
RECENT LEGISLATION

ADMINISTRATIVE LAW — REGULATORY DESIGN — FOOD SAFETY MODERNIZATION ACT IMPLEMENTS PRIVATE REGULATORY SCHEME. — FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified in scattered sections of the U.S. Code).

Ensuring food safety has been a key government function since *The Jungle*¹ motivated Congress to pass the Pure Food and Drug Act.² And yet Washington's powers have proved limited, and the Food and Drug Administration (FDA) has been unable to prevent a series of outbreaks of fatal foodborne illnesses.³ To address persistent gaps in FDA authority, on January 4, 2011, President Barack Obama signed into law the FDA Food Safety Modernization Act⁴ (Act), a “long overdue” reform of a regulatory regime that had not been significantly updated since 1938.⁵ The Act added a delegation of regulatory authority to private third parties to a food safety regime that historically emphasized government inspection. In creating such a scheme, however, Congress may not have given the FDA the capacity to monitor closely these private regulators, making it difficult for the FDA to ensure that private regulators are accountable to the agency. Congress may have given the FDA enough oversight power for the Act to be constitutional, but not enough for that oversight to be effective. Courts should recognize this lack of accountability by not granting the FDA any deference when it adopts third-party interpretations of food safety regulations.

Though food safety has been a persistent concern in policy circles,⁶ Congress began seriously reconsidering the issue only after a series of highly publicized deaths in the late 2000s, including two-hundred illnesses and three deaths in 2006 and 2007 that were caused by E. coli-contaminated spinach,⁷ and nine deaths related to salmonella-infected

¹ UPTON SINCLAIR, *THE JUNGLE* (1906). Sinclair's descriptions of unsanitary conditions in the meatpacking industry sparked public outrage, which helped lead to the Pure Food and Drug Act's passage. See Jeffrey E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 299 (2001).

² Pub. L. No. 59-384, 34 Stat. 768 (1906).

³ See sources cited *infra* notes 6 & 9.

⁴ Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified in scattered sections of the U.S. Code).

⁵ 156 CONG. REC. S8016 (daily ed. Nov. 18, 2010) (statement of Sen. Amy Klobuchar).

⁶ See, e.g., Michael R. Taylor, *Preparing America's Food Safety System for the Twenty-First Century — Who Is Responsible for What When It Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?*, 52 FOOD & DRUG L.J. 13, 23 (1997).

⁷ See RENÉE JOHNSON, CONG. RESEARCH SERV., R40403, *FOOD SAFETY IN THE 111TH CONGRESS I* (2010); see also 156 CONG. REC. S8027–28 (daily ed. Nov. 18, 2010) (statement of Sen. Tom Harkin) (describing individual food-related deaths).

peanut butter in 2009.⁸ The FDA regulated these products, but lacked the capacity to take effective preventative action.⁹ In response to these failures, as well as to the congressional recognition that the “ability of the [FDA] to oversee the safety of [the U.S.] food supply is compromised by inadequate authorities,”¹⁰ two major bills were introduced, both with similar content.¹¹ The first, H.R. 2749, was introduced by Representative John Dingell on June 8, 2009, and was adopted unanimously by the House Committee on Energy and Commerce on July 17, 2009.¹² It passed the full House, 283–142, on July 30, 2009.¹³ The second, S. 510, was introduced by Senator Dick Durbin and was approved by the Senate Committee on Health, Education, Labor, and Pensions on November 18, 2009.¹⁴ While the House bill passed easily, senators delayed passage of the Senate bill due to concerns about its impact on small food producers¹⁵ and its overall cost-effectiveness.¹⁶ However, after strong support from the business community,¹⁷ the bill passed the Senate seventy-three to twenty-five.¹⁸

The Act is organized in three main titles. The first, “Improving Capacity to Prevent Food Safety Problems,”¹⁹ expands the FDA’s authority to monitor domestic food sources. This title’s purpose is to reorient the agency from a reactive posture, where the agency deals with outbreaks only after they have occurred, to a preventative posture, where the agency would proactively work with food producers to prevent foodborne illness.²⁰ Domestic food producers must now perform a risk-based preventative analysis whereby they “evaluate known or reasonably foreseeable hazards” and then develop preventative con-

⁸ See JOHNSON, *supra* note 7, at 2.

⁹ See *id.* at 1–2; see also Katie Stewart & Lawrence O. Gostin, *Food and Drug Administration Regulation of Food Safety*, 306 JAMA 88, 88 (2011).

¹⁰ H.R. REP. NO. 111-234, at 36 (2009).

¹¹ Both bills included risk-based controls, import certifications, and third-party auditors. See H.R. 2749, 111th Cong. (2009); S. 510, 111th Cong. (2009); JOHNSON, *supra* note 7, at 9–10.

¹² H.R. REP. NO. 111-234, at 36–37.

¹³ 155 CONG. REC. H9164 (daily ed. July 30, 2009).

¹⁴ JOHNSON, *supra* note 7, at 7.

¹⁵ Senator Jon Tester offered an amendment exempting most producers with less than \$500,000 in total food revenues from new FDA regulations. *Tester Amendment*, JON TESTER, http://tester.senate.gov/Legislation/upload/tester_amendment_agreement.pdf (last visited Dec. 4, 2011). This amendment was incorporated into the final Act. Food Safety Modernization Act, 124 Stat. at 3892 (codified at 21 U.S.C. § 350g(l)(1)).

¹⁶ See 156 CONG. REC. S8014 (daily ed. Nov. 18, 2010) (statement of Sen. Tom Coburn) (“No matter how much money we spend, is there a diminishing return?”).

¹⁷ See *id.* at S8025 (statement of Sen. Tom Harkin) (praising the support of the Chamber of Commerce, the Food Marketing Institute, and the Snack Food Association).

¹⁸ *Id.* at S8267. All Democrats and independents supported the measure, while fifteen Republicans supported the bill and twenty-five opposed it. *Id.*

¹⁹ 21 U.S.C. §§ 2201–2206 (2006 & Supp. IV 2011).

²⁰ See Margaret A. Hamburg, *Food Safety Modernization Act: Putting the Focus on Prevention*, FOODSAFETY.GOV, <http://www.foodsafety.gov/news/fsma.html> (last visited Dec. 4, 2011).

trols to mitigate such risks.²¹ The FDA must set “science-based” regulations to govern food processing and harvesting²² and can now demand documentation or inspection records related to any food that the agency believes has a “reasonable probability” of causing serious adverse health effects.²³ The FDA may now also levy limited user fees on food importers and producers to help cover enforcement costs.²⁴

The second title, “Improving Capacity to Detect and Respond to Food Safety Problems,”²⁵ increases the FDA’s food inspection capacity. The Act requires the agency to identify high-risk facilities and to increase the frequency with which it inspects those locations.²⁶ Because mandating inspection without a concomitant grant of enforcement power to address issues identified during inspection would be of limited utility, the Act provides the FDA with mandatory recall authority: if the agency determines with “reasonable probability” that products are adulterated and pose a risk of serious health consequences, the agency may unilaterally recall the products if a producer refuses to do so.²⁷

The third title, “Improving the Safety of Imported Food,”²⁸ deals with food produced outside the United States. The Act requires importers to assess their foreign partners to ensure that suppliers have implemented “risk-based preventative controls” so that “food imported into the United States is as safe as food produced and sold within the United States.”²⁹ The FDA must issue regulations specifying what these provisions require, and the Act recommends that the FDA consider activities like “annual on-site inspections,” periodic testing and sampling, and the regular auditing of supplier risk assessment plans.³⁰ Importers who do not comply with these FDA regulations will not be able to import food products.³¹ The Act also gives the FDA the power to require import certifications,³² which may be issued by qualified

²¹ 21 U.S.C. § 350g(b)–(c).

²² *Id.* § 350g(n)(1).

²³ *Id.* § 350c(a)(2).

²⁴ *Id.* § 384d(c)(8). These costs include the FDA’s costs of inspecting certain facilities and administering a program to provide special clearance for qualified importers as well as certain accreditation fees for third-party auditors. *Id.*

²⁵ *Id.* §§ 2221–2226.

²⁶ *Id.* § 350j(a).

²⁷ *Id.* § 350l. A producer subject to a recall order is entitled to an informal hearing, where the Secretary of Health and Human Services (HHS) can modify the recall terms. *Id.*

²⁸ *Id.* §§ 2241–2243.

²⁹ *Id.* § 384a(c)(2).

³⁰ *Id.* § 384a(c)(4).

³¹ *Id.* § 331(zz).

³² *Id.* § 381(a). In determining whether to require import certifications, the HHS Secretary is required to consider whether “the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this chapter.” *Id.* § 381(q)(2)(C).

third-party auditors, before the agency permits food to enter the United States.³³ Finally, the FDA can now block imported food from any country that refuses to allow U.S. inspectors into its facilities.³⁴

The Act expands the scope of food regulation. But rather than relying on government inspectors, as had been the model,³⁵ the Act delegates some oversight authority to non-U.S. government actors: third-party foreign auditors who certify that imported food meets FDA standards. While the expansion of private governance into food safety is new, there have been institutionalized roles for private actors in other public governance schemes for many years.³⁶ Courts have generally allowed such arrangements only if agencies can adequately oversee their private partners. Though the Act probably meets baseline constitutional standards, it may not provide the FDA with sufficient capacity to fulfill its oversight mandate. As a result, courts should not grant the FDA judicial deference under a scheme that presumes such capacity and should play a more active role in ensuring private regulatory compliance with the Act.

Ensuring regulator accountability is a central goal of administrative law.³⁷ This goal is particularly important for private, nongovernmental regulatory actors, who lack many of the overt political accountability measures imposed on their state actor counterparts.³⁸ In evaluating the appropriateness of private regulation, courts are cognizant of concerns about reduced regulator accountability³⁹ and a lack of private

³³ *Id.* § 384d(c)(1)(C)(ii). Accredited third-party auditors can be foreign governments, cooperatives, or other third parties. *Id.* § 384d(c)(1). FDA-certified auditors may issue a food or facility certification that satisfies the import certification requirements established by the Act. *Id.* § 384d(c)(2)(B). The Secretary can set regulations governing audit procedures (such as that they be unannounced) and withdraw auditor accreditation. *Id.* § 384d(c)(4)–(6).

³⁴ *Id.* § 384c(b).

³⁵ See Richard L. Frank & Dennis R. Johnson, *The USDA's Compliance and Enforcement Programs*, 44 FOOD DRUG COSM. L.J. 205, 209–10 (1989) (discussing inspection programs).

³⁶ See, e.g., Gillian E. Metzger, *Privatization as Delegation*, 103 COLUM. L. REV. 1367, 1377–94 (2003) (describing examples of privatized governance regimes). The most prominent example is securities regulation, where private exchanges (such as the New York Stock Exchange) have broad power to regulate the activities of listed members. See Joel Seligman, *Cautious Evolution or Perennial Irresolution: Stock Market Self-Regulation During the First Seventy Years of the Securities and Exchange Commission*, 59 BUS. LAW. 1347, 1347–49 (2004).

³⁷ See, e.g., Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2331–39 (2001). But see Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461, 462–63 (2003) (arguing that accountability concerns are overstated and that the true challenge involves constraining arbitrary agency action).

³⁸ For example, the leadership of a private regulator is generally not appointed by the President (or his designee) and may not be removed by a government entity. See Metzger, *supra* note 36, at 1377–78. But see Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 549 (2000) (arguing that private organizations can provide “informal accountability” to complement public regulatory efforts).

³⁹ See, e.g., *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 565 (D.C. Cir. 2004). This view of accountability through a single decisionmaker is not unique to private regulators. Cf. THE FED-

regulator sensitivity to the public interest goals of the supervising agency.⁴⁰ In response to such concerns, courts have established criteria to judge the propriety of subdelegated regulatory activities⁴¹: (1) The agency must have some capacity to exercise actual oversight — not merely a “rubber stamp” over the private regulator.⁴² (2) Congress must have affirmatively authorized the private regulation.⁴³ (3) The agency must have the power to prescribe and enforce clearly defined standards governing private regulators⁴⁴ using a more nuanced tool than just the ability to terminate the participation of the private regulator.⁴⁵

The Act raises concerns under these criteria, but probably not to such an extent that courts would strike it down. As a formal matter, the Act meets the courts’ private delegation standards. Congress explicitly authorized the FDA to use third-party auditors to verify imported food safety.⁴⁶ The Act also requires the FDA to issue regulations to govern third-party accreditation standards,⁴⁷ and it grants the FDA the power to conduct periodic inspections of third-party auditors and accreditation agencies,⁴⁸ thus providing some measure of both actual oversight and standard-setting authority.

However, while the Act formally provides the level of oversight necessary to satisfy the legal test for permissibility of private regulation, that oversight is functionally weak and thus raises policy con-

ERALIST NO. 70, at 427 (Alexander Hamilton) (Clinton Rossiter ed., 2003) (“[T]he plurality of the Executive tends to deprive the people of the two greatest securities they can have for the faithful exercise of any delegated power . . . [one of which is] the opportunity of discovering with facility and clearness the misconduct of the persons they trust, in order either to their removal from office or to their actual punishment in cases which admit of it.”).

⁴⁰ See *U.S. Telecom*, 359 F.3d at 566; *Nat’l Park & Conservation Ass’n v. Stanton*, 54 F. Supp. 2d 7, 20 (D.D.C. 1999) (criticizing a private regulator as not sharing the agency’s “national vision and perspective”).

⁴¹ These concerns were articulated in the context of subdelegation to other state actors, but the general concerns are just as applicable, if not more so, with respect to private-party delegation. Cf. *U.S. Telecom*, 359 F.3d at 566 (“The fact that the subdelegation . . . is to state commissions rather than private organizations does not alter the analysis.”).

⁴² See *Assiniboine & Sioux Tribes of Fort Peck Indian Reservation v. Bd. of Oil & Gas Conservation*, 792 F.2d 782, 793 (9th Cir. 1986) (noting that unlawful delegation of authority occurs when there is “no meaningful independent review,” *id.* at 795).

⁴³ *U.S. Telecom*, 359 F.3d at 566.

⁴⁴ See *Fund for Animals v. Norton*, 365 F. Supp. 2d 394, 410–11 (S.D.N.Y. 2005), *aff’d sub nom.* *Fund for Animals v. Kempthorne*, 538 F.3d 124 (2d Cir. 2008).

⁴⁵ See *Nat’l Park & Conservation Ass’n*, 54 F. Supp. 2d at 21 (noting that terminating a third-party relationship is a “draconian remedy” and cannot be the agency’s only tool). Courts have not clearly stated how to apply these factors. Congressional authorization is necessary, but perhaps not sufficient, for private regulation. See *U.S. Telecom*, 359 F.3d at 566. Courts take a more flexible approach when evaluating the degree to which the agency is able to exercise oversight. See *Nat’l Park & Conservation Ass’n*, 54 F. Supp. 2d at 21 (considering relevant private regulation factors).

⁴⁶ 21 U.S.C. §§ 350j(a)(2)(E), 384a (2006 & Supp. IV 2011).

⁴⁷ *Id.* § 384d(b).

⁴⁸ *Id.* § 384d(f).

cerns about the degree to which the FDA can hold private regulators accountable for their actions. The FDA has limited direct involvement in third-party audits, and the agency's main enforcement power is discrediting regulators in the event of egregious food safety failures⁴⁹ — not the type of nuanced enforcement that courts prefer. Additionally, while the FDA can withhold certifications for food importation from countries that refuse to allow U.S. on-site inspections,⁵⁰ as a practical matter the FDA will have limited opportunities to conduct on-site verification inspections and thus limited opportunities to verify that auditors follow FDA mandates.⁵¹

The Act also establishes an additional regulatory layer that further calls into question the effectiveness of the FDA's oversight of private regulators. Under the Act, the agency can certify "accreditation bodies" to oversee third-party inspectors, rather than relying on direct FDA oversight.⁵² Such a process blurs the lines of accountability in two ways. First, it enacts a scheme whereby Congress delegates power to the FDA, which then delegates power to a private accreditation agency, which then accredits a third-party auditor, which then certifies that food is safe.⁵³ This multilayered procedure positions accreditation bodies to regulate *regulators*, not providers (as is generally the case in private delegation⁵⁴), further removing the FDA from contact with the food importers it is tasked with regulating. Second, the interests of accreditation bodies and the FDA are not perfectly aligned. While accreditation bodies located in food-exporting countries have an interest in ensuring their continued certification by the FDA, they may also have an overriding interest in promoting food exports, even those exports of questionable status.⁵⁵ This discrepancy of interests may limit the efficacy of the main independent check on third-party auditors.

These concerns over the lack of accountability stemming from the Act's provisions cannot be disregarded. Even if challenges to the Act's

⁴⁹ See *id.* § 384d(c)(6)(A).

⁵⁰ *Id.* § 384c(b).

⁵¹ The FDA can conduct an on-site inspection of any foreign food processing facility. *Id.* Given resource constraints, and the Act's mandate to focus on "high risk" facilities, *id.* § 384c(a), it should not be surprising that some observers have questioned the FDA's ability to adequately inspect foreign facilities. See PUBLIC MEETING ON THE FOOD SAFETY MODERNIZATION ACT: TITLE III NEW PARADIGM FOR IMPORTERS 119 (2011), available at <http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM250697.pdf> [hereinafter FDA HEARING].

⁵² 21 U.S.C. § 384d(b).

⁵³ See *id.* § 384d(b)–(c).

⁵⁴ See Douglas C. Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171, 218–19 (1995).

⁵⁵ Cf. FDA HEARING, *supra* note 51, at 146–47 (statement of Chris Waldrop, Dir., Food Policy Inst., Consumer Fed'n of Am.) ("Private third party auditors are not accountable to the public, and so consumer groups have seen a number of problems arise from that system . . . so we have some reservations about that.").

delegation fail, existing jurisprudence provides a mechanism by which courts may refuse to grant deference to statutory interpretations conducted by third-party auditors. Rather than directly tackling the lack of agency accountability through nondelegation doctrines, courts have traditionally manifested their policy concerns through a reluctance to grant judicial deference to interpretations promulgated under conditions of questionable oversight.⁵⁶ This hesitancy is best articulated through the *Skidmore*⁵⁷ standard, which applies to any statutory interpretations of the Act's certification provisions, whether they are made by agency staff or third-party auditors.⁵⁸ In applying *Skidmore*, courts premise judicial deference to an agency's statutory interpretations on the persuasive force of the agency's analysis and the conditions under which the agency reached its decisions.⁵⁹ For instance, the "thoroughness evident in [the agency's] consideration"⁶⁰ may not be considered if the interpreting party does not report to a political appointee or is not politically accountable.⁶¹ Additionally, less deference is granted if an interpretation does not represent an agency-wide position.⁶²

The FDA's interpretation of the Act fails the *Skidmore* persuasiveness test.⁶³ Implementing the Act's new scheme allows significant auditor discretion. Third-party auditors apply and interpret relatively vague statutory and regulatory standards, such as "serious risk to the

⁵⁶ Cf. David J. Barron & Elena Kagan, *Chevron's Nondelegation Doctrine*, 2001 SUP. CT. REV. 201, 242-43 (arguing that courts should not defer to the statutory interpretations of civil servants, as career staff are less accountable to the public than are appointed or elected officials). Inasmuch as a lack of accountability raises nondelegation concerns, courts have responded by refusing to grant deference even to reasonable agency statutory constructions. See Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 329-37 (2000) (discussing "hidden nondelegation principles" that underlie court action even if they do not constitute the formal bases for decisions).

⁵⁷ *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

⁵⁸ Only administrative action that has the force of law may be granted deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). See *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001). Here, a certification decision would likely *not* be granted *Chevron* deference: an import certification is facially similar to the tariff classification under review in *Mead*, and the certifications under the Act are issued through relatively informal proceedings, are binding only on the regulated exporter, lack review by an administrative law judge, and are not issued through notice-and-comment rulemaking. See 21 U.S.C. § 384d(c). Rather, the FDA's action would be governed by the *Skidmore* standard.

⁵⁹ *Skidmore* assesses agency interpretations by the "thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore*, 323 U.S. at 140.

⁶⁰ *Id.*

⁶¹ See *De La Mota v. U.S. Dep't of Educ.*, 412 F.3d 71, 80 (2d Cir. 2005).

⁶² See *Cathedral Candle Co. v. Int'l Trade Comm'n*, 400 F.3d 1352, 1366 (Fed. Cir. 2005).

⁶³ A court would reach these issues if an "adversely affected" party challenged the statutory interpretation used by the FDA to justify the decision to deny or allow the entrance of food into the United States. See 5 U.S.C. § 702 (2006). Challenging parties would be either food importers whose food was denied a certificate or consumer groups arguing that they would be threatened if allegedly unsafe food were to enter the U.S. food supply.

public health,⁶⁴ in reaching certification decisions. If the FDA were directly certifying imported food, a court could reasonably defer to interpretations of the certification provisions. FDA employees report directly to a presidentially appointed Commissioner,⁶⁵ who is sufficiently close to the underlying legal analysis performed by her direct subordinates to demonstrate that the agency has thoroughly considered its statutory position.⁶⁶ As a unitary entity, the FDA can also promulgate uniform interpretations across all food inspections. Interpretations under the Act lack these *Skidmore*-promoting safeguards: third-party regulators have no legal obligation to disclose their methodologies and statutory interpretations to the FDA;⁶⁷ are far removed from political appointees; and as independent, country-specific regulators, cannot coordinate global statutory interpretations of food regulations. As a result, third-party interpretations should not meet the *Skidmore* criteria for persuasiveness, and courts should not defer to these interpretations. Instead, in evaluating certifications, courts should independently interpret the Act and its regulations.⁶⁸

The accountability problem may seem remediable by the FDA. The FDA has broad power to issue regulations governing the participation and disclosures of third-party auditors.⁶⁹ The agency can thus increase the amount of information third-party auditors and accreditation bodies must disclose, in the hopes of creating enough data to better allow the agency to oversee the implementation of its regulatory scheme. The core of the dilemma, however, is structural: Congress deliberately broadened the FDA's regulatory powers while diluting the Agency's role as the primary overseer of the U.S. food supply. As a result, the FDA — and Congress — will have to accept limited oversight of third-party regulators. Just as courts continue to evaluate the accountability premises that underlie agency deference as the role of private regulators expands, so too should courts scrutinize third-party interpretations of the Act, both to prevent a regulatory vacuum and to ensure the fitness of the food safety system.

⁶⁴ 21 U.S.C. § 384d(c)(4)(A) (2006 & Supp. IV 2011). The FDA is tasked with creating more detailed accreditation standards by mid-2012. *Id.* § 384d(b)(2). However, even these standards will require interpretation by on-the-ground inspectors.

⁶⁵ *Id.* § 393(d)(1).

⁶⁶ *Cf. De La Mota*, 412 F.3d at 80.

⁶⁷ *See* 21 U.S.C. § 384d(c)(3)(A) (requiring only that auditors provide information such as the name of a contact at the audited entity and the date and time of the audit). To require the reporting of additional information, the agency must issue supplemental regulations. *See id.* § 384d(c)(3)(A)(iv).

⁶⁸ Courts would not, by this view, need to independently examine the facts (such as food contamination indications), but must merely analyze the standards by which those facts were evaluated.

⁶⁹ The FDA must issue implementing regulations by July 4, 2012. 21 U.S.C. § 384d(b)(2).