Bioterrorism and the Food Drug Administration: H.R. 3448, Related Legislation, and the FDA’s Expanding Role in Preventing and Responding to Biological Attack

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Bioterrorism and the Food Drug Administration:

H.R. 3448, Related Legislation, and the FDA’s Expanding Role in Preventing and Responding to Biological Attack

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(Harvard Law School, Class of 2002)

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and

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Abstract

This paper examines the potential impact of recent and proposed bioterrorism legislation on the U.S. Food and Drug Administration (FDA). It concludes that at least one such piece of legislation, H.R. 3448, the “Public Health Security and Bioterrorism Response Act of 2001,” would significantly impact the authority and activities of FDA, as well as affecting FDA-regulated entities and other stakeholders. The paper includes recommendations for further FDA action, noting that as the federal agency responsible for the safety and efficacy of food, drugs, medical devices, vaccines, and other biological and non-biological products across the nation, FDA holds a unique and critical position in bioterrorism prevention and response.

Introduction

In the wake of the terrorist attacks conducted against the people and institutions of the United States of America on September 11, 2001, as well as the bioterrorist anthrax mailings during September and October, 2001, federal legislators have proposed a significant amount of new legislation intended to improve the nation’s ability to prevent and respond to terrorism of all kinds. Many of the legislative proposals have provisions addressing bioterrorism. These provisions augment prevention, detection, and containment of biological agent or toxin attack via increased food inspection and enhanced food safety measures, as well as through accelerated development of drug, vaccine and device countermeasures, and a variety of other activities and requirements. If passed, numerous federal, state and local agencies will be involved in implementing the new legislation.

However, as the federal agency responsible for the safety and efficacy of food, drugs, medical devices, vaccines, and other biological and non-biological products across the nation, the U.S. Food and Drug Administration (“FDA”) continues to hold a unique and critical position in bioterrorism prevention and response.

This unique FDA role is encapsulated in a summary of the agency's mission: to protect the public health by ensuring the safety of food; the safety and efficacy of drugs, biological products and therapeutic devices; the safety of cosmetics, and the minimization of exposure to electronic product radiation. In fulfilling this mission over the years, FDA has many times prevented, detected and responded to both intentional and unintentional or naturally occurring contamination of food, drugs and biologics, as well as of other regulated products. Unquestionably, even if no bioterrorism legislation were passed FDA would continue working to protect consumers from such dangers under existing law and in fulfillment of its primary mandate to protect the public health.

However, the One Hundred Seventh Session of the U.S. Congress ("107th Congress") has already passed two laws with some relevance to FDA's bioterrorism prevention and response role: the USA PATRIOT Act of 2001 and the Defense Appropriations Act, 2002. While these laws neither mandate specific FDA activities, nor have substantial FDA-relevant provisions, it seems probable that the 107th Congress will yield additional laws with a significantly greater effect on FDA’s bioterrorism-related activities and underlying public health protection responsibilities. It is therefore the primary goal of this paper to examine how such legislation may impact FDA’s activities, responsibilities, and mission. The paper’s secondary goals are briefly to discuss the

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2 See Mission Statement, U.S. Food and Drug Administration, “FDA’s Mission,” (last updated Oct. 19, 1998), available at [www.fda.gov](http://www.fda.gov) (presenting FDA’s mission as defined in the FDA Modernization Act of 1997). See also S. Rep. No. 101-84, (1989), reprinted in PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS (2d ed.) (1991) (noting that, “[t]he mission of... (FDA) is to ensure that (1) food is safe, pure, and wholesome; (2) cosmetics are safe; (3) human and animal drugs, biological products, and therapeutic devices are safe and effective; and (4) radiological products and use procedures do not result in unnecessary exposure to radiation.”).


potential impact of such legislation on the FDA-regulated community and other stakeholders and to make several recommendations relating to FDA and its bioterrorism-related activities.

To fulfill these goals the paper analyzes a significant and representative piece of proposed bioterrorism legislation. Because to date no signed laws enacted by the 107th Congress significantly address FDA’s role in bioterrorism prevention and response,[7] the chosen legislation is an enrolled and engrossed resolution that appears reasonably likely to be enacted in a form substantially similar to its present provisions. It is House Resolution 3448 (H.R. 3448), the “Public Health Security and Bioterrorism Response Act of 2001,”[8] which has been passed by both Houses of Congress and is currently in conference.[9]

In summary, this paper first analyzes the provisions of H.R. 3448 in relation to their relevance or interest to FDA and then briefly addresses some of the potential implications of the provisions for FDA and for the FDA-regulated community and other stakeholders. Next, the paper summarizes FDA-relevant provisions of two 107th Congress laws: the USA PATRIOT Act and the Department of Defense Appropriations Act. Finally, the paper concludes with a number of bioterrorism-related recommendations to FDA developed in the context of the reviewed legislation, but also in consideration of relevant bioterrorism literature reviewed in researching this paper.

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[7] The USA PATRIOT Act, supra note 5, and the DoD Appropriations Act, supra note 6, each provide very few provisions relevant to FDA and bioterrorism. In contrast, H.R. 3448, the Public Health Security and Bioterrorism Response Act of 2001, infra note 8, provides a large number of provisions that significantly and specifically affect FDA’s bioterrorism-related activities. For this reason, the paper analyzes proposed H.R. 3448 rather than either of the two enacted laws.


H.R. 3448:

The Public Health Security and Bioterrorism Response Act of 2001

“This sweeping package includes everything from beefed up food safety regulations to tightened controls on deadly biological agents.... [this bill] will improve our ability to respond effectively and quickly to bioterrorist threats and other public health emergencies.”

–W.J. “Billy” Tauzin (R-LA), H.R. 3448 Sponsor
Chairman, House Committee on Energy and Commerce

With these words, Rep. Tauzin hailed the near-unanimous House passage[11] of H.R. 3448, the “Public Health Security and Bioterrorism Response Act of 2001,”[12] on December 12, 2001. Approval in the House was followed quickly by approval of an amended version of H.R. 3448 in the Senate and referral to conference committee under the aegis of the House Committee on Energy and Commerce for resolution of differences between the House and Senate versions of the legislation. As of April 27, 2002, H.R. 3448 has remained in conference for approximately two months, but appears to be moving steadily, if slowly, toward enactment.

H.R. 3448 contains numerous provisions that, if enacted, would significantly impact FDA, including provisions that would impact FDA’s internal operations, as well as provisions affecting FDA in its dealings with other government agencies and with FDA-regulated industries and individuals. These provisions are examined in detail below. In addition, in order to permit a more rapid review of significant provisions, a summary table of all H.R. 3448 titles and sections, including brief comments about their relevance or non-relevance to FDA, is provided as “Appendix A.”

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History and Current Status of H.R. 3448

H.R. 3448 is the result of a bicameral and bipartisan effort to enact legislation improving the national response to bioterrorism and similar public health emergencies following the terrorist and bioterrorist (anthrax) attacks of September and October 2001. The genesis, as well as many provisions, of H.R. 3448 are apparently found in an Administration bill submitted to Congress in October 2001, but the measure is also said to reflect industry comments and negotiation between the parties.

On December 12, 2001, H.R. 3448 passed the House and by December 20, 2001, H.R. 3448 had been received, amended and passed as amended by unanimous consent in the Senate. However, due to disagreement between the House and Senate over the Senate amendment, H.B. 3448 was committed to a conference committee on February 28, 2002, where it remains today, approximately two months later.

The disputed amendment proposes to provide a complete substitution, incorporating the provisions of S. 1765, the “Bioterrorism Preparedness Act of 2001,” into H.B. 3448 in place of the House provisions.

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15 See, e.g., Committee News Release, supra note 10.


17 Latest THOMAS Bill Summary & Status File on-line check was performed on April 27, 2002. See THOMAS, supra note 16. In addition to challenges resolving House/Senate differences, the delay may also partially be due to the burden of the Enron-related activities of committee conferees, as the House Committee on Energy and Commerce is handling substantial portions of that investigation.

18 S.Amdt. 2692, supra note 16.


20 In fact, the amendment begins, “[s]trike all after the enacting clause, and insert the following: [text of S. 1765].” S.Amdt. 2692, text as submitted in CR S13997-14009, at 13997.
These measures are substantially similar, but not identical. As a result, and probably anticipating House resistance to a universal substitution of Senate provisions for those passed by the House, on December 20, 2001, the same day that it passed the amended legislation, the Senate insisted on its amendment, asked for a conference, and appointed conferees.

On February 28, 2002, the House formally disagreed with the Senate amendment, but agreed to a conference. The same day, the House debated and agreed on conferee instructions and appointed conferees to the conference committee, to be placed under the aegis of the House Committee on Energy and Commerce. In addition to the Energy and Commerce Committee members, the House conferees also include members of the Committees on Agriculture and the Judiciary for specific portions of the bill, amendment, and modifications committed to conference.

Although H.R. 3448 remains in conference at the time of completion of this paper, it appears that the legislation is still moving steadily toward enactment, with movement out of committee possible as early as May, 2002.

H.R. 3448 Provisions–Sections Requiring FDA Action or Otherwise Relevant to FDA

21 See S. 1765, supra note 19. See also Memorandum for External Distribution, supra note 14, summarizing notable remaining House/Senate differences in the food safety area that will be resolved in conference as: breadth of administrative detention, commissioning and records inspection authorities; standards for triggering debarment; and exemption of farms and retail establishments from registration requirements.

22 Bill Summary & Status report for S. 1765, THOMAS, supra note 16. The Senate appointed as conferees Senators Kennedy and Frist [sponsors of S. 1765], as well as Senators Dodd, Harkin, Mikulski, Jeffords, Gregg, Enzi and Hutchinson.

23 Bill Summary & Status report for H.R. 3448, THOMAS, supra note 16.

24 Notably, the instructions require the House managers to “recognize the importance of, and not disrupt flow of funding for bioterrorism and public health emergencies,” and to “work diligently to reconcile differences between the two Houses,” among other responsibilities. Id.

25 The Speaker appointed as conferees Representatives Tauzin and Dingell [sponsors of H.R. 3448], as well as Representatives Bilirakis, Gillmor, Burr, Shimkus, Waxman, and Brown (OH) from the Committee on Energy and Commerce. Bill Summary & Status report for H.R. 3448, THOMAS, supra note 16.

26 For specific consideration of Title II of the House bill and Section 216 and Title V of the Senate amendment, the Speaker of the House also appointed Committee on Agriculture members Reps. Combest, Lucas (OK), Chambliss, Stenholm, and Holden. Id. For specific consideration of Title II of the House Bill and Sections 216 and 401 of the Senate amendment, the Speaker of the House also appointed Committee on the Judiciary members Reps. Sensenbrenner, Smith (TX), and Conyers. Id.

27 Telephone Conversation with unnamed staff member, Office of Rep. W.J. “Billy” Tauzin, (April x, 2002) (conversation notes on file with author). During a conversation about the status and prospects of H.R. 3448, the staff member informed the author that the legislation is moving forward and that it was hoped that H.R. 3448 would make it out of committee by sometime in May or June.
Most of the H.R. 3448 provisions which would significantly affect FDA activities and authority or significantly affect FDA-regulated industries are contained in Title II, “Enhancing Controls on Dangerous Biological Agents and Toxins,” and Title III, “Amendments to the Federal Food, Drug, and Cosmetic Act.” Both titles are explored in detail below. In addition, the bill contains several other provisions that are either directly or indirectly related to FDA activities. Most notably, these include directly relevant provisions in Title I, Subtitle B, “National Stockpile; Development of Priority Countermeasures,” relating to (a) the accelerated research, development and approval of “countermeasures” to biological terrorism and (b) to the use of animal trials in the approval of some drugs and biologics. These directly and indirectly relevant provisions are also addressed in this portion of the paper.

Title I—National Preparedness for Bioterrorism and Other Public Health Emergencies

Subtitle A—National Preparedness and Response Planning, Coordinating, and Reporting

Subtitle A does not mandate any specific or direct involvement of the FDA. However, the FDA is likely to be interested in several activities under this subtitle. More importantly, FDA should probably be involved, or at least represented, in some of these endeavors. For example, the subtitle provides for the development of a national “Preparedness Plan” for bioterrorism and other public health emergencies as well as requiring the immediate implementation of certain activities to enhance national preparedness, even before the Plan is developed and approved. Provisions of the subtitle that might be of interest or relevant to the FDA are identified below. Their potential implications for the agency are discussed in the next paper section, which addresses the implications of various H.R. 3448 provisions for FDA, the FDA-regulated community, and
other stakeholders.

Section 101. National preparedness and response.

Section 101 would amend the Public Health Service Act ("PHS Act") by adding a new title, "Title XXVIII—National Preparedness for Bioterrorism and Other Public Health Emergencies," and subtitle, "Subtitle A—National Preparedness and Response Planning, Coordinating, and Reporting." Among other provisions, Title XXVIII, Subtitle A would include the following activities that may be of interest or relevance to the FDA: creation of a national preparedness plan for response to bioterrorism and other public health emergencies; development and maintenance of medical countermeasures (including drugs, vaccines and medical devices) against biological agents and ensuring coordination and minimizing duplication of Federal, State and local activities, including during investigation of a disease outbreak.

Section 102. Assistant Secretary for Emergency Preparedness; National Disaster Medical System.

Section 102 would amend the PHS Act by adding a new subtitle, "Subtitle B—Emergency Preparedness and Response." Among other provisions, Subtitle B would include the following provision that seems likely to be of interest and relevance to the FDA: creation of a position of "Assistant Secretary for Emergency Preparedness; National Disaster Medical System."
Preparedness" whose duties shall include coordinating the activities of the Department of Health and Human Services ("HHS") with respect to "research and development of priority vaccines, other biological products, drugs, and devices useful for detecting or responding to a bioterrorist attack or other public health emergency."  

Section 103. Improving ability of Centers for Disease Control and Prevention with respect to bioterrorism and other public health emergencies; facilities.

Section 103 would amend Section 319D of the PHS Act to include a number of provisions related to "revitalizing" the Centers for Disease Control and Prevention ("CDC"). Among other provisions, amended Section 319D would include the following activity that may be of interest or relevance to the FDA: creation of a national public health communications and surveillance network.

Section 104. Advisory committees and communications.

Section 104 would amend Section 319F of the PHS Act to require establishment of various advisory committees and development of a communications strategy for use during biological attack. Among other provisions, amended Section 319F would include the following provisions that may be of interest or relevance to the FDA: the new "National Advisory Committee on Children and Terrorism" would provide recommen-

34 New Title XXVIII, Subtitle B, § 2811 (a), as proposed by H.R. 3448 § 102.
35 Id., § 2811 (a) (2) (D).
37 See H.R. 3448, supra note 8, § 103.
38 Amended PHS Act § 319D (b) (3), as proposed by H.R. 3448 § 103.
40 See H.R. 3448, supra note 8, § 104.
dations regarding vaccine stockpiling\textsuperscript{41} and the new “Emergency Public Information and Communications “EPIC” Advisory Committee” would provide recommendations regarding communication of biological attack information to the public\textsuperscript{42}

*Section 108. Enhancing preparedness activities for bioterrorism and other public health emergencies.*

Section 108 would amend Section 319F of the PHS Act\textsuperscript{43} to establish a “joint interdepartmental working group on preparedness and readiness for the medical and public health effects of a bioterrorist attack on the civilian population.”\textsuperscript{44} The working group seems likely to be of interest and relevance to FDA, particularly because, among other provisions, amended Section 319F provides that the working group activities shall include: coordination and prioritization of research, development, production and regulatory review of priority countermeasures for responding to bioterrorist attack\textsuperscript{45} and coordination of research and development of, and development of shared standards for, detection and protective equipment\textsuperscript{46}

An additional provision of this section that may be of interest or relevance to FDA is clarification of responsibilities among Federal officials for the investigation of suspicious outbreaks of disease\textsuperscript{47}

*Sections 105-107 and 109-114. Not relevant to FDA.*

For various reasons, FDA is unlikely to have significant involvement in activities under Sections 105 to 107 or Sections 109 to 114 of Subtitle A. In large part, these reasons are that the sections are relevant only to

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\textsuperscript{41}Amended PHS Act § 319F (c) (2) (B) (iii), as proposed by H.R. 3448 § 104.
\textsuperscript{42}Amended PHS Act § 319F (c) (3) (B), as proposed by H.R. 3448 § 104.
\textsuperscript{43}42 U.S.C. 247d-6.
\textsuperscript{44}See H.R. 3448, supra note 8, § 108.
\textsuperscript{45}Amended PHS Act § 319F (a) (1) – (a) (2), as proposed by H.R. 3448 § 108.
\textsuperscript{46}Amended PHS Act § 319F (a) (3) – (a) (4), as proposed by H.R. 3448 § 108.
\textsuperscript{47}Amended PHS Act § 319F (b) (2) (C), as proposed by H.R. 3448 § 108.
other agencies or only to activities outside the scope of FDA’s purpose and jurisdiction.\[^{48}\]

**Subtitle B—National Stockpile; Development of Priority Countermeasures**

Subtitle B includes two sections (122 and 123) that require FDA’s direct involvement. In addition, FDA is likely to be interested in several other activities under this subtitle, and should probably be involved, or at least represented, in some of them. Subtitle B has two primary purposes. First, it provides for the maintenance of a national stockpile of drugs, vaccines, medical devices and other supplies for use in a bioterrorist attack or other public health emergency. In addition, it provides for the accelerated research, development, evaluation and approval of priority countermeasures\[^{49}\] to a bioterrorist attack. Provisions of the subtitle that are or might be of interest or relevance to the FDA are identified below. Their potential implications for the agency are discussed in the next paper section.

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\[^{48}\]These non-FDA-relevant sections address: Education of health care personnel and their training regarding pediatric issues (\(\bullet\) 105); the provision of grants regarding shortages of certain health professionals (\(\bullet\) 106); the development of an emergency system for verification of the credentials of health professions volunteers (\(\bullet\) 107); the improvement of State and local core public health capacities (\(\bullet\) 109); the development of an antimicrobial resistance program (\(\bullet\) 110); a study regarding communications abilities of public health agencies (\(\bullet\) 111); the provision of supplies and services in lieu of award funds (\(\bullet\) 112); various additional amendments (\(\bullet\) 113); and a study regarding local emergency response methods (\(\bullet\) 114). See H.R. 3448, supra note 8, \(\S\)\S\ 105-107 and 109-114. See also Appendix A to this paper.

\[^{49}\]A “priority countermeasure” is defined differently in different sections of H.R. 3448, particularly in relation to the scope of the definition. In § 122 it is defined as “a drug or biological product that is a countermeasure to treat, identify, or prevent infection by a [listed] biological agent or toxin... or harm from any other agent that may cause a public health emergency.” H.R. 3448, supra note 8, § 122 (c). This definition is applicable to a number of other sections as well, but in § 125, priority measures are defined to include medical and technological devices and diagnostic tests in addition to drugs and biological products. H.R. 3448, id., § 125.
Section 121. National stockpile.

Section 121 would require the Secretary of Health and Human Services to maintain one or more stockpiles of “drugs, vaccines and other biological products, medical devices, and other supplies” sufficient to meet the health security needs of the United States. It seems likely that the Secretary would consult with FDA regarding the research, development, and approval status of such products.

Section 122. Accelerated approval of priority countermeasures.

Section 122 would clearly and directly involve FDA, as it would permit the HHS Secretary to designate a priority countermeasure as a fast-track product pursuant to section 506 of the Food, Drug and Cosmetic Act (“FD&C Act”). This designation could be made by the Secretary on his or her own initiative (prior to the request for such designation by the sponsor) or upon a sponsor’s request. The section is not intended to prohibit sponsors from declining such a designation.

The section also provides that priority countermeasures that are not designated as fast-track products are subject to the [normal] performance goals of the FDA Commissioner.

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50 See H.R. 3448, supra note 8, § 121.
51 For definition of this term, please see supra note 49.
53 See H.R. 3448, supra note 8, § 122.
54 Id., § 122 (a) (1).
55 Id., § 122 (a) (2).
56 Id.
57 Id., § 122 (b).
Section 123. Use of animal trials in approval of certain drugs and biologics; issuance of rule.

Section 122 would clearly and directly involve FDA: it would mandate the completion of a specific FDA-initiated rulemaking. The section would require that the HHS Secretary complete the process of [FDA] rulemaking regarding the use of animal trials in approval of some products that began with issuance of the proposed rule, “New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot be Conducted,” within 180 days after enactment of H.R. 3448.

Section 124. Security for countermeasure development and production.

Section 124 would amend section 319J of the PHS Act by adding a new section 319K, permitting the HHS Secretary, in consultation with the Attorney General and the Secretary of Defense, to provide technical or other assistance in securing persons or facilities that “conduct development, production, distribution, or storage of priority countermeasures.” This is likely to be relevant to FDA only inssofar as it relates to

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58 Aside from the direct impact on FDA and related implications discussed in the paper, § 123 seems to raise some potential administrative law issues. Specifically, once Congress has delegated away rule-making authority to an agency, may it then require the agency to issue specific rules within specific times? (For example, why do this rather than passing the regulation that it wants through the normal legislative process?)

59 New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot be Conducted, 64 Fed. Reg. 53960 (proposed Oct. 5, 1999).

60 See H.R. 3448, supra note 8, § 123.

61 42 U.S.C. 243 et seq.

62 H.R. 3448, supra note 8, § 124.
FDA’s research, holding, evaluation, and other relevant facilities and personnel.

Section 125. Accelerated countermeasure research and development.

Among other changes, Section 125 would amend Section 319F (h) of the PHS Act\textsuperscript{63} to require the HHS Secretary to award grants, contracts, and cooperative agreements for research relating to various aspects of priority countermeasure development\textsuperscript{64}. Two identified research areas may of particular interest or relevance to FDA: development of new vaccines and therapeutics\textsuperscript{65} and development of diagnostic tests for detection of biological agents and toxins\textsuperscript{66}.

Section 126. Evaluation of new and emerging technologies regarding bioterrorist attack and other public health emergencies.

Section 126 requires the HHS Secretary promptly to identify, evaluate, and report on new and emerging technologies designed to improve the ability to detect, identify, diagnose or otherwise conduct surveillance activities related to bioterrorist attack or public health emergency\textsuperscript{67}. It seems likely that FDA will be involved, or at least consulted, by the Secretary in implementing this survey and report.

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{63} 42 U.S.C. 247d-6.
\item \textsuperscript{64} For purposes of this section, the definition of priority countermeasures includes medical and technological devices and diagnostic tests in addition to drugs and biological products. H.R. 3448, supra note 8, § 125. This includes an even wider scope of products than is covered by the priority countermeasures definition applicable to §122 and various other sections. See, e.g., H.R. 3448, id., § 125, and supra note 49.
\item \textsuperscript{65} Amended PHS Act § 319F (h) (2) (A) (ii), as proposed by H.R. 3448 § 125.
\item \textsuperscript{66} Amended PHS Act § 319F (h) (2) (A) (iii), as proposed by H.R. 3448 § 125.
\item \textsuperscript{67} See H.R. 3448, supra note 8, § 126.
\end{itemize}
\end{footnotesize}
Sections 127. Potassium Iodide

Section 127 seems unlikely to require significant FDA involvement or interest. The section involves various requirements for the Federal stockpiling and distribution, and State and local availability, of potassium iodide tablets in relation to potential nuclear incidents.  

Subtitle C–Emergency Authorities; Additional Provisions

Subtitle C does not mandate any specific or direct involvement of the FDA and it is unlikely that the activities under this subtitle would be of significant interest to FDA. Sections 131 to 139 of Subtitle C provide for a variety of emergency authorities, research requirements, and other provisions relevant to other agencies.  

For various reasons, FDA is unlikely to have significant involvement in activities under any of the Sections 131 to 139 of Subtitle C. In large part, these reasons are that the sections are relevant only to other agencies or only to activities outside the scope of FDA’s purpose and jurisdiction. Therefore the sections are not discussed separately or in detail here or in the following paper section (“Implications”).

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68See H.R. 3448, supra note 8, §127.
69See H.R. 3448, supra note 8, §§ 131-139.
70These non-FDA-relevant sections address: expansion of the authority of the HHS Secretary to respond to public health emergencies (§131); streamlining and clarifying communicable disease quarantine provisions (§ 132); provision of emergency waivers of Medicare, Medicaid, and SCHIP requirements (§133); provision for the expiration of public health emergencies (§134); requirement of a designated State public emergency announcement plan (§135); provision for expanded research by Secretary of Energy (§136); provisions relating to the Agency for Toxic Substances and Disease Registry (§137); expansion of research on worker health and safety (§138); and provision of funding support of the technology opportunities program (§139). See H.R. 3448, supra note 8, §§ 131-139. See also Appendix A to this paper.
Subtitle D—Authorization of Appropriations

Sec. 151. Authorization of Appropriations.

Subtitle D, Section 151 would be likely to encompass some FDA activities, even though it does not specifically identify FDA in any of its appropriation authorizations. This is because the section provides a general authorization of appropriation for activities under Title I of H.R. 3448 and other specific portions of the PHS Act. As discussed above in relation to Subtitles A through C of Title I, this may involve FDA in a significant number of covered activities. Section 151 authorizes appropriation of $2,720,000,000 to HHS for eligible activities in fiscal year 2002, and “such sums as may be necessary” for fiscal years 2003 through 2006.

Title II—Enhancing Controls on Dangerous Biological Agents and Toxins

Although Title II and its sole section (201) do not specifically reference FDA, the provisions of this title and section would likely have a notable effect in relation to some FDA activities, particularly research and evaluation of drugs and other biologic products. In addition, the section’s provisions would have a significant impact on some FDA-regulated entities.

In brief, Section 201 would mandate creation of a regulatory control regime for certain biological agents

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71 Eligible activities include those carried out in accordance with: provisions of Title I of H.R. 3448; sections 319A-319K of the PHS Act; the newly created Title XXVIII of the PHS Act; and section 301 of the PHS Act to the extent that such 301 activities are done to supplement the prior three types of activities (and excluding National Institutes of Health (“NIH”) activities). See H.R. 3443, supra note 8, § 151 (b).

72 See H.R. 3448, supra note 8, § 151 (a).
and toxins. This control regime would include: registration of those who possess, use or transfer listed agents; creation of a national database of registrants, with traceability mechanisms; regulation of transfers; establishment of standards governing possession and use; inspections; security and screening requirements for registered persons; access limitations; disclosure limitations; and civil and criminal penalties for certain acts or omissions. Finally, Section 201-mandated security upgrades to HHS facilities where listed agents, toxins or vaccines are housed or researched would likely be relevant to some FDA facilities.

Section 201. Regulation of certain biological agents and toxins.

Section 201 (a) Biological Agents Provisions of the Antiterrorism and Effective Death Penalty Act of 1996; Codification in the Public Health Service Act, With Amendments.

Section 201(a) would amend the PHS Act by adding a new section “Sec. 351A. Enhanced control of dangerous biological agents and toxins.” This section would require the HHS Secretary to, by regulation: establish, maintain, and publish a list of dangerous biological agents and toxins; establish and enforce safety procedures for the transfer of listed agents; and establish and enforce standards and procedures governing the possession and use of listed agents. In addition, these regulations would have to require registration of the possession, use and transfer of listed agents; the regulations must include (if available) characterization of listed agents to enhance their identification and traceability; and the Secretary must...

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73 42 U.S.C. 262 et seq.
75 Amended PHS Act § 351A (a) (1) - (a) (2), as proposed by H.R. 3448 § 201 (a).
76 Amended PHS Act § 351A (b), as proposed by H.R. 3448 § 201 (a).
77 Amended PHS Act § 351A (c), as proposed by H.R. 3448 § 201 (a).
maintain a national database of the location and characterization of listed agents. This section would also permit the Secretary to conduct inspections to ensure compliance and to establish exemptions under certain limited conditions.

Notably, the section would also require the Secretary, in consultation with the Attorney General, to establish security requirements (including screening requirements) for persons possessing, using, or transferring listed agents, and to ensure compliance as a condition of registration. These security requirements are to include restricting access to listed agents to those with a legitimate need for access as determined by registration and denying access to a variety of persons, including those under investigation or named in a warrant for terrorist, criminal, or violent activities, those suspected of seeking to obtain information on behalf of a foreign nation, and those defined as “restricted persons” in U.S.C. Title 18, Section 175b.

The Secretary would also have to require that registered persons submit names and identifying information for all individuals considered for access to listed agents, as described above, to the Secretary and to the Attorney General. The Attorney General would then use criminal, immigration, and national security databases to determine if the individuals meet the conditions for access. The Secretary would be permitted to make funds and technical assistance available to affected entities to improve security at the facilities of registered persons.

This section would also limit disclosure of information held by Federal agencies as to the identity, geographic location, site- or agent-specific information, or security information related to listed agents or the persons

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78 Amended PHS Act § 351A (d), as proposed by H.R. 3448 § 201 (a).
79 Amended PHS Act § 351A (e) - (f), as proposed by H.R. 3448 § 201 (a).
80 Presumably, the term “person or persons” refers to legal rather than natural persons, i.e., entities as well as individuals.
81 Amended PHS Act § 351A (g) and (g) (1), as proposed by H.R. 3448 § 201 (a).
82 Amended PHS Act § 351A (g) (2) (A) (i), as proposed by H.R. 3448 § 201 (a).
83 Amended PHS Act § 351A (g) (2) (A) (ii) (I) - (II), as proposed by H.R. 3448 § 201 (a).
84 Amended PHS Act § 351A (g) (2) (B), as proposed by H.R. 3448 § 201 (a).
85 Id.
86 Amended PHS Act § 351A (g) (3), as proposed by H.R. 3448 § 201 (a).
registered to possess, use, or transfer them. This provision is not to be construed as preventing the head of a Federal agency from disclosure of such information to protect the public health and safety or pursuant to proper Congressional request.

The section would provide a civil money penalty for violations of amended PHS Act subsections 351A (a) (1) (A) (b) and (c).

The section would provide for coordination with regulations under the Virus-Serum-Toxin Act administered by the Secretary of Agriculture as well as providing for special registration conditions for persons with a permit or license from the Department of Agriculture for the possession or use of listed agents.

There are miscellaneous additional provisions for appropriations, conforming amendments and other matters.

Section 201 (b) Criminal Penalties Regarding Select Agents.

Section 201 (b) would amend 18 U.S.C. 175b to provide criminal penalties up to five years imprisonment and undefined fines for knowingly transferring a listed agent to a person without first verifying with the HHS Secretary that the person has a valid registration. It would provide the same criminal penalties for knowing possession of a listed agent for which the person has not obtained a required registration. There would also be miscellaneous additional provisions for conforming amendments, technical corrections, and other matters.

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87 Amended PHS Act § 351A (h) (1), as proposed by H.R. 3448 § 201 (a).
88 Amended PHS Act § 351A (h) (2), as proposed by H.R. 3448 § 201 (a).
89 Amended PHS Act § 351A (i), as proposed by H.R. 3448 § 201 (a).
90 Amended PHS Act § 351A (j) (1), as proposed by H.R. 3448 § 201 (a).
91 Amended PHS Act § 351A (j) (2), as proposed by H.R. 3448 § 201 (a).
92 See amended PHS Act § 351A (k) - (l), as proposed by H.R. 3448 § 201 (a).
93 Amended 18 U.S.C. 175b (b), as proposed by H.R. 3448 § 201 (b) (1).
94 Amended 18 U.S.C. 175c (c), as proposed by H.R. 3448 § 201 (b) (1).
95 See H.R. 3448, supra note 8, § 201 (b) (2) - (4).
Section 201 (c) Security Upgrades at the Department of Health and Human Services.

Section 201 (c) would authorize appropriation of “such sums as may be necessary” to the HHS Secretary for securing Department facilities where listed agents or vaccines are housed or researched. Presumably, FDA some facilities might be eligible for security upgrade funding under this section.

Section 201 (d) Report to Congress.

FDA is unlikely to have significant involvement in activities under this section.

Title III—Amendments to Federal Food, Drug, and Cosmetic Act

Subtitle A—Protection of Food Supply

Section 301. Protection against intentional adulteration of food.

Section 301 (a), “Increasing Inspections for Detection of the Intentional Adulteration of Food,” would amend Section 801 of the Food, Drug, and Cosmetic Act (“FD&C Act”) by adding a new subsection requiring that the HHS Secretary give high priority to increasing the number of inspections of foods offered for import at U.S. ports of entry, with “the greatest priority given to inspections to detect the intentional adulteration of food.”

96 H.R. 3448, supra note 8, § 201 (c).
97 21 U.S.C. 381.
98 See H.R. 3448, supra note 8, § 301 (a).
99 Amended FD&C Act 801 (h)(1), as proposed by H.R. 3448 § 301 (a).
Section 301 (b), “Improvements to Information Management Systems,” would further amend Section 801 to require that the HHS Secretary make improvements to FDA information management systems relating to foods imported or offered for import into the United States (“imported foods”) and report to Congress on increased inspections of imported food and information management system improvements.\footnote{Amended FD&C Act 801 (h)(2) - (3), as proposed by H.R. 3448 § 301 (b).}

Section 301 (c), “Testing for Rapid Detection of Intentional Adulteration of Food,” would further amend 801 by adding a subsection to require research on the development of tests and sampling methodologies to more rapidly test food for adulteration.\footnote{Amended FD&C Act 801 (i)(1), as proposed by H.R. 3448 § 301 (c).} The section also requires the Secretary to give priority to research test methods suitable for use at ports of entry, to coordinate as appropriate with specific other agencies, and to submit an annual research report to Congress.\footnote{Amended FD&C Act 801 (i)(2) - (4), as proposed by H.R. 3448 § 301 (c).}

Section 301 (d), “Assessment of Threat of Intentional Adulteration of Food,” would require the Secretary, acting through the FDA Commissioner, to ensure that by six months after enactment of H.R. 3448 a food adulteration threat assessment is completed and a report is submitted to Congress.\footnote{See H.R. 3448, supra note 8, § 301 (d).}

Section 301 (e), “Authorization of Appropriations,” would authorize appropriation of $100,000,000 to carry out Section 301 activities for fiscal year 2002, as well as “such sums as may be necessary” for fiscal years 2002 through 2006, “in addition to other authorizations of appropriations that are available for such purpose.”\footnote{See H.R. 3448, supra note 8, § 301 (e) (emphasis added).}

Section 302. Administrative detention.

Section 302 would amend the FD&C Act to expand the FDA’s authority to order administrative detention of
food upon “credible evidence or information” indicating that such food article “presents a threat of serious adverse health consequences or death to humans or animals,” [hereinafter “serious health threat”].

Section 302 (a), “Expanded Authority,” would amend Section 304 of the FD&C Act by adding a new subsection providing that “[a]n officer or qualified employee [of FDA]” may order the detention of any article of food found during an inspection, examination, or investigation, providing that he or she has “credible evidence or information” indicating that such food article presents a serious health threat. The section would limit the detention authority by requiring that an article of food may be ordered detained only if the HHS Secretary or a designated official approves the order. Only district directors of the district where the article is located, or officials senior to them may be designated to approve these detention orders.

The section would limit the period of detention to 20 days, unless a longer time, not to exceed 30 days, is necessary to enable the Secretary to institute further action. It would allow detention orders under the section to require food articles to be marked as detained, and to be removed to a secure facility. No one may transfer the article from the place of detention or secure removal until release by the Secretary or expiration of the detention period.

Detention orders would be appealable to the Secretary, who would be required to confirm or terminate the order within 72 hours. If the Secretary confirms the order it would be considered final agency action. If the Secretary does not act within 72 hours, the order would be deemed terminated.

Section 302 (b), “Prohibited Act,” would amend Section 301 of the FD&C Act to make the transfer of

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105 See H.R. 3448, supra note 8, § 302.
107 Amended FD&C Act 304 (h) (1) (A), as proposed by H.R. 3448 § 302 (a).
108 Amended FD&C Act 304 (h) (1) (B), as proposed by H.R. 3448 § 302 (a).
109 Id.
110 Amended FD&C Act 304 (h) (2), as proposed by H.R. 3448 § 302 (a).
111 Amended FD&C Act 304 (h) (3), as proposed by H.R. 3448 § 302 (a).
112 Amended FD&C Act 304 (h) (4), as proposed by H.R. 3448 § 302 (a).
Section 302 (c), “Temporary Holds at Ports of Entry,” would amend Section 801 of the FD&C Act\textsuperscript{115} to add a new subsection allowing FDA officials or qualified employees to request a temporary hold (no more than 24 hours) at the port of entry prior to inspection if the officer or employee (1) has credible evidence or information of a serious threat, (2) is unable to inspect the article upon its being offered for import at a port of entry, and (3) the Secretary or a designated official approves the request\textsuperscript{116} The section would also allow requests to be removed to a secure facility. No one may transfer it while it is being so held. Finally, the section requires notification of the State in which the port of entry involved is located\textsuperscript{117}

Section 303. Permissive debarment regarding food importation.

Section 303 (a) would amend Section 306 (b) of the FD&C Act\textsuperscript{118} to provide that persons are subject to permissive debarment if the person has been convicted of a felony related to food importation, or has repeatedly imported or offered for import adulterated articles of food\textsuperscript{119} Sections 303 (b) and (c) would address conforming amendments and effective dates.

Section 303 (d) would amend Section 801 of the FD&C Act\textsuperscript{120} to make “importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred

\textsuperscript{114}Amended FD&C Act 301 (bb), as proposed by H.R. 3448 § 302 (b).
\textsuperscript{115}21 U.S.C. 381.
\textsuperscript{116}Amended FD&C Act 801 (j) (1) - (3), as proposed by H.R. 3448 § 302 (b).
\textsuperscript{117}Amended FD&C Act 801 (j) (4), as proposed by H.R. 3448 § 302 (b).
\textsuperscript{118}21 U.S.C. 335a(b).
\textsuperscript{119}See H.R. 3448, supra note 8, § 303 (a) and Amended FD&C Act 306 (b) (1) (C), as proposed by H.R. 3448 § 303 (a).
\textsuperscript{120}21 U.S.C. 331.
under [Amended] section 306 (b)(1)(C)” a Prohibited Act.\textsuperscript{121}

\textsuperscript{121} Amended FD&C Act 301 (cc), as proposed by H.R. 3448 § 303 (d).
Section 304. Maintenance and inspection of records for foods.

Section 304 (a), “In General,” would amend Chapter IV of the FD&C Act\textsuperscript{122} by adding a new section, “Sec. 414. Maintenance and Inspection of Records,” relating to records of food manufacturing, processing, packing, distribution, receipt, holding or importing\textsuperscript{123}.

Proposed Section 414 (a), “Records Inspection,” would provide that if the HHS Secretary has credible evidence or information of serious health threat from an article of food, Secretary or designee could require each person (except farms and restaurants) who “manufactures, processes, packs, distributes, receives, holds, or imports such article” to allow FDA to have access to and to copy “all records relating to such article that are needed to assist the Secretary in investigating the evidence or information.”\textsuperscript{124} The designated FDA official or employee would be required to present credentials and a written notice. The official or employee would be required to access and copy the records, “at reasonable times and within reasonable limits and in a reasonable manner.” Covered records would include those relating to all parts of the food production and distribution chain identified above, in any format (including electronic), and at any location\textsuperscript{125}.

Proposed Section 414 (b), “Regulations Concerning Recordkeeping,” would permit the HHS Secretary, in consultation with other relevant food safety agencies, to establish regulatory requirements regarding record maintenance as may be necessary to trace the food source, chain of distribution, and packaging in order to address serious and credible health threats\textsuperscript{126}.

Proposed Section 414 (c), “Protection of Sensitive Information,” would require the Secretary to take steps to prevent the unauthorized disclosure of trade secrets or confidential information obtained pursuant to the

\textsuperscript{122}21 U.S.C. 341 et seq.
\textsuperscript{123}See H.R. 3448, supra note 8, § 304.
\textsuperscript{124}Amended FD&C Act 414 (a), as proposed by H.R. 3448 § 304 (a).
\textsuperscript{125}Id.
\textsuperscript{126}Amended FD&C Act 414 (b), as proposed by H.R. 3448 § 304 (a).
activities in this section.\textsuperscript{127}

Proposed Section 414 (d), “Limitations,” would state that the section may not be construed to: limit the authority of the Secretary to inspect or require records under any other section of the Act; authorize the Secretary to impose any requirements with respect to food in the exclusive jurisdiction of the Secretary of Agriculture; have any legal effect on 5 U.S.C. 552 or 18 U.S.C. 1905; or to include food recipes, financial, pricing, personnel or research data, or sales data other than shipment data.\textsuperscript{128}

Section 304 (b), “Factory Inspection,” would amend Section 704 (a) of the FD&C Act\textsuperscript{129} to provide that inspections under the section shall “extend to all records and other information described in section 414” when the Secretary has evidence of a serious and credible health threat.\textsuperscript{130}

Section 304 (c), “Prohibited Acts,” would amend Section 301 (e) of the FD&C Act\textsuperscript{131} to make refusal to permit access to or copying of relevant records, as well as failure to establish or maintain required records, Prohibited Acts.\textsuperscript{132}

Section 305. Registration.

Section 305 (a), “In General,” would amend Chapter IV of the FD&C Act\textsuperscript{133} by adding a new section, “Sec. 415, “Registration,” relating to the registration of all facilities in the food production and distribution chain, except farms.\textsuperscript{134}
Proposed Section 415 (a), “Registration,” would require any facility (foreign or domestic, except farms) that is engaged in “manufacturing, processing, packing, or holding food for consumption in the United States” to register with the HHS Secretary. Foreign facilities would also be required to provide the name of the U.S. agent for the facility. The registration would have to include (and update if changed) the identity and address of each facility at which, and all trade names under which, the registrant conducts business, as well as the general food category of any food manufactured, processed, packed or held at such facility (the last is only required when determined to be necessary by the Secretary). The Secretary would be required to assign a registration number to each facility and to notify registrant of the receipt of registration, as well as to maintain a current list of registered facilities. The list and other information provided under this subsection would not be subject to Freedom of Information Act (FOIA) requirements.

Proposed Section 415 (b), “Exemption,” would permit the Secretary to exempt types of retail establishments via regulation, upon determination that registration of such establishments is not needed for effective enforcement.

Proposed Section 415 (c), “Facility,” would define “facility” to include “any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer), that manufactures, processes, packs, or holds food.” The term does not include “restaurants or other establishments in which food is served solely for immediate human consumption.”

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135 Amended FD&C Act 415 (a) (1), as proposed by H.R. 3448 § 305 (a).
136 Amended FD&C Act 415 (a) (1) (B), as proposed by H.R. 3448 § 305 (a).
137 Amended FD&C Act 415 (a) (2), as proposed by H.R. 3448 § 305 (a).
138 Amended FD&C Act 415 (a) (3), as proposed by H.R. 3448 § 305 (a).
139 Amended FD&C Act 415 (a) (4), as proposed by H.R. 3448 § 305 (a).
140 5 U.S.C. 552.
141 Amended FD&C Act 415 (a) (4), as proposed by H.R. 3448 § 305 (a).
142 Amended FD&C Act 415 (b), as proposed by H.R. 3448 § 305 (a).
143 Amended FD&C Act 415 (c), as proposed by H.R. 3448 § 305 (a).
144 Id.
Proposed Section 415 (d), “Rule of Construction,” would provide that the section may not be construed to authorize the Secretary to require an application, review, or licensing process.\footnote{Amended FD&C Act 415 (d), as proposed by H.R. 3448 § 305 (a).}

Section 305 (b), “Prohibited Acts,” would amend Section 301 of the FD&C Act\footnote{21 U.S.C. 331.} to make failure to register a Prohibited Act.\footnote{Amended FD&C Act 301(dd), as proposed by H.R. 3448 § 305 (b).} It would also amend Section 403 of the FD&C Act\footnote{21 U.S.C. 343.} to provide that food that is manufactured, processed, packed or held in a facility that is not registered will be deemed a Misbranded Food.\footnote{Amended FD&C Act 403 (t), as proposed by H.R. 3448 § 305 (b).}

Section 305 (c), “Effective Date,” would provide that the Prohibited Acts and Misbranded Foods provisions would take effect 180 days after the enactment of H.R. 3448.\footnote{See H.R. 3448, supra note 8, § 305 (c).}

Section 305 (d), “Notice,” would require the Secretary, within 60 days after enactment of H.R. 3448 and after consultation with State and local officials, to take sufficient measures to notify affected entities and facilities of the registration requirement, and to develop guidance as necessary.\footnote{See H.R. 3448, supra note 8, § 305 (d).}

Section 305 (e), “Electronic Filing,” would permit the Secretary to provide for and encourage use of electronic registration submission methods. The Secretary would be required to ensure adequate authentication protocols and data validation.\footnote{See H.R. 3448, supra note 8, § 305 (e).}

Section 305 (f), “Savings Clause,” provides that Section 305 may not be construed as authorizing the HHS
Secretary to encroach on the jurisdiction of the Secretary of Agriculture.

Section 306. Prior notice of imported food shipments.

Section 306 (a), “In General,” would amend Section 801 of the FD&C Act to require the submission to the HHS Secretary of a notice of food import enabling the article of food to be inspected at U.S. ports of entry. The notice would have to provide the identity of: the article of food, the manufacturer and shipper, the grower (if known within time of notice), the country of origin and the country from which shipped, and the anticipated port of entry of the article. The section would provide that the notice regulations must specify a time period for notice between 24 and 72 hours in advance of the importation or offering for import of the article of food.

The section would also provide that any article of food imported or offered for import without submission of the notice “shall be refused admission to the United States.” Further, it would provide that such non-noticed article of food shall be held at the port of entry until notice is submitted to the Secretary and is determined to be in accordance with the notice regulations. In relation to evaluation of the notice, the HHS Secretary must determine whether there is credible evidence or information of serious health threat.

The section would provide the following limitations: the section should not be construed as a limitation on the

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153 See H.R. 3448, supra note 8, § 305 (f).
154 21 U.S.C. 381.
155 See H.R. 3448, supra note 8, § 306, and see Amended FD&C Act 801 (k) (1), as proposed by H.R. 3448 § 306 (a).
156 Amended FD&C Act 801 (k) (1), as proposed by H.R. 3448 § 306 (a).
157 Amended FD&C Act 801 (k) (2) (A), as proposed by H.R. 3448 § 306 (a).
158 Amended FD&C Act 801 (k) (1), as proposed by H.R. 3448 § 306 (a) (emphasis added).
159 Amended FD&C Act 801 (k) (2) (B) (i), as proposed by H.R. 3448 § 306 (a).
160 Amended FD&C Act 801 (k) (2) (B) (ii), as proposed by H.R. 3448 § 306 (a).
[choice of a] port of entry for an article of food\textsuperscript{161} the delivery of a notice for an article held awaiting notice should not be construed to authorize delivery pursuant to a bond prior to the Secretary’s determination with respect to the notice\textsuperscript{162} the section should not be construed to limit the Secretary’s authority to obtain information under any other provision of the act\textsuperscript{163} and the section should not be construed to authorize the HHS Secretary to encroach on the jurisdiction of the Department of Agriculture\textsuperscript{164}

Section 306 (b) would amend Section 301 of the FD&C Act\textsuperscript{165} to include among Prohibited Acts the importing or offering to import into the United States of an articles of food in violation of the prior notice regulations promulgated under this section\textsuperscript{166}

Section 307. Authority to mark articles refused admission into United States.

Section 307 would provide authority related to clearly marking refused articles of food\textsuperscript{167} Section 307(a) would amend Section 801 of the FD&C Act\textsuperscript{168} to provide that if a food has been refused admission under proposed FD&C Act Sec. 801 (a) (presenting a serious health threat) and if it is not a food required to be destroyed, the HHS Secretary may require the owner or consignee to attach a label to the food container that “clearly and conspicuously bears the statement: ‘UNITED STATES: REFUSED ENTRY.’”\textsuperscript{169}

\textsuperscript{161}Amended FD&C Act 801 (k) (1), as proposed by H.R. 3448 § 306 (a).
\textsuperscript{162}Amended FD&C Act 801 (k) (2) (B) (i), as proposed by H.R. 3448 § 306 (a).
\textsuperscript{163}Amended FD&C Act 801 (k) (3) (A), as proposed by H.R. 3448 § 306 (a).
\textsuperscript{164}Amended FD&C Act 801 (k) (3) (B), as proposed by H.R. 3448 § 306 (a).
\textsuperscript{165}21 U.S.C. 331.
\textsuperscript{166}Amended FD&C Act 301 (ee), as proposed by H.R. 3448 § 306 (b).
\textsuperscript{167}See H.R. 3448, supra note 8, § 307.
\textsuperscript{168}21 U.S.C. 381.
\textsuperscript{169}Amended FD&C Act 801 (l) (1), as proposed by H.R. 3448 § 307 (a).
This cost of such labeling would be the responsibility of the owner or consignee of the food, and any default of such payment would constitute a lien against future importation by the owner or consignee.\textsuperscript{170}

The labeling requirement would remain in effect until the Secretary determines that the food has been brought into compliance with the Act.\textsuperscript{171}

Section 307 (b) would amend Section 403 of the FD&C Act\textsuperscript{172} to provide that food that fails to bear a “refused” label, when required, is deemed Misbranded.\textsuperscript{173}

Finally, Section 307 (c) would provide that the section should not be construed to limit the Secretary’s authority to require labeling under other provision of law.\textsuperscript{174}

Section 308. Prohibition against port shopping for importation.

Section 308 would amend Section 402 of the FD&C Act\textsuperscript{175} to provide that an article of imported food would be deemed adulterated if it has previously been refused admission under Proposed FD&C Act Sec. 801 (a) (serious health threat) unless the re-offeror affirmatively establishes, to the Secretary’s satisfaction, that the article is not adulterated.\textsuperscript{176}

Section 309. Notices to States regarding imported food.

\textsuperscript{170}Amended FD&C Act 801 (l) (2), as proposed by H.R. 3448 § 307 (a).
\textsuperscript{171}Amended FD&C Act 801 (l) (3), as proposed by H.R. 3448 § 307 (a).
\textsuperscript{172}21 U.S.C. 343.
\textsuperscript{173}Amended FD&C Act 403 (u), as proposed by H.R. 3448 § 307 (a).
\textsuperscript{174}See H.R. 3448, supra note 8, § 307 (c).
\textsuperscript{175}21 U.S.C. 342.
\textsuperscript{176}Amended FD&C Act 402 (b), as proposed by H.R. 3448 § 308.
Section 309 would amend Chapter IX of the FD&C Act by adding a new section, “Sec. 908. Notices to States Regarding Imported Food,” which would require the HHS Secretary, upon credible evidence or information indicating that a shipment of imported food poses a serious health threat, to notify the States in which the food is or will be held, as well as the States in which the manufacturer, packer, or distributor of the food is located. The notification would be required to include a request that the State take such action as it considers appropriate to protect the public health.

The section would provide that it should not be construed to limit the authority of the Secretary with respect to adulterated food under any other provision of the Act.

Section 310. Grants to States for inspections; response to notice regarding adulterated imported food.

Section 310 would amend Chapter IX of the FD&C Act to add a new section, “Sec. 909. Grants to States Regarding Food Inspections,” which would: permit the HHS Secretary to make grants to States for inspections by persons commissioned as Department officers, and to assist States with the expenses of actions they take in response to the notice detailed in Sec. 309 (notice regarding imported food posing serious health threat). The section also authorizes appropriations to support these activities.

Subtitle B—Protection of Drug Supply

177 21 U.S.C. 391 et seq.
178 Amended FD&C Act 908 (a), as proposed by H.R. 3448 § 309.
179 Id.
180 Amended FD&C Act 908 (b), as proposed by H.R. 3448 § 309.
181 21 U.S.C. 391 et seq.
182 Amended FD&C Act 909 (a) – (b), as proposed by H.R. 3448 § 310.
183 Amended FD&C Act 909 (c), as proposed by H.R. 3448 § 310.
Section 311. Annual registration of foreign manufacturers; shipping information; drug and device listing.

Section 311 (a) would amend Section 510 of the FD&C Act to require annual registration of foreign manufacturers and to require the name of each importer of its drug or device known to the establishment, as well as the name of each carrier used by the establishment in transporting the drug or device to the United States for importation.

Section 311 (b) (1) would amend Section 801 of the FD&C Act to permit refusal of admission to the United States for a drug or device if its importer does not, at the time of import, submit a statement identifying the required registration under Amended Section 510 of the FD&C Act.

Section 311 (b) (2) would amend Section 301 of the FD&C Act to include as a Prohibited Act the importing or offering for import of a drug or device with respect to which there is a failure to submit to the Secretary the registration statement required by this section.

Section 312. Requirement of additional information regarding import components intended for use in export products.

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185 Amended FD&C Act 510 (i) (l) (i), as proposed by H.R. 3448 § 311 (a) (1).
186 Amended FD&C Act 510 (i) (l) (iii), as proposed by H.R. 3448 § 311 (a) (1).
188 Amended FD&C Act 801 (m), as proposed by H.R. 3448 § 311 (b) (1).
190 Amended FD&C Act 301 (ff), as proposed by H.R. 3448 § 311.
Section 312 (a) would amend Section 801 (d) (3) of the FD&C Act\textsuperscript{192} to provide that “no component of a drug, no component part or accessory of a device, or other article...requiring further processing...” and no article of a food or color additive, or diet supplement, or product in its bulk form would be subject to exclusion into the United States if each of several conditions are met\textsuperscript{192}. The conditions are: intention for further processing and use in a product that will be exported; identification of the manufacturer(s), processor(s), distributor(s), carrier(s), or other entities in the chain of possession of the article; certificates of analysis as to component chemical or biological substances; execution of a bond for payment of liquidated damages in event of default; use and importation in accordance with the statement of intent; maintenance of relevant records; and submission of an accounting of export or destruction of the article, upon request of the Secretary\textsuperscript{193}.

The section would be subject to the limitation that the conditional protection provided in this section would not apply if the HHS Secretary determines that there is credible evidence or information that the products pose a serious health threat.

Section 312 (b) would amend Section 301 (w) of the FD&C Act\textsuperscript{194} to include as Prohibited Acts a variety of offenses related to the statement, including: false statements, failure to submit analysis certificates, failure to maintain or submit records, and the release of any article covered in the section into interstate commerce\textsuperscript{195}.

Title IV–Drinking Water Security and Safety

\textsuperscript{191}21 U.S.C. 381 (d) (3).
\textsuperscript{192}Amended FD&C Act 801 (d) (3) (A), as proposed by H.R. 3448 § 312(a).
\textsuperscript{193}Amended FD&C Act 801 (d) (3) (A) (i) – (iv), as proposed by H.R. 3448 § 312.
\textsuperscript{194}21 U.S.C. 331(w).
\textsuperscript{195}Amended FD&C Act 301 (w), as proposed by H.R. 3448 § 312.
Section 401. Amendment of the Safe Drinking Water Act.

The provisions in Section 401 appear to apply only to community water systems, and not to bottled water, the activities under this section would be the responsibility of the Environmental Protection Agency ("EPA"), and FDA is unlikely to have significant involvement in any activities under this section.
Title I—National Preparedness for Bioterrorism and Other Public Health Emergencies

Subtitle A—National Preparedness and Response Planning, Coordinating, and Reporting

Implications for FDA

As a general matter, Subtitle A would mandate a number of working groups, networks, and initiatives in which FDA may want to be involved due to the crossover between the activities of these entities and initiatives and FDA’s core responsibilities in ensuring the safety and efficacy of food, drugs, vaccines, and other products. In particular, FDA could, and perhaps should, play an important role in the following:

- Section 101’s development of a “National Preparedness Plan” for response to bioterrorism and other public health emergencies.
It seems quite important that FDA be included directly in the development of this Plan, because it seems nearly certain to require FDA involvement in its implementation. In addition FDA involvement would contribute to an adequate scope of planning and preparedness (e.g., in relation to food safety) and FDA could contribute a great deal of expertise in preventing, detecting, and responding to contamination of food, drugs, and other consumer products.


It also seems quite important that FDA should be among the agencies included in this working group, particularly in relation to its identified goals to “facilitate the development, production, and regulatory review of priority countermeasures” (e.g., drugs, vaccines, and other FDA-regulated products).

That Section 103’s establishment of a national public health communications surveillance network to be headed by the Centers for Disease Control and Prevention (“CDC”).

It seems reasonably important that FDA be included in this network, particularly in relation to its role in the detection and detention of contaminated foods and drugs.

That Section 104’s creation of an “Emergency Public Information and Communications “EPIC” Advisory Committee” (of interest due to FDAs experience in communicating information regarding food and drug contaminants and public health emergency information to the public) and a “National Advisory Committee on Children and Terrorism” (relevant due to the Committee’s responsibilities in relation to vaccine stockpiles).

FDA’s involvement here seems less critical in relation to potential impact on FDA activities, but the committees may be of interest to FDA and the agency certainly has expertise that would be of benefit to both committees.
In addition to the groups and initiatives mentioned above, FDA is likely to have significant interaction with the Sec. 102-created “Assistant Secretary for Emergency Preparedness.” This is particularly true in relation to his or her fulfillment of duties to “coordinate the activities of the Department [HHS] with respect to... priority vaccines, other biological products, drugs and devices [for countering bioterrorism].”

Implications for FDA-regulated Entities and other Stakeholders

Implications of Subtitle A for FDA-regulated entities and other stakeholders would seem to be indirect. For FDA-regulated entities, one significant potential FDA activity under Subtitle A might be that in the “Working Group on Preparedness for Acts of Bioterrorism.” This is because the group’s focus on expediting the development and approval of countermeasures would likely impact the pharmaceutical and medical device industries. For other stakeholders and the general public, FDAs involvement in these national bioterrorism preparedness activities would likely provide benefits in both the actuality and the perception of increased safety.\footnote{See, e.g., Fact Sheet, U.S. Food and Drug Administration, “FDA Protects the Public’s Health; Ranks High in Public Trust,” (Feb. 2002), available at \url{www.fda.gov} (noting that, “[n] in a 1999 nationwide survey by the Pew Research Center and Princeton Survey Research Associates, the FDA received an overall favorable rating of over 80 percent, more than twice the approval rate of the entire government).}

Subtitle B—National Stockpile; Development of Priority Countermeasures

Implications for FDA
FDA is likely to be consulted by the HHS Secretary pursuant to his or her Sec. 121-mandated duty of maintaining national stockpile(s) of drugs, vaccines, etc. In particular, FDA may be involved in reporting status of drug and vaccine manufacturers and the progress of new products in the approval process.

FDA will be impacted directly by Section 122, and its allowance of the HHS Secretary’s designation of priority countermeasures as fast-track products. While the section also provides that priority measures not designated as fast-track products remain “subject to the performance goals established by the Commissioner of Food and Drugs,” it seems that this provision is likely to increase pressure on FDA to speed new products through the approval process, perhaps to the detriment of comprehensive evaluation of safety and efficacy.

FDA will also be impacted directly by Section 123’s mandate to complete FDA proposed rule “New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot be Conducted” (64 Fed. Reg. 53960) (Oct. 5, 1999) the rulemaking process within 180 days after enactment. There are important arguments both for and against this rule, and it is important that FDA consider them and remain free objectively to determine the soundness and appropriate parameters of this rule.

Section 124 is likely to affect FDA insofar as it relates to its research, holding, evaluation, and other relevant facilities that house biological agents and toxins and that might potentially be eligible for technical or other assistance to achieve increased security.

FDA may be involved in Section 125’s funding of direct research. This would be in relation to two of the section’s four identified research goals: “the development of diagnostic tests to detect such pathogens and other agents,” and “the development of new vaccines and therapeutics.” These research areas appear to be complementary to FDA’s product approval responsibilities as well as its anticipated increased inspection
duties under H.R. 3448, Title III. However, it is unclear if FDA is eligible to receive these funds.

It seems likely that FDA will be involved, at least as a consulting agency, in Section 126’s evaluation of new and emerging countermeasure technologies. This is because many, if not most, of these technologies (drugs, biologics, medical devices, etc.) will be subject to FDA review and approval.

**Implications for FDA-regulated Entities and other Stakeholders**

Under Subtitle B, FDA-regulated entities who research, develop, or produce priority countermeasures are likely to be positively benefited by the expanded access to the fast-track designation for their products. The animal model rule-making may offer potential benefits in timesaving, but also offers risks in less certainty as to safety and efficacy in humans. Regulated manufacturers of vaccines to be included in the national stockpile are could benefit greatly from the attention to, and authorization of funding to purchase, their products. They are likely to desire a more rapid approval process as well.

**Subtitle C—Emergency Authorities; Additional Provisions**

Subtitle C contains no FDA-relevant provisions to analyze.
Subtitle D—Authorization of Appropriations

Regarding Subtitle D, to the extent that FDA is involved in activities under Title I of H.R. 3448, Sections 301 and 319A-319K of the PHS Act, and under the proposed new Title XXVIII of that Act, it might receive some portion of the funds authorized to be appropriated to the Secretary of HHS under Subtitle D, Section 151.

Title II—Enhancing Controls on Dangerous Biological Agents and Toxins

Implications for FDA

FDA will be certainly be affected by Section 201 to the extent that any of its laboratories or facilities hold or use listed biological agents or toxins, for whatever purpose. It seems that the stringent requirements of this section will require a significant investment of agency time and resources. In addition, FDA may face some issues with security clearances for any scientists and officials who are foreign citizens or otherwise may run afoul of the screening and access restriction portions of the section.

FDA may also be affected by Section 201-mandated security upgrades to HHS facilities where listed agents, toxins or vaccines are housed or researched.

Implications for FDA-regulated Entities and other Stakeholders
Like FDA, regulated entities will be significantly affected to the extent that any of their facilities or personnel hold or use listed biological agents or toxins, for whatever purpose. Also like FDA, they are likely to face substantial costs in implementing the security, screening, and registration requirements and may face challenges in terms of bringing any foreign personnel through the screening process. They may also have private sector concerns about protecting confidential information, trade secrets, etc.

Other stakeholders, including the general public, are likely to be benefited in terms of safety by Section 201. In addition, public health and safety agencies, including FDA, but also law enforcement, CDC, etc. are likely to view positively the greatly increased knowledge about and control of who is doing what with biological agents and toxins, and the increased ability to trace the route of such agents in the event of an incident.

Title III–Amendments to the Federal Food, Drug, and Cosmetic Act
Subtitle A–Protection of Food Supply

Implications for FDA

As discussed in the detailed analysis of H.R. 3448 above, all sections of Subtitle A involve FDA and will impact its authority and activities to a significant extent. Some notable effects include:

(1) increased FDA investigatory powers and responsibilities, including inspection of imported foods; inspection of records of a wide range of entities involved in the production and distribution of food; maintenance and use of the registered entity database in investigations; and greater interaction with the States during investigations.
Increased FDA enforcement powers and responsibilities, including expanded authority for administrative detention; permissive debarment authority; marking and labeling detained or rejected foods, including the clear and conspicuous “United States—Refused Entry;” prior notice requirements; entry port holds; increased interaction with States in relation to enforcement activities, and expanded misbranding and prohibited act violations and penalties.

Increased FDA regulatory powers and responsibilities, including promulgation of the regulations to effect the investigative and enforcement powers described above, particularly the registration of a broad range of food-related entities.

Implications for FDA-Regulated Entities and other Stakeholders

“As New Bioterrorism Legislation has Significant Consequences for Food Industry”
– Covington & Burling External Memorandum Regarding H.R. 3448

As suggested in the words above, compliance with the raft of new FDA- and non-FDA-mediated requirements contained in H.R. 3448 is likely to prove challenging and potentially costly to FDA-regulated entities in the food industries. In particular, the registration and records maintenance provisions are likely to impact those in the food industry across the board, while provisions such as prior notice requirements and expanded detention of imported foods will significantly affect narrower portions of the industry.

For other stakeholders, including the general public, the implications may be more mixed. Generally increased food safety pursuant to the new measures and increase in inspection resources and personnel would

197 See Covington & Burling Memorandum, supra note 14.
certainly be a boon, and the prevention of a bioterrorist attack with many casualties is beyond price. However, it is likely that increased regulatory costs will be passed on to the consumer, and there may be unintended effects in forming “bottlenecks” in import of specific products.

Subtitle B–Protection of Drug Supply

Implications for FDA

The implications of these measures for FDA are significant, but much less so than those related to food safety and discussed above. The use of annual rather than less frequent registration of foreign drug manufacturers and other drug import entities, and the provision of shipper information does not seem overly burdensome, particularly if adequately funded, and it may prove crucial in future traceback investigations of accidental or intentional contamination.

Likewise, the exemption for specific components that will ultimately be exported seems to provide a reasonable balance between safety and efficiency. It will likely result in more paperwork and authentication workload to FDA, but seems to be a less significant burden on the agency than it otherwise might be in comparison with the food safety measures, and in light of badly-needed increases in authorization and appropriations for additional FDA personnel.

Implications for FDA-Regulated Entities and Other Stakeholders
As for FDA, the industry implications seem fairly reasonable in themselves, and particularly so in comparison to the industry impact of the proposed food safety measures under Title III, Subtitle A, as well as the security requirements for those entities that work with biological agents and toxins, discussed in Title II.

In relation to other stakeholders, including the general public, these seem to be the type of behind-the-scenes measures that may protect them, but are unlikely to be noticed except by those directly affected.

In comparison, the registration of every entity that manufactures, packages, holds, or distributes food, of whatever size and whether foreign or domestic, is likely to at least gain the attention of, and possibly more directly affect, the general population.

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**Other Relevant Legislation from the 107th Congress**

As discussed at the beginning of this paper, as of April 27, 2002, only two laws from the 107th Congress that contain provisions relating to the FDA and its role in countering bioterrorism had been signed and enacted: the USA PATRIOT Act of 2001 and the Department of Defense Appropriations Act, 2002.

Neither law references FDA or its activities with anything near the scope of H.R. 3448, yet both contain provisions that are relevant to many of the FDA-relevant provisions included in H.R. 3448 and addressed above. Both laws are addressed briefly, below.

**The USA PATRIOT Act of 2001**

The USA PATRIOT Act[199] signed into law on October 26, 2001[200] supports increased funding for two...
critical FDA responsibilities: drug and device review and food safety. However, this legislation does not go beyond an expression recommending increased financial support to mandate or detail any specific actions by FDA. In fact, the Act directly references FDA in only one section. There are also a few other provisions, directed generally at the Secretary of HHS, which may be relevant to FDA. Both the direct references and the potentially relevant provisions are addressed below.

Direct references to FDA in the USA PATRIOT Act are limited to two portions of Section 1013, which is entitled “Expressing the sense of the Senate concerning the provision of funding for bioterrorism preparedness and response.”\(^\text{201}\) In this section, among other listed areas of focus, the Senate supports “substantial new investment” toward, “[t]argeting research to assist with the development of appropriate therapeutics and vaccines for likely bioterrorist agents and assisting with expedited drug and device review through the Food and Drug Administration.”\(^\text{202}\) In addition, it supports “[t]argeting activities to increase food safety at the Food and Drug Administration.”\(^\text{203}\) Finally, the findings of the Senate in Section 1013 stating that, “[I]mprovements must be made in assuring the safety of the food supply,”\(^\text{204}\) and that “[n]ew vaccines and treatments are needed to assure that we have an adequate response to a biochemical attack,”\(^\text{205}\) seem directly to implicate activities within FDA’s jurisdiction. The increased funding called for in this section will be critical in enabling FDA to achieve the general goals of expediting drug and device review and increasing food safety.

Other potentially relevant provisions include additional Senate findings in Section 1013 regarding bioterrorism preparedness and the establishment of a “National Infrastructure Simulation and Analysis Center” in Section 1016. Provisions of potential interest to FDA in Section 1013 include the statements that:

\(^{201}\) USA PATRIOT ACT, supra note 199, § 1013.
\(^{202}\) USA PATRIOT ACT, supra note 199, § 1013 (b) (5) (emphasis added).
\(^{203}\) Id., § 1013 (b) (5) (emphasis added).
\(^{204}\) Id., § 1013 (a) (9).
\(^{205}\) Id., § 1013 (a) (10).
• “Coordination of Federal, State, and local terrorism research, preparedness, and response programs must be improved.”[206] This is relevant to FDA because many FDA counter-terrorism activities already require, or will require, coordination with other Federal, State and local agencies.[207]

• “Additional supplies may be essential to increase the readiness of the United States to respond to a bioterror-attack.”[208] This is relevant to FDA because it relates both to an increased national stockpile of countermeasures, many of which are subject to FDA approval, and, more specifically, to increased pressures on FDA to expedite the approval process.

• “Government research, preparedness, and response programs need to utilize private sector expertise and resources.”[209] This is especially relevant to FDA in relation to its interaction with the regulated community, particularly where the strict observance of Good Manufacturing Practices[210] may be the best (and most economical) first line defense against bioterrorism. FDA has already demonstrated its capacity to engage in successful public-private partnerships through programs such as its “Leveraging for Business Initiative.”[211]

Section 1016’s establishment of a “National Infrastructure Simulation and Analysis Center (NISAC)”[212] may be of interest to FDA for at least two reasons. The first is that FDA may want to work with this new Center to develop “bioterror readiness games” such as Dark Winter[213] but specifically tailored to FDA

[206] Id., § 1013 (a) (3) (emphasis added).
[207] For example, consider recent and continuing coordination between FDA, CDC, and other agencies regarding the use of additional drugs for treatment of inhalational anthrax. Also consider the future coordination that would be required by H.R. 3448’s Title III requirement that FDA provide notice to and request for action by States in the case of a finding of credible evidence of imported food posing a serious threat to the health of humans or animals.
[208] USA PATRIOT ACT, supra note 199, § 1013 (a) (8) (emphasis added).
[209] USA PATRIOT ACT, supra note 199, § 1013 (a) (11) (emphasis added).
[210] This includes such things as tamper-proof packaging for over-the-counter drugs and proper preserving, packaging, and labeling of food.
jurisdiction and activities. The second is that even if FDA either does not wish to engage in such games at all, or does not wish to involve NISAC, it seems important to determine which, if any, of FDA’s activities or the activities of its regulated entities are included in NISAC’s definition and understanding of critical national infrastructures. For example, it seems that one critical national infrastructure must surely be the increasingly complex food production and delivery systems that bring foods from all over the world, into the United States and to consumers. FDA’s expertise in working with relevant stakeholders, identifying the important interaction points, conducting inspections, bringing enforcement actions, etc., would certainly be important and might be critical to the work of the committee.

In summary, although the USA PATRIOT Act does not provide detailed mandates to FDA, it clearly places a high priority and focus on FDA drug and device review and food safety activities. In addition, several other provisions of the Act may be of interest to FDA. However, it is the second law of the 107th Congress that addresses both bioterrorism and the FDA, the Department of Defense Appropriations Act, that begins to makes tangible the Senate’s expressed support for increased investment in counter terrorism activities and that begins to put significant federal resources behind the goals identified in the USA PATRIOT Act.

Department of Defense Appropriations Act, 2002

The Department of Defense Appropriations Act, 2002 was signed into law on January 10, 2002. It makes a number of appropriations that may or will benefit the FDA in its drug and device review and food safety activities. For example, the provision appropriating monies to the Food and Drug Administration for salaries and expenses opens, “[F]or emergency expenses to respond to the September 11, 2001, terrorist attacks on the United States . . . .” DoD Appropriations Act, 2002.
the legislation also provides that the funds shall “remain available until expended.”\(^{218}\) and at least one relevant appropriation specifically references ongoing and future bioterrorism preparedness activities.\(^{219}\)

The first provision of interest is directly relevant to the FDA: it is an appropriation of $151,100,000 for salaries and expenses within the agency.\(^{220}\) The second provision may be relevant to FDA to the extent that it is involved in activities conducted in the listed categories or by the listed agencies (FDA is not one of these). It is an appropriation of $2,504,314,000 to the “Public Health and Social Services Emergency Fund” administered by the Secretary of Health and Human Services, for “emergency expenses to support activities countering potential biological, disease and chemical threats to civilian populations.”\(^{221}\) Notably, this amount includes $55,814,000 for bioterrorism preparedness and disaster response activities in the Office of the Secretary, and the Secretary is authorized to transfer all listed amounts between categories at his or her discretion, subject to normal reprogramming procedures.\(^{222}\)

\(^{218}\) Id.

\(^{219}\) See DoD Appropriations Act, supra note 216, at 2314 (stating that, “[f]or emergency expenses necessary to support activities related to countering potential biological, disease, and chemical threats to civilian populations... $2,504,314,000, to remain available until expended... $55,814,000 shall be for bioterrorism preparedness and disaster response activities in the Office of the Secretary [of Health and Human Services].”).

\(^{220}\) DoD Appropriations Act, supra note 216, at 2291.

\(^{221}\) Id. at 2314 (emphasis added).

\(^{222}\) Id.
Recommendations for FDA Action

In Relation to H.R. 3448 and to Counter-Bioterrorism More Generally

- Either in consultation with experienced agencies or alone, FDA should design and run FDA-specific “games” such as the Dark Winter\(^{223}\) mock bioterrorism attack exercise sponsored by the Johns Hopkins Center for Civilian Biodefense. Such exercises could be useful in testing FDA preparedness for various bioterrorism attack scenarios and/or naturally occurring public health emergencies.

Although FDA may or may not want to run such extensive games, even a more modest exercise might be quite useful. Such mock exercises are important in order to identify gaps in various systems and lines of communication and authority, determine where and how to prioritize scarce resources, and improve coordination among necessary agencies. FDA has several options in determining the scope of such evaluative games, deciding with which other agencies, if any, it wishes to run them (e.g., the Department of Agriculture might be an important agency to include for a run through of potential food contamination), and in determining how to provide the resources to run them. Such exercises may also help FDA to separate the more likely and higher threat scenarios from those that are less likely and/or lower threat. One suggestion is to work with the newly created “National Infrastructure Simulation and Analysis Center (NISAC),” established by the USA PATRIOT Act of 2001.\(^{224}\)

\(^{223}\)See description of Dark Winter exercise, supra note 213.
\(^{224}\)See discussion of NISAC, supra note 212 and accompanying text.
• FDA should ensure that it is adequately represented in the numerous and powerful bioterrorism panels, commissions, etc. already in existence and those created in recent and upcoming legislation.

The literature and legislation review for this paper suggested that in many cases, the multiple critical roles of FDA in protecting the public health are either unknown, under appreciated, or ignored. Not only does this have real costs to FDA in terms of lesser appropriations, risk of being “out of the loop,” and risk of less weight being given to FDA input, but it also poses real challenges to the nation in the creation of a seamless, effective, coordinated and adequate national response to bioterrorism.

• FDA should keep its traditional focus on safety and efficacy, even while working toward solutions to expedite the development, evaluation, and approval of countermeasures.

While it is certainly important that countermeasures vital to the prevention and treatment of bioterrorism are developed and made available quickly, it is also important that such countermeasures receive adequate safety and efficacy evaluation. It seems apparent that great additional pressure will be brought on FDA to expedite its approval process (along with some of the long-needed resources that will go a long way toward alleviating the problem). While working to streamline its processes, FDA may want to consider reminding other agencies, lawmakers, and the public, of its “first principles” and the reasoning that underlies its approval requirements.

225 See, e.g., Kathryn C. Zoon, Vaccines, Pharmaceutical Products, and Bioterrorism: Challenges for the U.S. Food and Drug Administration, 5 Emerging Infectious Diseases 534 (July-August 1999). At the time of publication of this article, Ms. Zoon was Director of the FDA Center for Biologics Evaluation and Research (CBER).
226 See, e.g., Christina M. Markus, FDA Fights Flexibly: Agency must ensure that our best biotech can battle bioterrorism, LEGAL TIMES, Vol. 24, No. 44 (Nov. 5, 2001).
• Given the increasing reliance of FDA (along with its regulated entities, other government entities, and the public) on computers, automated processing and interconnected systems, FDA should consider and take steps to prevent possible connections between cyber attacks and bioterrorism.

For example, the probability of increased electronic filing and maintenance of registrations containing confidential information for food industry facilities, the proposed electronic registries containing information about facilities handling dangerous biological agents, and existing and proposed registries including confidential information about pharmaceutical company products and manufacturing practices raises the specter of malign hacking or even a combined cyber/bioterrorist attack (e.g., by electronically attacking food distribution points or entering and overriding the electronically-controlled portions of a company’s food or drug production process so as to affect the quality, composition, or safety of the ultimate products.\footnote{See, e.g., Cybersecurity Intelligence Threat Assessment, Federation of American Scientists, Matthew J. Littleton, Naval Postgraduate School, \textit{Information Age Terrorism: Toward CyberTerror} (Dec. 1995), available at \url{http://www.cs.georgetown.edu/~denning/infosec/pollitt.html} (on file with author).} FDA could suggest that regulated manufacturers undergo a similar assessment of potentially vulnerable areas in their information technology systems, particularly where they have a highly automated production line.

• In relation to the implementation challenges posed by H.R. 3448 and similar legislation, FDA should continue its practice of working constructively with regulated entities and other stakeholders to craft a workable solution to problems encountered in developing, implementing, and enforcing legislation.

FDA has demonstrated success in this area\footnote{See, e.g., Press Release, National Food Producers Institute, “NFPA Says FDA Food Security Guidance Strengthens Barriers to Food Security Threats,” (Jan. 8, 2002), available at \url{www.nfpa-food.org} (praising recent FDA guidelines and stating that, “[t]he FDA food security preventive measures guidance is both comprehensive and flexible, allowing companies within our very complex and diverse food supply to determine how best to apply it to their own operations”). See also discussion of public-private leveraging, supra note 211, and accompanying text, and reference to high public satisfaction with FDA, supra note 196.} and its expertise in successful public-private endeavors may
be sorely needed across federal agencies as they implement the new requirements of protective and important, but challenging, legislation, such as H.R. 3448.

**Conclusion**

In summary, the proposed new bioterrorism legislation will provide FDA with new implementation challenges in the context of its ongoing mission: protecting the public health by assuring the safety and efficacy of a variety of important products. FDA is the right agency to meet this challenge, particularly as it builds on traditions of success in relevant areas as diverse as preventing and responding to contamination of food, drugs, and vaccines, and working with industry to solve regulatory dilemmas.

**Appendix A** (Page i of viii)

HR 3448[^230] and Food and Drug Administration (“FDA”)-relevant Provisions
*(All Sections Provided—In the Order Presented in the Bill)*

[^230]: There are four versions of Bill Number HR 3448 for the 107th Congress. See THOMAS: Legislative Information on the Internet [hereinafter “THOMAS”], a Library of Congress website, available at [www.thomas.loc.gov](http://www.thomas.loc.gov), last visited April 26, 2002. This table includes the FDA-relevant provisions presented in HR 3448 EH (Engrossed in the House). As of April 26, 2002, H.B. 3448 remains in Conference Committee to resolve differences between HB 3448 EH, analyzed here, and HB 3448 EAS (Engrossed Senate Amendment). Significant differences between these two versions of the bill are discussed in the text of this paper but are not presented in this table. The other two versions of the bill are HR 3448 IH (Introduced in the House) and HR 3448 RDS (Received in the Senate). THOMAS, *id.*
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<th>Title</th>
<th>Subtitle</th>
<th>Section</th>
<th>Directly Requires or Mandates FDA Involvement?</th>
<th>Possibly or Probably Involves FDA? (But no explicit mention of FDA)</th>
<th>Summary of FDA Involvement</th>
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<tr>
<td><strong>Title</strong> I—National Preparedness for Bioterrorism and Other Public Health Emergencies</td>
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<td>§ 101. National preparedness and response</td>
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Because of FDA’s roles in vaccine and drug approval and food and drug safety, FDA may and should be included in Sec. 101’s development of a “National Preparedness Plan” for response to bioterrorism and other public health emergencies.
FDA is likely to interact with the Sec.

42 U.S.C. 2201(b).

59
| §103. Improving ability of Centers for Disease Control and Prevention with respect to bioterrorism and other public health emergencies; facilities. | No. | Possible. | FDA may and should be among the agencies included in the Centers for Disease Control and Prevention ("CDC")'s Sec. 103-mandated establishment of a national public health communications surveillance network. It seems especially important... |
§ 104. Advisory committees and communications.

No. Possible.

FSA may be included in Sec. 104 created "Emergency Public Information and Communications Committee" (in relation to communicating to the public) or the "National Advisory Committee on Children and Terrorism" (in relation to vaccine stockpile issues).
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<td>Grants regarding shortages of certain health professionals.</td>
<td>FDA is unlikely to have significant involvement in activities under this section.</td>
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107. Emergency system for verification of credentials of health professionals volunteers.

No. No. FDA is unlikely to have significant involvement in activities under this section.
Enhancing preparedness activities for bioterrorism and other public health emergencies.

No. Probable. FDA should be among the agencies included in the Sec. 108-created "Working Group on Preparedness for Acts of Bioterrorism," particularly in relation to its goals to "facilitate the development, production, and regulatory review of priority countermeasures."
109. Improving State and local public health capacities. CDC or FDA is unlikely to have significant involvement in activities under this section.

110. Antimicrobial resistance program. CDC or FDA is unlikely to have significant involvement in activities under this section.
§ 111. Study regarding communicabilities of public health agencies.

No. No. FDA is unlikely to have significant involvement in activities under this section.

§ 112. Supplies and services in lieu of award funds.

No. No. FDA is unlikely to have significant involvement in activities under this section.

§ 113. Additional amendments.

No. No. FDA is unlikely to have significant involvement in activities under this section.
<table>
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<th>Subtitle B—National Stockpile; Development of Priority Countermeasures</th>
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121. National stockpile. No. Probable. FDA is likely to be consulted by the Secretary of Health and Human Services (“HHS”) in his/her Sec. 121-mandated duty of maintaining national stockpile(s) of drugs, vaccines, etc. In particular, FDA may be involved in reporting status of drug, vaccine, etc. manufacturers and progress of new products in the approval process.
Accelerated approval of priority countermeasures. Sec. 122(a) allows the HHS Secretary to designate a priority countermeasure as a fast-track product pursuant to Sec. 506 of the Food, Drug and Cosmetic Act ("FD&C Act"). Sec. 122(b) provides that priority measures not designated as fast-track products remain "subject to the performance goals established by the Commissioner of Food and Drugs." Sec. 122(c) defines "priority countermeasure" as a "drug or biological product that is a countermeasure to treat, identify, or prevent infection by a biological agent or toxin [per specific list, or]... other agent that may cause a public health emergency."
Section 123 requires the HHS Secretary, within 180 days after enactment, to complete the rule-making process commenced with FDA proposed rule “New Drug and Biological Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot be Conducted” (64 Fed. Reg. 53960) (Oct. 5, 1999).
As Sec. 124 permits the HHS Secretary, in consultation with the Attorney General and the Secretary of Defense, to provide technical or other assistance in securing persons or facilities that "conduct development, production, distribution, or storage of priority countermeasures," the section is likely to be relevant to FDA insofar as it relates to FDA's research, holding, evaluation, and other relevant facilities and personnel.
Accelerated countermeasure research and development.

No. Possible. It is possible that FDA may be involved in Sec. 125's funding of direct research. This would be in relation to two of Sec. 125's four sections identified research goals: "development of new vaccines and therapeutics," and "the development of diagnostic tests to detect such pathogens and other agents."

These research areas may be complementary to FDA's product approval responsibilities as well as its increased inspection duties under HR 3448, Title III, infra, although it is unclear if FDA is eligible to receive these funds.
Evaluation of new and emerging technologies regarding bioterrorist attack and other public health emergencies.

Probable. It is likely that FDA will be involved, at least as a consulting agency, in Sec. 126's evaluation of new and emerging countermeasure technologies. This is because many, if not most, of these technologies (drugs, biologics, medical devices, etc.) will be subject to FDA review and approval.
<table>
<thead>
<tr>
<th>Subtitle C–Emergency Authorities; Additional Provisions</th>
<th>131. Expanded authority of Secretary of Health and Human Services to respond to public health emergencies.</th>
<th>No.</th>
<th>No.</th>
<th>FDA is unlikely to have significant involvement in activities under this section.</th>
</tr>
</thead>
<tbody>
<tr>
<td>132. Streamlining and clarifying communicable disease quarantine provisions.</td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
<td>FDA is unlikely to have significant involvement in activities under this section.</td>
</tr>
<tr>
<td>133. Emergency waiver of Medicare, Medicaid, and SCHIP requirements.</td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
<td>FDA is unlikely to have significant involvement in activities under this section.</td>
</tr>
<tr>
<td>134. Provision for expiration of public health emergencies.</td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
<td>FDA is unlikely to have significant involvement in activities under this section.</td>
</tr>
<tr>
<td>Section</td>
<td>Title</td>
<td>FDA Involvement</td>
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<td></td>
<td></td>
<td>No.</td>
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<tr>
<td>136.</td>
<td>Expanded research by Secretary of Energy.</td>
<td>No.</td>
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<td>No.</td>
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<td>137.</td>
<td>Agency for Toxic Substances and Disease Registry.</td>
<td>No.</td>
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<td>No.</td>
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<td>138.</td>
<td>Expanded research on worker health and safety.</td>
<td>No.</td>
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<td>No.</td>
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<td>139.</td>
<td>Technology opportunities program support.</td>
<td>No.</td>
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**Subtitle D–Authorization of Appropriations**
Authorization of Appropriations.

No. Probable. To the extent that FDA is involved in covered activities under Title I of HR 3448, sections 301 and 319A-319K of the Public Health Service Act, and the newly created Title XXVIII of the Act, it may receive some portion of the funds authorized to be appropriated to the Secretary of HHS under Sec. 151.
Title II–Enhancing Controls on Dangerous Biological Agents and Toxins
Regulation of certain biological agents and toxins.

FDA will be affected by Sec. 201 to the extent that any of its laboratories or facilities hold or use listed biological agents or toxins, for whatever purpose. Sec. 201 requires the Secretary of HHS to
<table>
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<tr>
<th>Title</th>
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<tr>
<td>III—Amendments</td>
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<td>to the Federal</td>
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<td>Food, Drug, and</td>
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<td>Cosmetic Act</td>
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<td>Sub-title</td>
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<tr>
<td>A—Protection</td>
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<td>of Food Supply</td>
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301. Protection against intentional adulteration of food.
Ad-minis-trative detention.

Sec. 302 expands the FDA’s authority to order detention of food upon “cred-ible evi-dence or in-for-mation” of seri-ous threat to hu-man or ani-mal health. The or-der may in-clude a re-quire-ment to mark or label food “de-tained” or re-move it to a se-cure facil-it-y. The or-der must be ap-proved by the HHS Sec-re-tary or de-signee and is may be ap-pealed. The trans-fer of food in vi-o-la-tion of such an or-der, or the re-move of any mark or label is made a pro-hibited act un-der Sec. 301 of the FD&C Act.

Sec. 302 al-lows FDA to re-quest a tem-po-rary hold (24 hours) at the port of en-try prior to in-spec-tion. The sec-tion re-quires noti-fica-tion of the State in which the port of en-try in-volved is lo-cated.
Sec. 303 amends the FD&C Act to provide that persons who (a) have been convicted of a felony related to food importation, or (b) have repeatedly imported or offered for import adulterated food are subject to permisive debarment from food importation. Sec. 303 also amends "Prohibited Acts" to include "importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under [the newly amended sections]."
304. Maintenance and inspection of records for foods.

Sec. 304 authorizes the HHS Secretary or designee to require that each person (except farms and restaurants) who "manufactures, processes, packs, distributes, receives, holds, or imports such article" to have access to and to copy "all records relating to such article that are needed to assist the Secretary..."

Sec. 304 permits the HHS Secretary, in consultation with relevant food safety agencies, to establish regulatory requirements regarding record maintenance as may be necessary to trace the food source, chain of distribution, and packaging.

Records covered under Sec. 304 specifically do not include food recipes; financial, pricing, personnel or research data; or sales data other than shipment data.

The HHS Secretary is required to take appropriate measures to prevent the unauthorized disclosure of trade secrets and confidential information.

The FD&C Act is amended by Sec. 304 to provide that in specitations of the persons described above (e.g., manufacturers, processors, importers) shall extend to all records described above, upon credible evidence or information of a serious health threat.

Sec. 304 amends "Prohibited Acts" to include: refusal to permit access to or copying of relevant records, and failure to establish or maintain required records.
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Prior notice of imported food shipments.

Sec. 306 requires the submission of a notice of food import enabling the article to be inspected at U.S. ports of entry. The notice must identify the article of food, manufacturer and shipper, country of origin and country from which shipped, and grower (if known within time of notice).

Any article of food imported or offered for import without submission of the notice must be refused admission to the United States. The notice regulations must specify a time period between 24-72 hours in advance of importation or offering for import. If a notice is not provided, the food article shall be held at the port of entry until such notice is submitted.

In relation to evaluation of the notice, the HHS Secretary must determine whether there is credible evidence or information of serious health threat.

Limitations: Sec. 306 shall not be construed to:

- limit authority to obtain information under any other provision of the Act;
- authorize the HHS Secretary to encroach on the jurisdiction of the Department of Agriculture;
- be a limitation on a port of entry for a food article;
- or to authorize delivery pursuant to a bond prior to the Secretary's direction with respect to the notice.

Sec. 306 amends "Prohibited Acts" to include importing or offering to import food articles in violation of the notice requirements.
307. Authority to mark articles refused admission into United States.

Yes.

If a food (1) has been refused admission under FD&C Act Sec. 801 (a) and (2) is determined to present a serious health threat, the HHS Secretary may require labeling of the container with the statement "UNITED STATES: REFUSED ENTRY." Such a requirement remains in effect until the food has been brought into compliance with the act, and all costs of such labeling are to be borne by the owner or consignee.

Food failing to bear such a label, when required, is deemed "Misbranded." Sec. 307 shall not be construed to limit the Secretary's authority to require labeling under other violation of law.
Prohibition against port shopping for importation.

Sec. 308. (a) An article of imported food is adulterated if it has previously been refused admission under FD&C Act Sec. 801, unless the offeror affirmatively establishes, to the Secretary's satisfaction, that the article is not adulterated.
309. Notices to States regarding imported food.
310. Grants to States for inspections; response to notice regarding adulterated imported food.
Subtitle
B−
Protection of Drug Supply
311. Annual registration of foreign manufacturers; shipping information; drug and device listing.

Sec. 311 amends the FD&C Act to:
- require annual registration of foreign manufacturers;
- require the name of each drug or device importer known to the establishment as well as the name of each carrier used in transportation to the U.S. for importation.

Sec. 311 permits refusal of admission for a drug or device if its importer does not, at the time of import, submit a statement identifying any required registration.

Sec. 311 amends “Prohibited Acts” to include importation or offering for import any drug or device where there is failure to submit a required statement of registration.
312. Requirement of additional information regarding import components intended for use in export products.

Sec. 312 sets conditions, which, if met and submitted with a statement to the HHS Secretary, protect components of drugs, devices, food and color additives, dietary supplements, etc., which require further processing and which will be used in export products. The conditions include:

- intention for further processing and use in a product that will be exported;
- identification of the manufacturer(s), processor(s), distributor(s), carrier(s), or other entities in the chain of possession of the article;
- certificates of analysis as to component chemical or biological substances;
- execution of a bond; use and importation in accordance with the statement of intent;
- maintenance of relevant records;
- submission of an accounting of export or destruction of the article, on request.

Limitation: the conditional protection does not apply if the HHS Secretary determines that there is credible evidence or information of a serious threat to health.

Sec. 312 amends "Prohibited Acts" to include a variety of offenses related to the statement, including:

- false statements,
- failure to submit analysis certificates,
- failure to maintain or submit records,
- and the release of any article covered in the section into interstate commerce.
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<td>IV– Drinking Water Security and Safety</td>
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As the violations in Sec. 401 appear to apply only to community water systems, and not bottled water, FDA is unlikely to have significant involvement in activities under this section.