Anti-Bioterrorism Laws that Affect Technology Transfer at Academic Institutions

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In the post-September 11, 2001, era, the threat of biological terrorism is receiving heightened focus by law enforcement and national security agencies, and there is an increase in the scope and type of laws and regulations governing transfer of biological materials and related equipment. Two new federal laws, the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act)1 and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BPARA)2 and its regulations impose new and very stringent requirements on the transfer of, and on certain other activities with, biological agents, toxins, and related equipment.

All Biological Agents and Toxins and Their Delivery Systems: USA PATRIOT Act

One provision of the USA PATRIOT Act, Section 817(1), amends Chapter 10 of Title 18 of the United States Code (U.S. Criminal Code) to criminalize a greater range of activities involving all types of biological agents and toxins (not only the so-called select agents addressed later in this chapter under "Select Biological Agents and Toxins: USA PATRIOT Act") and the equipment that may be considered a delivery system for such materials.3 Section 175(a) of the U.S. Criminal Code remains in effect and provides that anyone who "*knowingly* develops, produces, stockpiles, *transfers, acquires,* retains, or

possesses *any* biological agent, toxin, or delivery system *for use as a weapon*," not including (under Section 175(b)) activities that are prophylactic, protective, or peaceful, or who knowingly helps a foreign state or organization to do so, or who attempts to do these things, may be punished by criminal fines of up to \$500,000 for entities, and by imprisonment for any term of years or for life, criminal fines of up to \$250,000, or by both for individuals, both subject to increase or decrease for certain aggravating and mitigating factors.4