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.

• U.S. Centers for Disease Control and Prevention (CDC) at www.cdc.gov.

• U.S. Department of Health and Human Services (DHHS) at www.hhs.gov.

• Government Food Safety website at www.foodsafety.gov

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


• General Accounting Office at www.gao.gov

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


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
  (Per the website, 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
  (Per the website, 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.miis.edu.

- Twenty-first (21st) Century Disasters at www.globaldisaster.org
  (includes pages specific to nuclear-biological-chemical terrorism and cyberterrorism)

- Federation of American Scientists at www.fas.org
  (includes pages specific to terrorism)

Some Government and Non-government Bioterrorism-specific Websites


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.


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

Twenty-first (21st) Century Disasters: Nuclear-Biological-Chemical Terrorism Resource Center at www.globaldisaster.org/nbcrescen.shtml (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 (key website for cybersecurity–provides reports, alerts, recommendations)

Counterpane Internet Security at www.counterpane.com (private company with large archive of reports of cybersecurity breaches and attacks)

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

• Twenty-first (21st) Century Disasters: Cyberterrorism Resource Center at 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 Notice, Prescription Drug Products; Doxycycline and Penicillin G Procaine Administration for Inhalational Anthrax (Post-Exposure), Docket No. 01N-0494.


Some Relevant Bills and Laws

Bills


Laws


• Food, Drug, and Cosmetic Act.

• Federal Anti-Tampering Act.


Legislative History/Bill Status Updates

• Bill Summary & Status File for H.R. 3448, from THOMAS, reviewed periodically and last viewed Apr. 29, 2002.

• Bill Summary & Status File for S. 1765 (Introduced in Senate), from THOMAS, reviewed periodically and last viewed Apr. 24, 2002.

Government-Produced or -Sponsored Reports


GAO Report, Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamina-


NSTC Report, Global Microbial Threats in the 1990s, NSTC Committee on International Science, available


Government-Produced Workplans, Press Releases, Fact Sheets, Fact Pages, etc.


Work Plan Fiscal Year 2000, Department of Health and Human Services Documents, Practising Law Institute, Corporate Law and Practice Course Handbook Series, PLI Order No. B0-00IU, May 1-2, 2000 (includes brief description of FDA’s bioterrorism research program).


Fact Sheet, HHS Initiative Prepares for Possible Bioterrorism Threat, U.S. Department of Health and Hu-


Some Research Institute and Similar Entity Reports, Articles, etc.


- Tara O’Toole, M.D., Summary of Lessons Learned: Shining Light on Dark Winter, The Johns Hopkins Uni-


Casebooks and Treatises


Some Relevant Law Review and Other Professional Journal Articles


- LTC George Christopher, et al., Biological Warfare: A Historical Perspective, Journal of the American


• Shellie A. Kolavic et al., An Outbreak of *Shigella dysenteriae* Type 2 Among Laboratory Workers Due to Intentional Food Contamination, Journal of the American Medical Association (JAMA), Vol. 278, No. 5, Aug. 6, 1997.


• Thomas J. Török et al., A Large Community Outbreak of Salmonellosis Caused by intentional Contamination of Restaurant Salad Bars, Journal of the American Medical Association (JAMA), Vol. 278, No. 5,
Aug. 6, 1997.


- Kathryn C. Zoon, Vaccines, Pharmaceutical Products, and Bioterrorism: Challenges for the U.S. Food and Drug Administration, 5 Emerging Infectious Diseases 534, Jul.-Aug. 1999 (Special Issue).

News Articles, non-Government Press Releases, and other Press Resources


- Jeanne Meserve, FDA to propose antiterrorist food safety guidelines, CNN.com, Jan. 8, 2002, available at
Presentations, Press Releases, Floor Statements, etc. by Public Officials and Committees


Some Relevant Testimony Before Congress (in reverse chronological order)


- Statement of Tommy G. Thompson, Secretary, Department of Health and Human Services, Federal Efforts to Coordinate and Prepare for Bioterrorism: The HHS Role, before the Senate Committee on Governmental Affairs and Subcommittee on International Security, Proliferation and Federal Services, Oct. 17, 2001 (available at http://www.hhs.gov/asl/testify/t011017.html).


- Statement of Scott R. Lillibridge, M.D., Special Assistant to the Secretary for National Security and Emergency Management, Department of Health and Human Services, HHS Bioterrorism Preparedness, before the


Some Additional Relevant Information

Law Firm Articles/Reports:


Miscellaneous Documents:

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)