaction. Notably absent from this discussion is the judiciary. By continuing to talk to advocacy groups, and repeatedly promising action, the agency has thus far been able to avoid suit.

Is litigation the answer? I have previously advocated for more litigation in the food-safety context, and noted that the paucity of such litigation is a function of custom and history, not barriers to suit.¹⁹ Filing suit would surely be a step toward a resolution of this issue, but it is far from a satisfying answer. If an advocacy group filed a formal petition with an agency that failed to respond or responded negatively and the group then sued the delay inherent in the suit would be appended to the thirteen prior years of inaction. And in the context of health and safety regulation, this delay is unacceptable. There must be other mechanisms in addition to private enforcement to force agency action in situations where the agency itself has evidence that action is warranted, but action is stalled due to industry or political pressure.

First, Congress should increase its use of statutory hammers. Hammers are legislative mechanisms that impose consequences on an agency that fails to act in compliance with a statutory mandate. For example, one type of hammer imposes substantive standards to go into effect if an agency fails to regulate by a certain date.²⁰ Another converts proposed regulations to final regulations if an agency fails to promulgate final regulations in a timely manner.²¹

Second, interest groups, including both regulated industry and those representing the consuming public should be able to petition the Office of Information and Regulatory Affairs (OIRA), within the OMB, to review agency inaction. Simply put, OIRA, which provides centralized review to certain major regulations to assess compliance with cost-benefit principles,²² is theoretically positioned to assume a larger role in reviewing agency inaction. This suggestion is subject to several major objections, including OIRA's limited scope (its review is cabined to "significant" regulations, and it currently has no mandate to review inaction), and the susceptibility of OIRA to industry pressure and a non-regulatory bias.²³ Nevertheless, OIRA's potential as a rationalizing body should not be overlooked.

This Paper proceeds as follows: Part I discusses mechanically tenderized

19. Diana R. H. Winters, *Not Sick Yet: Food-Safety-Impact Litigation and Barriers to Justiciability*, 77 BROOK. L. REV. 905 (2012).

20. M. Elizabeth Magill, *Congressional Control Over Agency Rulemaking: The Nutrition Labeling and Education Act's Hammer Provisions*, 50 FOOD & DRUG L.J. 149, 154 (1995). Magill notes that the 1984 Amendments to the Resource Conservation and Recovery Act contain several of these devices. *Id.* at 154 n.19.

21. *Id.* at 150.

22. Curtis Copeland, *The Role of the Office of Information and Regulatory Affairs in Federal Rulemaking*, 33 FORDHAM URB. L.J. 1257, 1259 (2006).

23. See, e.g., Nicholas Bagley and Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1267-68 (2006) (arguing that OIRA only reviews regulations to see if they are too stringent, not too lax; that OIRA rarely, if ever, reviews decisions to deregulate; that an agency inaction is not scrutinized; and that these three factors bias the agency against regulation).

meat, and its regulatory history, including a discussion of the history of the dialogue that has taken place regarding needled meat between the USDA, the meat industry, and the consuming public; Part II discusses the shortcomings of private enforcement, including the role that the failure by interest groups to bring suit against the agency plays in regulatory inertia, and the potential detriments to judicial review; and Part III discusses my proposals, including an increased use of statutory hammers and the expansion of OIRA review.

I. THE REGULATION OF MECHANICALLY TENDERIZED BEEF OVER THE LAST DECADE

A. *The Process of Mechanical Tenderization*

As described above, mechanical tenderization is a process where tiny incisions are made in a piece of meat, for example, a steak or a roast, by needles or blades. This cuts the connective tissue, and immediately tenderizes the meat.²⁴ More than 90 percent of beef producers are using mechanical tenderization on some cuts to improve the quality of the meat, and over fifty million pounds of mechanically tenderized meat is sold to restaurants, institutions, and stores each month.²⁵ Mechanically tenderized meat is indistinguishable from intact meat, and the USDA does not require that it be labeled.

As the needles or blades penetrate the meat, they can carry pathogens, such as *E. coli*,²⁶ that are on the surface of the meat, to the interior of the meat. Because cooking kills many of these pathogens, including *E. coli*, driving the pathogens into the meat makes it more difficult to eradicate any potentially dangerous bacteria.

This is why the USDA recommends that consumers cook beef steaks (“intact meat”) and roasts to an internal temperature of 145 degrees, but recommends that ground meat be cooked to 160 degrees.²⁷ The higher temperature is necessary to kill pathogens distributed throughout the product in the grinding process.

Whether mechanically tenderized meat is actually more susceptible to contamination by pathogens is contested. The American Meat Institute (AMI), a meat and poultry trade organization, states “the risk of illness from *E. coli* O157:H7 in such products ‘is not significantly higher.’”²⁸ The AMI cited a 2008 USDA study. In 2011, however, the Journal of Food Protection found blade-tenderized steaks to be two to four times riskier than intact meat.²⁹

Notwithstanding its acknowledgement that mechanically tenderized meat can

24. Marler, *supra* note 1.

25. McGraw, *supra* note 2.

26. *E. coli* O157:H7 is a pathogen capable of causing serious foodborne illness in humans. There are other dangerous strains of *E. coli*, but the USDA only began testing for these strains in September 2011. See Press Release, U.S. DEPT. OF AGRIC., USDA Takes New Steps to Fight *E. Coli*, Protect Food Supply (Sept. 13, 2011) available at <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2011/09/0400.xml>.

27. Diane Van, *Cooking Meat? Check the New Recommended Temperatures*, USDA BLOG (May 25, 2011, 4:28 PM), <http://blogs.usda.gov/2011/05/25/cooking-meat-check-the-new-recommended-temperatures/>.

28. McGraw, *supra* note 2.

29. *Id.*

carry *E. coli* contamination, the FSIS does not test this meat for *E. coli* O157:H7.³⁰ The FSIS does test ground beef, and beef trimmings used to make ground beef for this pathogen.³¹

B. Foodborne Illness Outbreaks Associated with Mechanically Tenderized Meat

Since 2000, there have been at least six, and perhaps more, recalls of mechanically tenderized meat.³² The *Kansas City Star* reports “mechanically tenderized beef could have been the source of as many as 100 outbreaks of *E. coli* and other illnesses in the United States in recent years . . . affect[ing] more than 3,100 people who ate contaminated meat.”³³

These recalls include one in June 2003, when 739,000 pounds of meat were recalled for *E. coli* contamination.³⁴ At least eleven cases of foodborne illness associated with this recalled meat were reported.³⁵ In December 2009, a quarter million pounds of mechanically tenderized meat was recalled after twenty-one consumers in sixteen states were sickened with *E. coli* poisoning. Nine of the consumers were hospitalized.³⁶ The Washington Post reported that this was at least the fourth recall associated with mechanically tenderized beef since 2000.³⁷ There were two recalls of mechanically tenderized meat in 2012, one of 2,057 pounds, and one of 890,000 pounds of meat.³⁸

The amount of meat recalled over the last decade or so, and the number of people made ill by mechanically tenderized meat are difficult to pin down. Foodborne illness is historically underreported (many people suffer alone, and even those who do go to doctors may not be tested for foodborne illness), and foodborne illness is notoriously difficult to trace (even if an affected person could remember what exactly she ate, correlating that food with other illness and tracing the food to its source are extremely difficult). Moreover, the USDA does not require meat producers to compile and report statistics as to the amount of mechanically tenderized meat that they sell.

30. Food Safety and Inspection Serv., *For Business and Industry: Notice 32-05- Verification of Establishment's Reassessment of HACCP Plans to Address Mechanically Tenderized Beef*, USDA.GOV, http://www.fsis.usda.gov/HELP/FAQs_TSC_Notice32_05/index.asp (last modified Feb. 13, 2006).

31. See Food Safety and Inspection Serv., *Microbiology Testing Program for Escherichia coli O157:H7 and non-O157 Shiga toxin-producing Escherichia coli (STEC)*, USDA.GOV, http://www.fsis.usda.gov/Science/Ground_Beef_E.Coli_Testing_Results/index.asp (last modified Jan. 31, 2012).

32. See McGraw, *supra* note 2; See also Zhang, *supra* note 5.

33. McGraw, *supra* note 2.

34. HACCP Plan Reassessment for Mechanically Tenderized Beef Products, 70 Fed. Reg. 30331, 30332 (May 26, 2005) (to be codified at 9 C.F.R. pt. 417).

35. *Id.*

36. Lyndsey Layton, *E. Coli-Tainted Beer Infects 21 People in 16 States*, WASH. POST., Dec. 30, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/12/29/AR2009122902772.html?hpid=moreheadlines>.

37. *Id.*

38. See Recall Release, U.S. DEPT. OF AGRIC., Maine Firm Recalls Ground and Tenderized Beef Products Due to Possible *E. Coli* O157:H7 Contamination (Apr. 11, 2012) *available at* http://www.fsis.usda.gov/News_&_Events/Recall_024_2012_Release/index.asp; Gretchen Goetz, *Canadian Beef Recall Grows, Again*, FOOD SAFETY NEWS (Oct. 2, 2012) http://www.foodsafetynews.com/2012/10/canadian-beef-recall-grows-again/#.UNTW46C8_ww.

It is clear, though, that mechanically tenderized meat has been repeatedly and consistently associated with outbreaks of foodborne illness. This phenomenon has not escaped the notice of consumer and food-safety interest groups, which have been advocating for USDA to more strictly regulate mechanically tenderized beef for at least a decade.

C. The Conversation About Mechanically Tenderized Meat

Since at least 1999, the USDA, industry, and consumer advocacy groups have been discussing the safety of needle tenderized meat through a mixture of policy statements, informal letters, formal petitions, and scientific studies.

In January 1999, the FSIS issued a policy statement regarding the contamination of meat by *E. coli* O157:H7. The statement explained that, as of 1994, ground beef contaminated with this strain of *E. coli* was considered “adulterated” under the FMIA, and clarified that:

[W]ith the exception of beef products that are intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a ready-to-eat product—i.e., a food product that may be consumed safely without any further cooking or other preparation.³⁹

The FSIS also explained that:

[I]n evaluating beef products contaminated with *E. coli* O157:H7, intact cuts of muscle that are to be distributed for consumption as intact cuts should be distinguished from non-intact products, as well as from intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption.

...

Non-intact beef products include beef that has been injected with solutions, mechanically tenderized by needling, cubing, Frenching, or pounding devices, or reconstructed into formed entrees (e.g., beef that has been scored to incorporate a marinade, beef that has a solution of proteolytic enzymes applied to or injected into the cut of meat, or a formed and shaped product such as beef gyros). Pathogens may be introduced below the surface of these products as a result of the processes by which they are made.⁴⁰

In other words, any non-intact beef product, including needle tenderized meat, contaminated with *E. coli* O157:H7 was to be considered “adulterated,” and therefore would be prohibited from entering the marketplace. Intact cuts of meat contaminated with this strain of *E. coli* are not considered adulterated, and can be sold in the marketplace. This is because heat can kill pathogens such as *E. coli*, and cooking will thereby kill pathogens on the outside of intact meat. However, the pathogens found on the interior of non-intact meat are harder to kill.

39. Beef Products Contaminated With *Escherichia Coli* O157:H7, 64 Fed. Reg. 2803, 2804 (proposed Jan. 19, 1999) (to be codified at 9 C.F.R. pt. 3). Policy statements do not carry the binding force of law, but are intended to inform regulated entities and the public about the agency’s proposed interpretation of its statutes. Here, for example, USDA is indicating that these are the types of meat that it will consider adulterated under the FMIA, although the policy statement itself is not binding.

40. *Id.*

In 2002, in response to lobbying by the meat industry to include mechanically tenderized meat in the intact-meat exception, the FSIS affirmed the policy that non-intact meat, including mechanically tenderized meat, was to be considered adulterated if found to be contaminated with *E. coli* O157:H7.⁴¹ The agency stated that in 2001, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) concluded that “non-intact, blade tenderized beef steaks could potentially contain an infective dose of *E. coli* O157:H7 in their interior . . . [and] that blade-tenderized steaks may pose a risk, particularly to immune-compromised individuals, when served very rare with cold spots (that is, when cooked to an internal temperature of less than 120[deg]F).”⁴²

In 2002, a three-year-old girl named Brianna Kriefall died and numerous other individuals were sickened after eating food at a Sizzler restaurant that had been cross-contaminated with *E. coli* O157:H7 from raw cuts of intact meat. The company that sold the restaurant the meat acknowledged that the meat was contaminated, but argued that it was not adulterated under the Federal Meat Inspection Act because the FSIS, pursuant to its 1999 policy statement, did not consider such meat to be adulterated.⁴³

After this incident, Denis Stearns, a prominent food safety advocate, formally petitioned USDA to amend its 1999 policy statement to “exclude any intact cut of meat intended for further processing at retail,” which would have included the meat sold to the Sizzler restaurant.⁴⁴ Thus, if a restaurant planned to buy intact meat and either grind, or tenderize this meat on premises, it could be sure that the meat was not contaminated by *E. coli*. This policy would theoretically prevent incidents like the Sizzler outbreak, where other food was cross-contaminated by pathogens spread through on-site processing. In 2009, in a blog post regarding USDA’s policy on intact and non-intact meat and adulteration with *E. coli*, Stearns wrote that “the USDA simply punted, stating that ‘because the issues raised in your petition are related to the matters discussed in the October 7, 2002 notice . . . the Agency will consider your petition in conjunction with the comments received in response to that document.’ And that was over five years ago.”⁴⁵

In June 2009, the Safe Food Coalition, which comprises the Center for Science in the Public Interest, the Center for Foodborne Illness Research and Prevention, the Consumer Federation of America, and Food & Water Watch, wrote

41. *E. Coli* O157:H7 Contamination of Beef Products, 67 Fed. Reg. 62325 (proposed Oct. 7, 2002) (to be codified at 9 C.F.R. pt. 417); Letter from Nat’l Meat Ass’n to Food Safety and Inspection Serv. (Apr. 28, 2000) available at <http://www.fsis.usda.gov/OPPDE/Comments/99-060N/99-060N-294.pdf> (requesting the exception of tenderized meat from the FSIS’s *E. coli* O157:H7 policy); FOOD SAFETY AND INSPECTION SERV., COMPARATIVE RISK ASSESSMENT FOR INTACT (NON-TENDERIZED) AND NON-INTACT (TENDERIZED) BEEF: EXECUTIVE SUMMARY (2002) available at http://www.fsis.usda.gov/PDF/Beef_Risk_Assess_ExecSumm_Mar2002.pdf.

42. *E. Coli* O157:H7 Contamination of Beef Products, *supra* note 41, at 62333.

43. *Estate of Kriefall v. Sizzler USA Franchise, Inc.*, 665 N.W.2d 417, 421 (Wis. Ct. App. 2003) (finding state tort claims against the company not foreclosed by USDA’s policy statement).

44. Petition from Denis Stearns to the USDA (Oct. 3, 2002) (on file with author).

45. Denis Diderot, *More USDA Doubletalk on E. Coli and Swift Meat Recall*, DAILY KOS (Jul. 13, 2009, 2:13 PM), <http://www.dailykos.com/story/2009/07/13/753082/-More-USDA-Doubletalk-on-E-coli-Swift-Meat-Recall> (discussing the USDA’s history regarding the *E. coli* contamination of intact and non-intact meat).

a letter to Tom Vilsack, the Secretary of the Department of Agriculture, requesting that the USDA immediately initiate regulatory action to require the labeling of mechanically tenderized meat, and to begin educating the consuming public of the dangers of this process.⁴⁶

In a document providing background information to Secretary Vilsack, the Coalition explained that each month, over 50 million pounds of mechanically tenderized beef products was produced, and that “a preponderance of beef plants are processing, distributing and selling [mechanically tenderized] beef products,” and noted that there had been several foodborne illness outbreaks associated with mechanically tenderized meat “[i]n recent years.”⁴⁷ The Coalition was concerned about three things: (1) the lack of testing of mechanically tenderized beef source materials, (2) the lack of labeling requirements for mechanically tenderized beef, and (3) misleading cooking guidelines for mechanically tenderized meat published by USDA.⁴⁸

Simply put, because the USDA expects consumers to protect themselves from pathogens by cooking mechanically tenderized meat to a higher temperature than intact steak, it should require that such meat be labeled so that consumers know what they are buying. USDA, however, does not require that mechanically tenderized beef be labeled, thereby leaving consumers no way of knowing how they should cook their meat. The Coalition wrote that it “strongly believes that the lack of labeling of MT [mechanically tenderized] beef products, along with FSIS’ low recommended cooking guidelines and temperatures for intact beef products, poses a serious and unnecessary threat to public health.”⁴⁹

The meat producing industry, including the American Meat Institute, the trade organization representing meat and poultry producers, opposes mandatory labeling guidelines for needled meat, on two grounds. First, the organization asserts that meat treated in this manner is as safe as intact steak, and therefore requires no special labeling.⁵⁰ Second, regardless of the comparable safety of mechanically tenderized meat, the industry asserts that labeling will not improve food safety. In this view, labeling will discourage meat producers from intervening to prevent foodborne pathogens from contaminating the meat at the source. Moreover, representatives of the industry say that it is possible that restaurants will ignore the labels and continue to cook meat to order. These two developments combined could potentially lead to more foodborne illness, as producers decrease pathogen elimination measures in response to labeling and consumers ignore the labels.⁵¹

46. Letter from Safe Food Coal., *supra* note 8.

47. Memorandum from Safe Food Coal. on Background Information for Letter to Secretary Vilsack on Mechanically Tenderized (MT) Beef Products, *available at* http://www.foodsafetynews.com/SFC_backgrounder_to_Vilsack_Meat_Tenderization.pdf.

48. *Id.*

49. *Id.*

50. P. Scott Shearer, *Tenderized Meat Labels*, NAT’L HOG FARMER (Jan. 4, 2010), <http://nationalhogfarmer.com/weekly-preview/0104-tenderized-meat-labels>; Helena Bottemiller, *AMI: Tenderized Steaks No More Risky*, FOOD SAFETY NEWS (Dec. 30, 2009), http://www.foodsafetynews.com/2009/12/amtenderized-steaks-not-significantly-riskier/#.UOHIP6C8_ww.

51. James Marsden, *The Gathering Storm—Non-Intact Beef Part II*, MEATINGPLACE (Dec. 3, 2012), <http://www.meatingplace.com/Industry/Blogs/Details/38075>. Marsden is a Professor at Kansas State University, and Meatingplace is a blog sponsored by the meat industry.

These concerns about labeling dovetail with those of the former Undersecretary for Food Safety at USDA, Dr. Raymond, who felt that the potential harm that labeling could do to the industry was not counterbalanced by the good that labels could do.⁵²

D. Conclusion

The dialogue regarding mechanically tenderized meat that has taken place over the last decade between industry, advocacy groups, and the administrative agency in charge of meat products highlights the shortcomings of the current regulatory system for food safety and the inability of private enforcement to overcome these shortcomings. There is a defined and discrete problem—the increased potential for the contamination by foodborne pathogens of mechanically tenderized meat over intact meat—and a relatively simple solution, which is better labeling and consumer education. There is an awareness of the problem among food safety specialists, regulators, industry, and, recently, the mainstream media.

If we see the dialogue itself as a positive, the regulatory system is working just as it should. Dialogue between government, industry, and the public as regulatory beneficiary can arguably increase the legitimacy of the regulatory process, which is “associated with such conventional notions as ensurance of legality, protection against arbitrariness and selectivity, promotion of procedural regularity, and ensurance against the twin evils of factional tyranny and self-interested representation.”⁵³ If we see “the purpose of administrative agencies [as] help[ing] to define and realize social and economic norms in industrialized society,” and regulation as “part of a continuing process of deciding what sort of society we shall be,”⁵⁴ then the decade of back and forth is productive in and of itself, even absent regulatory action. It is hard, however, to view the goal of the regulatory system as fulfilled by dialogue when the public continues to get sick from eating unlabeled mechanically tenderized meat.

Why has there been no regulatory action? Perhaps this is just a small problem, and labeling needled meat would harm the industry more than it would help the consumer, as argued by certain government officials and industry representatives. There are several flaws in this argument, however. The first flaw is the frequent and repeated foodborne illness outbreaks associated with mechanically tenderized meat.

The second is its untested nature. Maybe there are no more outbreaks associated with needled meat than with intact steak. Maybe the incidence of *E. coli* contamination is decreasing across the board. But it is impossible for the consuming public to neutrally evaluate these claims, or to evaluate the claims of food safety advocates calling for labeling requirements. Publicly available studies contain conflicting and obtuse information.

Moreover, this is a subject that is perfectly amenable to regulation. It is

52. Goetz, *supra* note 5.

53. Cass R. Sunstein, *On the Costs and Benefits of Aggressive Judicial Review of Agency Action*, 1989 DUKE L.J. 522, 525 (1989).

54. Richard B. Stewart & Cass R. Sunstein, *Public Programs and Private Rights*, 95 HARV. L. REV. 1193, 1238 (1982).

sufficiently arcane that the consuming public will not only have no knowledge of the vicissitudes of the meat it eats, nor will it care. The USDA is charged with keeping the meat supply safe, and the American public trusts it, and needs it to do its job.

Who then should determine whether regulation really is called for here? Such a dispute may call for a judicial solution, or at least for judicial review. Judicial review could provide a forum for the presentation of the research on both sides of the issue, and an evaluation of whether the agency has done its job here and adhered to its statutory mandate of protecting the safety of the American food supply. But, of course, the judiciary is not involved here, because suit has not been brought against the USDA. Even if judicial review was invoked, it could add a layer of difficulty to the evaluation of the need to regulate mechanically tenderized meat. And herein lies the problem (or problems) with the mechanism of private enforcement.

II. THE SHORTCOMINGS OF PRIVATE ENFORCEMENT

Agency-forcing suits, wherein a private party sues an administrative agency to force or change agency action, are integral to the American regulatory system. These suits serve a valuable function, by increasing public participation, mitigating industry influence, and encouraging the agency to comply with its statutory mandate. However, an over-reliance on this private enforcement mechanism, coupled with the absence of any other mechanisms to spur regulatory action, leads to regulatory inertia in some situations. This Part looks at why this is so, analyzing the problems caused by interest group pressure and the threat of suit, as well as the problems caused by judicial review itself.

A. *The Potential Detriments of Advocacy Group Pressure*

The potential for private parties to bring agency-forcing suits is part of the structure of the regulatory system, and shapes the regulatory process from the outset.⁵⁵ Over the last sixty years or so, the regulatory apparatus has adjusted to and become reliant on private rights of enforcement to enforce, and also to shape the regulatory regime.

Private parties and the availability of the private right of initiation are a presence during the congressional shaping of a statutory mandate, and through the transformation of this mandate into regulation. Special interests have a voice when statutes are written, and are taken into account when general statutory mandates are translated into specific implementable regulations. Under the Clean Air Act, for

55. See J. Maria Glover, *The Structural Role of Private Enforcement Mechanisms in Public Law*, 53 WM. & MARY L. REV. 1137, 1141 (2012) ("Regulation of wrongdoing by private parties is not merely an ad hoc, 'private law' supplement to public enforcement by regulators. It is often an institutional feature of our public law . . ."). Although Glover's examples are based on private parties suing private parties for statutory violations, her argument translates to agency-forcing suits as well. Matthew Stephenson also notes the public function of private enforcement, although also in the context of private suits to correct statutory violations. See Matthew C. Stephenson, *Public Regulation of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91 VA. L. REV. 93, 97-98 (2005).

example, the Administrator of the EPA is directed to establish a list of air pollutants “emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare”⁵⁶ The EPA must translate the phrase “endanger public health or welfare” to an emissions amount for each regulated air pollutant. This process, although couched in terms of science, is heavily policy-influenced, and therefore susceptible to special interest pressure.⁵⁷

Regulations next move through the notice and comment period,⁵⁸ which provides a formal voice to private parties, but is also approached by agencies with an eye toward preparing a record for any ensuing challenge. After a final regulation is issued, private parties may challenge the agency’s decision-making process in regards to the issuance of the regulation and the implementation of the regulation.

So what we have is a regime where the right of private enforcement works both implicitly and explicitly to influence regulation throughout. How can this be detrimental one may ask? Even if the input of advocacy groups and other special interest does not always facilitate the regulatory process, how can broadened participation *hurt* the system? There are at least two ways in which the potential for agency-forcing suits can be detrimental. First is the process’s exclusionary nature, and second is its discretionary nature.

To call the process exclusive may seem counterintuitive, because again, participation appears to be broadened. In the private enforcement scheme, regulation is not something imposed by government on the public, but is rather shaped and adjusted to take into account the advocacy of various members of society. Regulated entities and regulated beneficiaries have a voice in the process.

But engaging in this process entails high costs. An individual or group that desires to take part in the regulatory process must first of all have the expertise needed to address the often complex and scientific nature of health and safety regulation. It must also have the resources available to actually engage in conversation with a regulated agency, which include personnel and connections. And finally, the individual or group must have the resources and the expertise to engage in suit if necessary. The specter of judicial review is a necessary bargaining tool.

In addition, the individual benefit afforded by the regulatory process may be small and diffuse. Think, for example, of mechanically tenderized meat. Advocacy groups are calling for product labeling and consumer education, which would benefit consumers as a whole, but the benefits of which would be hard to assess individually.

For these reasons, the groups involved in the regulatory process are restricted to several repeat players, such as the Center for Science in the Public Interest and the Natural Resources Defense Council. These groups play an extremely valuable role in the regulatory process but their small number threatens to ossify the

56. 42 U.S.C.A. § 7408(a)(1)(A) (2003 & Supp. 2012).

57. See Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1618-19 (1995).

58. 5 U.S.C.A. § 553(b), (c) (2003 & Supp. 2012).

conversation, both in terms of public perception and in reality. Members of the public who are not part of any of the active groups involved in the conversation are shut out.

And second, the reliance on private enforcement to goad and correct the regulatory process is dependent on the discretion of private parties. This is only a problem in that the groups involved in the regulatory process are subject to constraints that may artificially restrict on which subjects they bring to bear their power. These constraints include the needs and desires of their constituency, their resource allocation decisions, and even the personal interests and preferences of their staff attorneys. For example, the Center for Science in the Public Interest brought several suits against the Food and Drug Administration (FDA) in the 1980s on food safety issues, but is now focusing its litigation energy on fraudulent marketing suits focused on combatting the obesity epidemic. Although this is very important, food safety issues have not lessened since the 1980s.

The discretionary nature of private enforcement is harmful to the regulatory process because agencies focus their attention on issues brought to their attention by private parties to the exclusion of other topics. Moreover, ongoing dialogue with these parties may actually increase the time before agency action, especially in areas of political tension. Even in areas that are not particularly politically charged, such as mechanically tenderized meat, we see a prolonged dialogue between certain advocacy groups, industry, and government, with no lawsuits filed against the agency, and no regulatory action.

B. Some Problems with the Judicial Review of Agency Action or Inaction

Next, if a private party does bring suit against an agency, aspects of the judicial process can have a detrimental effect on the regulatory process. First, there is an expertise gap between the judiciary, which usually consists of non-scientists, and the agency. Health, safety, and environmental regulation often entail issues of scientific complexity and uncertainty. The structure of the judicial review of agency decision making incorporates different levels of deference and review, which are both statutorily prescribed and policy-driven, to account for this gap.⁵⁹ Nevertheless, the need for courts to review specialized and scientific determinations is time-consuming and open to error. Moreover, it may be difficult for courts to distinguish scientific judgments from policy judgments in determining the legality of agency action or inaction.⁶⁰

Second, if the judiciary is not itself neutral, its utility as a neutral overseer of agency action is lessened. Judicial review subjects agency decision making to outside scrutiny by allegedly nonpartisan and nonpolitical adjudicators. Ideally, this review will ferret out corruption and self-interested or political decision

59. There is a large literature on this topic. See, e.g., Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 739-42 (2011).

60. See *id.* at 744-48; see also Frank B. Cross, *Shattering the Fragile Case For Judicial Review of Rulemaking*, 85 VA. L. REV. 1243, 1269 (1999); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1618 (1995).

making, and can realign the agency with its statutory mandate.⁶¹ But studies have shown that judges vote consistently with the values espoused by the political party of their sponsors.⁶² Commentators also argue that levels of deference can be manipulated by judges expressing political preference.⁶³

Agency-forcing suits can also intrude into agency decision making. Although it is possible to positively view judicial focus on specific disputes before the court,⁶⁴ this focus can also preclude a consideration of the wide view that incorporates factors external to the particular controversy.⁶⁵ For example, in a recent case, a judge ordered the FDA to hold hearings on the withdrawal of approval for the subtherapeutic (levels below those necessary to treat disease) use of certain antibiotics.⁶⁶ He noted that the FDA, in opposing these hearings, argued that it had shifted its approach regarding these antibiotics, and that the hearings were no longer necessary.⁶⁷ Although the judge found this explanation implausible,⁶⁸ it is possible to see that the court order may have the effect of redirecting an agency's entire policy on antibiotics in animal feed, as well as affecting the agency's resource decisions in other matters.⁶⁹

Finally, the long process of judicial review may inject an element of uncertainty into the regulatory process, undermining public confidence in the regulatory bodies. During review, a regulatory decision generally remains in effect, "but the agency's position surely has a cloud of uncertainty during this time. Even after a judicial decision, nonacquiescence may leave the state of a regulation uncertain for years."⁷⁰ For example, in 2009, a court ordered the FDA to reconsider its decision on the over-the-counter availability of emergency contraception. The FDA, however, did nothing until the advocacy groups that had originally sued the agency filed a motion to hold the FDA in contempt.⁷¹

61. Courts have recognized that agency-forcing suits "allow representatives of public values to articulate a point of view that might otherwise be disregarded in the formulation of regulatory policy," and for this reason, among others, have adapted doctrines of justiciability to allow regulatory beneficiaries the right to sue agencies. Stewart & Sunstein, *supra* note 54, at 1280.

62. See, e.g., Adam Liptak, 'Politicians in Robes'? Not Exactly, But . . . , N.Y. TIMES, Nov. 26, 2012, <http://www.nytimes.com/2012/11/27/us/judges-rulings-follow-partisan-lines.html?hpw>.

63. See, e.g., Bill Araiza, *The Deference Question, Part I: Why Care?*, PRAWFS BLAWG BLOGPOST (Nov. 28, 2012, 6:08 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2012/11/index.html>.

64. See, e.g., Jonathan Siegel, *The Institutional Case for Judicial Review*, 97 IOWA L. REV. 1147, 1150 (2012).

65. See Cross, *supra* note 60, at 1280.

66. *Natural Res. Def. Council, Inc. v. U.S. Food and Drug Admin.*, No. 11 Civ. 3562, 2012 WL 983544, at *1 (S.D.N.Y. Mar. 22, 2012).

67. *Id.* at *20.

68. *Id.*

69. See Eric Biber, *The Importance of Resource Allocation in Administrative Law*, 60 ADMIN. L. REV. 1, 17 (2008); see also Jacob E. Gersen & Anne Joseph O'Connell, *Deadlines in Administrative Law*, 156 U. PA. L. REV. 923, 977-978 (2008). I am not arguing here that the judge was wrong, or that the FDA's explanation is plausible. I am showing that agency-forcing suits may not be the most desirable solution to agency inaction driven by political pressure, while not advocating for their elimination. If there is no other way to force an agency to act, these suits are crucial to the administrative scheme.

70. Cross, *supra* note 60, at 1255.

71. Rachel Slajda, *FDA Ducks Contempt Claim After Nixing OTC Contraceptives*, LAW360 (Dec. 13, 2011). The FDA's ruling mooted the contempt motion.

III. TWO PROPOSALS

By providing a snapshot of one small, yet persistent regulatory problem, I have tried to demonstrate the inadequacy of private enforcement to spur regulatory action. This is not to say that private enforcement should be eliminated, however. Agency-forcing suits play an important role in the regulatory process, and can, in some circumstances, improve regulatory outcomes.⁷² Additional mechanisms, however, are necessary to counter the problem of agency inertia in areas affecting the public health and safety, and here I present two suggestions.

A. The Increased Use of Statutory Deadlines and Hammers

Congress has numerous methods to control the behavior of administrative agencies, including the manipulation of funding, “the specification of requisite procedures for agency decision making,” the prescription of substantive standards for the agency to meet, the use of administrative deadlines, and the imposition of statutory hammers.⁷³ I discuss the possible benefits of the increased use of administrative deadlines and statutory hammers.

What are hammers? Statutory hammers add a layer of consequence to a statutory deadline. For example, some statutes provide a deadline before which an agency must act, and prescribe substantive standards that will go into effect if the deadline is not met.⁷⁴ The Nutrition Labeling and Education Act contains a different kind of hammer—it required the agency to establish proposed regulations within twelve months, which became final if final regulations were not promulgated in the next twelve months.⁷⁵

It is relatively easy to imagine how the increased use of statutory deadlines coupled with hammers could accelerate the regulatory process in an area such as mechanically tenderized meat. Congress could amend the Federal Meat Inspection Act to mandate that the USDA pass regulations on the labeling of non-intact meat with its production process and suggested cooking temperatures. This amended provision could include a deadline and a hammer. The USDA could therefore work with industry to attempt to ameliorate consumer confusion regarding mechanically tenderized meat, but if it missed its deadline, mandatory labeling would go into place.

Of course, Congress may not be inclined to pass such a measure because it too may be subject to pressure or influence from the meat industry. Moreover, even when statutes are prescriptive, agency discretion remains. For example, the USDA could redefine mechanically tenderized meat out of the “non-intact” meat

72. Eric Biber and Berry Brosi, *Officious Intermeddlers or Citizen Experts? Petitions and Public Production of Information in Environmental Law*, 58 UCLA L. REV. 321 (2010); Robert L. Glicksman, *The Value of Agency-Forcing Citizen Suits to Enforce Nondiscretionary Duties*, 10 WIDENER L. REV. 353 (2004).

73. Jacob E. Gersen & Anne Joseph O’Connell, *supra* note 69, at 924; See also M. Elizabeth Magill, *Congressional Control Over Agency Rulemaking: The Nutrition Labeling and Education Act’s Hammer Provisions*, 50 FOOD & DRUG L.J. 149, 153 (1995).

74. Magill, *supra* note 74, at 153-54. Magill notes that the 1984 Amendments to the Resource Conservation and Recovery Act contain several of these devices. *Id.* at n.19.

75. *Id.* at 150.

category (although it would probably not do so at this point, and such a decision would be open to judicial challenge).

B. Allowing Petitions to OIRA to Review Agency Inaction

Another possible solution is for the Executive to amend the mandate of the Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget (OMB), to authorize it to review agency inaction as well as significant agency actions. The OIRA was created in 1980 by the Paperwork Reduction Act,⁷⁶ and the office was initially responsible for reviewing agencies' information collection requests.⁷⁷ Under President Reagan, however, the office became, and remains, charged with the centralized review of regulation. President Reagan issued Executive Order 12,291, which required agencies to prepare a cost/benefit analysis for major rules, and to send a copy of each proposed or final rule to the OIRA before publication.⁷⁸ The goals of centralized review during the Reagan era were twofold: (1) to coordinate the regulatory state and promote efficiency and cost-effectiveness; and (2) to cut down on unnecessary (and overzealous) regulation.⁷⁹ Critics have shown, however, that OIRA's main focus during the Reagan years was deregulation, and that the coordinating role of OIRA was deprioritized.⁸⁰

President Clinton replaced Order 12,291 with Order 12,866, which maintained the framework of executive review of regulatory decision making, while increasing transparency and introducing certain considerations in rulemaking review that arguably reduced the body's anti-regulatory bias.⁸¹ President George W. Bush again modified OIRA's mandate, and imposed an explicitly anti-regulation expansion of presidential oversight over agency decision making.⁸² President Obama, however, reinstated Clinton's Order 12,866 after he took office.⁸³

President Clinton's innovations notwithstanding, critics argue that the OIRA review is structured to be anti-regulation because the OIRA only reviews regulations to see if they are too stringent, not too lax; that the OIRA rarely, if ever, reviews decisions to deregulate; and that agency inaction is not scrutinized.⁸⁴ However, the OIRA, as a "centralized agency with command over the regulatory state," is uniquely positioned to play a larger role in ensuring that agencies adhere to their statutory mandates.⁸⁵ Agency inaction can arguably be an equal or greater economic drain than regulatory action, and the OIRA should have the authority to

76. 44 U.S.C. §§ 3501-3504 (2007 & Supp. 2012).

77. Copeland, *supra* note 22, at 1259.

78. *Id.* at 1261.

79. Bagley & Revesz, *supra* note 23, at 1264.

80. *See, e.g., id.* at 1265.

81. *Id.* at 1266-67; Copeland, *supra* note 22, at 1271-72.

82. *See* Michael Hissam, *The Impact of Presidential Order 13,422 on Presidential Oversight of Agency Administration*, 76 GEO. WASH. L. REV. 1292 (2008) (discussing criticism).

83. Press Release, The White House: Office of the Press Secretary, Revocation of Certain Executive Orders Concerning Regulatory Planning and Review, (Jan. 30, 2009) *available at* <http://www.whitehouse.gov/the-press-office/revocation-certain-executive-orders-concerning-regulatory-planning-and-review>.

84. *See* Bagley & Revesz, *supra* note 23, at 1267-68.

85. *Id.* at 1329.

review an agency's failure to act.

CONCLUSION

The increased potential for contamination by foodborne pathogen of mechanically tenderized meat is a problem well-suited for federal regulation. Meat is distributed nationally, and uniformity of the product is important to purchasers. The problem here can be ameliorated with a mandatory labeling requirement and increased consumer education, which are relatively easy solutions. If the market for mechanically tenderized meat decreased after mandatory labeling requirements, meat producers would have to find a way to make the meat that they sold safer.

This is not a situation where the USDA can argue that it has made different resource allocation decisions (i.e., it has regulated elsewhere and therefore has no resources left over to focus on mechanically tenderized meat). The amount of time spent on dialogue with advocacy groups and the numerous studies done regarding this type of meat show that resources have already been expended. Yet over a decade, no regulatory action has been taken. Dialogue has gone nowhere.

No single label defines the problem here. Industry pressure, resource allocation decisions, and diffuse agency inertia have all played a part. Regardless, however, of the source of the problem, private enforcement is inadequate to force change. To improve the regulation of public health and safety, either Congress or the Executive, or both, must act.