

SCHOOL OF MEDICINE

John D. Clements, Ph.D.  
*Professor and Chair*  
*Department of Microbiology and Immunology*

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Centers for Disease Control and Prevention  
Division of Select Agents and Toxins  
1600 Clifton Road, MS A-46  
Atlanta, GA 30333

I would like to speak in favor of stratifying the Select Agent (SA) list to include only (or principally) those microorganisms with high potential for use as Biothreat Agents. For the sake of full disclosure, I was a member of the NRC Committee that formulated the report on Responsible Research With Biological Select Agents and Toxins and that recommended the stratification. In my opinion, the major problem with the current SA list (and process) is that it resembles a Public Health Threat List (in which case it is too short) and not a Biothreat List (in which case it is too long). The recent proposal to add SARS to the list is a case in point.

The SA list in its current form evolved from the military threat list based on microorganisms that were weaponizable and suitable for biological warfare. There is a real and important distinction between biological warfare and bioterrorism that is especially germane when dealing with select agents and toxins, as well as public health. Biological warfare is primarily conducted by armies against armies and is designed to deny terrain or degrade the warfighting capability of an opposing force. Biological warfare requires significant quantities of a refined, stabilized product that can be packaged, stored, and delivered (usually in a specialized ammunition or highly engineered dispersal device). These are usually milled, dry powders, 1-10 microns in particle size, that remain suspended in air when released and cannot be efficiently delivered by a crop duster or other low tech device. There are a relatively small number of biological agents that fit this profile and both the US and the Former Soviet Union (FSU), along with other countries, previously explored both offensive and defensive use of such weapons. Biological warfare requires a large infrastructure and is usually state supported. The greatest risk we face/faced in this regard was the acquisition of unsecured weaponized material left over from the FSU.

By contrast, the primary purpose of biological terrorism is to create terror. Thus, a small amount of relatively unrefined material may be sufficient to achieve the desired outcome. For this, an individual would not need something off the SA or Especially Dangerous Pathogen (EDP) list, but something easily accessible in nature and introduced into an unsuspecting community by a traditional or nontraditional route. All that would be required would be to then claim credit and terror would ensue. This type of agent does not require genetic manipulation, sophisticated technology, biohazard suites, or highly engineered delivery systems. One does not need to scale fences or pass cameras and armed guards and locked freezers to obtain these materials; they are abundant in nature and encountered on a

*Health Sciences Center*

1430 Tulane Avenue, SL-38, New Orleans, LA 70112-2699 tel/504.988.5070 fax 504.988.5144 jcllemen@tulane.edu

routine basis in rural health clinics where these diseases are endemic. By conflating the two terms we, in fact, become less safe because we focus on facilities and EDPs and “movie plot” bioterrorism and not on preparing for (or preventing) a much more likely event. We also take our eye off the broader question of “Who would?” rather than “Who could?” Almost any trained microbiologist with malicious intent could acquire a suitable microorganism from the environment or a local health clinic and create a bio-terror event.

In addition, the most likely threat today is from a disgruntled insider and not from someone scaling the wall of a secure facility, past guns and gate and guards to obtain a select agent (Al Crazy and not Al Qaeda). By further isolating individuals who work with dangerous microorganisms from mainstream department and lab operations, we increase the likelihood that disgruntled employees will access EDPs and not resolve their issues through available channels. Locked freezers and vial counting and cameras cannot stop a determined and knowledgeable individual from removing a select agent from a facility. By contrast, there are a number of countries with more or less robust biological warfare programs that would be happy to give a terrorist as much refined biological material as they wanted, and probably pay their airfare.

Consequently, our inclusion of more and more pathogens on the SA list requires more and more resources directed toward preventing the most unlikely occurrence and, in the end, makes us less safe as a society. It would make more practical sense, and better security, to narrow the list to those microorganisms that are easy to grow and somewhat easy to weaponize (i.e., anthrax) and require the highest levels of biosecurity for those organisms. We could still have an EDP registration so we know who has access or is working with specific pathogenic microorganisms, but we should not require the highly secured facilities and infrastructure for those, the emphasis there being on biosafety.

The decision as to which specific organisms should be on which list requires considerable discussion. There is some inclination by investigators to want their organisms on the SA list because that opens new avenues of funding, and motive should be considered when evaluating recommendations. In general, I would suggest eliminating most if not all biological toxins from the list. It is much more likely that someone will blow up a tank car full of sulfuric acid in a major downtown area than that an individual will acquire enough purified biological toxin and an appropriate delivery system to cause more than a few casualties. Managing the ensuing panic would be much more difficult than treating the casualties from a biological event associated with a toxin. The hemorrhagic fever viruses are another case in point. Most of these viruses exist in nature and even in endemic areas are not easily transmissible from person to person (close contact with body fluids from infected individuals being the most likely mechanism). Given the difficulty of propagating and concentrating these virus and the lack of technology to weaponize, stabilize, and distribute the viruses, I would question how much safer we are to have them on the SA list. There are a few (i.e., Monkeypox and Variola) that have to remain on the list because they can be easily grown and are stable for a long time in the environment, although the recent case of imported Monkeypox in the US demonstrated that the virus is not as transmissible from person to person as previously imagined.

My own personal list would probably include *B. anthracis*, 1918 pandemic influenza, and avian influenza. *B. anthracis* is the only bacterial pathogen on the list that is easy to produce in a large volume of semi-purified material with high infectivity. The fact that it forms infectious spores makes it unique among the bacterial pathogens on the current list. For security reasons, I don't want to get too much into details, but the process of weaponizing a crude spore preparation of anthrax is not difficult (although not widely known). Influenza viruses are not difficult to grow and are highly transmissible. These two have significant epidemic potential and warrant close scrutiny.

The USDA list requires a little more inspection because of the high transmissibility of some agents associated with our current husbandry practices and the potential economic impact. For instance, FMDV makes sense, but Camel Pox does not. Vector borne diseases like Rift Valley Fever Virus don't really belong on either list because they are too hard to distribute and usually not transmissible directly from person to person.

Currently, the underlying definition of "Select Agent" includes any biological pathogens and associated toxins that could be deliberately misused to cause significant harm to humans or agricultural resources. This definition too broad and trying to place the highest level of security on all dangerous pathogens dilutes the resources we need to truly protect society. It also gives us a false sense of security because many natural biological agents and industrial chemicals are easier to access and use.

Sincerely yours,

A handwritten signature in black ink that reads "John D. Clements". The signature is written in a cursive style with a large initial 'J' and a long, sweeping underline.

John D. Clements, Ph.D.