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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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## Research Bibliography

(for paper researched by Christine Kirk, Jan - Apr 2002)

This bibliography includes documents and websites/webpages reviewed in conducting research for my 3L paper, "Bioterrorism and the Food and Drug Administration: H.R. 3448, Related Legislation, and the FDA's Expanding Role in Preventing and Responding to Biological Attack." In researching this paper, I reviewed a large number of documents related to bioterrorism, the role of the Food and Drug Administration (FDA) in preventing and responding to bioterrorism, and related topics. Because my paper was narrowly focused on HR3448, I used only a fraction of the useful information I found in the paper itself, and therefore put together this bibliography in hopes that it might be helpful to someone doing similar research in the future. It is not exhaustive but does represent a wide sample of available information in this area.

The bibliography includes law review and professional journal articles; useful websites; proposed and existing laws, regulations, and official guidance; government reports and other documents; research institution reports; media articles; and other documents.

### Some Relevant and Useful Websites

#### *Some Relevant General Government Websites*

- U.S. Food and Drug Administration (FDA) at [www.fda.gov](http://www.fda.gov).
- U.S. Centers for Disease Control and Prevention (CDC) at [www.cdc.gov](http://www.cdc.gov).
- U.S. Department of Health and Human Services (DHHS) at [www.hhs.gov](http://www.hhs.gov).
- Government Food Safety website at [www.foodsafety.gov](http://www.foodsafety.gov)

(Cooperative effort by U.S. Food and Drug Administration, Department of Agriculture, Environmental Protection Agency, Centers for Disease Control and Prevention)

δ National Food Safety Programs page at <http://www.foodsafety.gov/~dms/fs-toc.html>

- General Accounting Office at [www.gao.gov](http://www.gao.gov)

(Federal reports on many topics—includes terrorism report link)

- House Committee on Energy and Commerce website at <http://energycommerce.house.gov/>.
- Office of Homeland Security website at <http://www.whitehouse.gov/homeland/>.
- THOMAS: Legislative Information on the Internet [hereinafter “THOMAS”], a service of the Library of Congress, at [www.thomas.loc.gov](http://www.thomas.loc.gov).

*Some Government Counter-terrorism and Disaster Prevention Websites*

- The Center for Nonproliferation Studies at the Monterey Institute of International Studies
- Critical Infrastructure Assurance Office at [www.ciao.gov](http://www.ciao.gov)

(Per the webwebsite, the CIAO was established in 1996 to “address the vulnerabilities created in the new information age,” and to, “formulate a comprehensive national strategy for protecting the infrastructures we all depend on from physical and ‘cyber’ threats.”)

- National Infrastructure Protection Center at [www.nipc.gov](http://www.nipc.gov)

(Per the webwebsite, the NIPC “serves as a national critical infrastructure threat assessment, warning, vulnerability, and law enforcement investigation and response entity.”)

*Some General Non-government Counter-terrorism and Disaster Prevention Websites*

- Center for Nonproliferation Studies (CNS) at the Monterey Institute of International Studies at [www.cns.miiis.edu](http://www.cns.miiis.edu).
- Twenty-first (21<sup>st</sup>) Century Disasters at [www.globaldisaster.org](http://www.globaldisaster.org)

(includes pages specific to nuclear-biological-chemical terrorism and cyberterrorism)

- Federation of American Scientists at [www.fas.org](http://www.fas.org)

(includes pages specific to terrorism)

*Some Government and Non-government Bioterrorism-specific Websites*

- Center for Nonproliferation Studies (CNS)’s “Chemical and Biological Weapons Resource Page” at <http://cns.miiis.edu/research/> last visited Apr. 25, 2002.
- DHHS’s “Anthrax and Biological Incidents: Preparedness and Response” page at <http://www.hhs.gov/hottopics/healing/bioterrorism/> last revised Apr. 1, 2002.
- FDA’s general “Bioterrorism” information page at <http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html>

(last viewed Apr. 24, 2002; last updated Mar. 8, 2002).

- FDA's Center for Biologics Evaluation and Research (CBER)'s "Countering Bioterrorism" page at <http://www.fda.gov/cber/>, last updated Mar. 29, 2002.

- FDA's Center for Food Safety and Applied Nutrition (CFSAN)'s "Food Safety and Terrorism" page at <http://www.cfsan.fda.gov/~dms/fsterr.html>.

- [www.FoodSafety.gov](http://www.FoodSafety.gov)'s "Countering Bioterrorism and Other Threats to the Food Supply" page at <http://www.foodsafety.gov/>, last updated Jan. 9, 2002.

- CDC's "Public Health Emergency Preparedness & Response" page at <http://www.bt.cdc.gov/>, last updated Apr. 10, 2002.

- Hardin Library for the Health Sciences at the University of Iowa's "Hardin MD Focus Page: Bioterrorism/Biological Warfare" page at <http://www.lib.uiowa.edu/hardin/md/bioterrorism.html>.

- Johns Hopkins University's Center for Civilian Biodefense Strategies website at <http://www.hopkins-biodefense.org/index.html>.

- MEDLINE's "MEDLINEplus: Biological and Chemical Weapons" page at <http://www.nlm.nih.gov/medlineplus/biologicala>

- Saint Louis University's Center for the Study of Bioterrorism and Emerging Infections website at <http://bioterrorism.slu.edu/>

- Twenty-first (21<sup>st</sup>) Century Disasters: Nuclear-Biological-Chemical Terrorism Resource Center at [www.globaldisaster.org/nl](http://www.globaldisaster.org/nl)

(links to relevant articles and websites)

#### *Government and Non-government Cyberterrorism-specific Websites*

- Carnegie Mellon Computer Emergency Response Team (CERT) Coordination Center) at [www.cert.org](http://www.cert.org) (key website for cybersecurity—provides reports, alerts, recommendations)

- Counterpane Internet Security at [www.counterpane.com](http://www.counterpane.com)

(private company with large archive of reports of cybersecurity breaches and attacks)

- Federation of American Scientists' Intelligence Resource Program: CyberSecurity Intelligence Threat Assessments at <http://www.fas.org/irp/threat/cyber/index.html>

- The Institute for Security Technology Studies at Dartmouth College at <http://www.ists.dartmouth.edu/>

- Institute for the Advanced Study of Information Warfare at [www.psycom.net/iwar.1.html](http://www.psycom.net/iwar.1.html)

(this website provides a large number of useful links to related articles and websites)

- Twenty-first (21<sup>st</sup>) Century Disasters: Cyberterrorism Resource Center at [www.globaldisaster.org/cyberterrorrescen.shtml](http://www.globaldisaster.org/cyberterrorrescen.shtml)

(links to relevant articles and websites)

*Some Senators' and Representatives' websites and pages with bioterrorism information:*

- Congressman Gary Miller at <http://www.house.gov/garymiller/>

(as of April 24, 2002, this website included relevant “Information Links & Biological Threat Fact Sheets”)

- Congressman W.J. “Billy” Tauzin at <http://www.house.gov/tauzin>  
(Representative Tauzin is a House sponsor of H.R. 3448)

Some Relevant FDA Rules/Guidelines/Notices:

- 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 (proposed Oct. 5, 1999), Docket No. 98N-0237, OC 9818.
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### **Some Relevant Bills and Laws**

*Bills*

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- Bioterrorism Preparedness Act of 2001, S. 1765, 107<sup>th</sup> Congress (2001).

#### *Laws*

- Department of Defense and Emergency Supplemental Appropriation for Recovery From and Response to Terrorist Attacks on the United States Act, 2002, Pub. L. No. 107-117, 115 Stat. 2230.
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- International Coordination for Cyber Crime and Terrorism in the 21<sup>st</sup> Century, available at <http://www.cert.org/reports/sta> (last viewed Apr. 17, 2002).

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- Statement by Michael Friedman, M.D., Deputy Commissioner for Operations, U.S. Food and Drug Administration, “Protecting the U.S. Consumer from Food Borne Illnesses,” before the House Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Affairs, May 10, 1996, available at <http://www.fda.gov/ola/1996/foodbor.html>.
- Senate Report No. 101-84 (1989), reprinted in Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law: Cases and Materials* (2d ed.) (1991) at p. 21-22 (addressing FDA’s mission).

### **Some Additional Relevant Information**

#### *Law Firm Articles/Reports:*

- Memorandum for External Distribution, Covington & Burling, *New Bioterrorism Legislation has Significant Consequences for Food Industry*, Dec. 21, 2001.

#### *Miscellaneous Documents:*

- Thesis, Matthew J. Littleton, Naval Postgraduate School, *Information Age Terrorism: Toward Cyberterror*, Dec. 1995, available at <http://www.fas.org/irp/threat/cyber/docs/npgs/terror.htm>

*Some additional articles that I did not review but that appear potentially relevant:*

- Ronald Atlas, Combating the Threat of Biowarfare and Bioterrorism: Defending Against Biological Weapons is Critical to Global Security, *Bioscience*, June 1, 1999, at 465.
- Barry Kellman, Biological Terrorism: Legal Measures for Preventing Catastrophe, 24 *Harvard Journal of Law and Public Policy* 417 (2001)
- Donald A. Henderson, The Looming Threat of Bioterrorism, 283 *Science* 1279 (1999).