From the Courtroom to Congress: Forecasting Responsible Official Liability for Select Agent Violations

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In 1966, the United States Supreme Court decided Miranda v. Arizona. That case prohibits police officers from questioning arrestees without first advising them of their Fifth Amendment right to remain silent. We take it for granted now, but it took nearly 200 years for the legal system to forge this interpretation of the Fifth Amendment. Miranda is proof-positive that even the most fundamental laws engender uncertainty and legal wrangling. Since the Select Agent regulations are laws, they are not immune from these issues. Responsible Official (RO) personal liability is perhaps the greatest uncertainty contained in the regulations. Both the Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have failed to state whether ROs can be held liable for select agent violations committed by their entities. Faced with uncertainty about RO liability, all we can do is assess various considerations and forecast a result. Factors such as public policy and principles of fairness will help decide RO liability. But, state-of-the-art legal arguments and legislative forces may be dispositive. Below is a survey of issues that ROs need to know in regard to their potential liability.

The Regulations Do Not Exempt ROs

Federal regulations often create compliance exemptions. For example, certain buildings are exempt from the requirements of the Americans with Disabilities Act (ADA). Yet, the Select Agent regulations do not exempt ROs from personal liability. HHS and USDA could have very easily placed language in the regulations stating, “An RO shall not be personally liable for violations committed by an entity.” Yet, they did not. In fact, RO liability is not even discussed in the “Comments” sections of the Federal Register. When interpreting laws, judges and lawyers often presume that in the absence of an exemption, liability is permissible. Here, since the regulations and their commentary are silent about exemptions, it may be presumed that ROs can be held liable.

Other Federal Regulatory Schemes Hold Responsible Parties Accountable

Legal concepts from other regulatory fields suggest that RO personal liability is possible. Clean Water Act (CWA) cases and other federal regulatory cases have devised a concept called the Responsible Corporate Officer (RCO) doctrine. The RCO doctrine is a legal creation that penalizes individuals for violations committed by their company. For example, the government has assessed civil penalties against employees when their company polluted waterways. The purpose behind the RCO doctrine is to punish people in corporations who have the ability to act but fail to stop violations. The logic behind the doctrine is that individuals with personal liability are less likely to perpetrate or ignore violations than individuals who are exempt from liability. The judicial system created the RCO doctrine. We cannot
predict whether courts will adopt it in the Select Agent field. However, because it exists in other legal fields, the RCO doctrine may be an avenue by which ROs are held liable.

Congress to the Rescue?

Congress may be the RO’s staunchest ally. Congress has not addressed the plight of ROs, but its members have called for an end to regulatory hurdles that hinder the scientific community.

Former Congressman Jim Turner of the House Select Committee on Homeland Security published a May 2004 report titled “Beyond Anthrax: Confronting the Future Biological Weapons Threat.” Proposed legislation that coincided with the report’s publication is currently being reviewed for comment by numerous House committees. The Report calls for all government agencies to assist the scientific community in expediting the detection and cure of infectious diseases. The Report adopts the belief that “if we do not work together to find fundamentally faster, more predictable, and less costly ways to turn good biomedical ideas into safe and effective treatments, the hoped for benefits of the biomedical century may not come to pass, or may not be affordable.”

The “Beyond Anthrax” report lists findings of fact and makes recommendations for expediting detection, prevention, and cure of infectious diseases. The Report concludes that “the current regulatory environment” hampers research and development. It also recommends that “bottlenecks” to research and development should be identified and reduced.

The “Beyond Anthrax” report calls for the eradication of regulations that hinder biomedical research. For this reason, we know that Congress would eschew personal liability for ROs. Personal liability would:
1. force talented, experienced individuals from their posts
2. make it nearly impossible for entities to find people to act as ROs
3. ultimately increase the costs associated with select agent and toxin research.

In short, personal liability would completely undermine the Report’s intended goals.

While the “Beyond Anthrax” report does not mention ROs or single out the Select Agent regulations, it does proclaim a unifying directive. The federal government should act swiftly to remove burdens to research and development for infectious diseases. RO personal liability is arguably one of the single largest impediments to effective research in infectious diseases. For this reason, Congress may champion the cause of the RO by drafting legislation or addressing the topic with HHS and USDA.

Conclusion

For brevity, this article highlights just a few big-picture issues. Public policy and practical considerations are equally important and should be discussed at ABSA conferences and meetings. Many arguments exist that cannot be addressed in this forum. With that said, the HHS and USDA Select Agent Programs are in their infancy, and RO liability is a wide-open question. If anything, the present legal landscape foreshadows liability. The best hope for RO immunity may lie with ABSA members and their ability to influence Congress.