Sap Comments (CDC)

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To: Sap Comments (CDC)
Subject: Comments on the changes to the list of select agents

Regarding possible tier classification of select agents, given the wide variation in the suitability, probability, and effectiveness of the various microbes as bioterrorism agents, tiers do make sense. The most sensible criteria for tier classification would be the properties of the agent relative to the properties needed for an agent to be used effectively as a bioterrorism weapon. Three of the most important properties of an effective bioterrorism agent are its stability, transmissibility, and the availability of effective treatments for it. Stability is important for effective inoculation of the targeted population. The most likely means are via aerosol or water-borne, so stability of an agent in these environments would be important considerations. Transmissibility of an agent is important for two reasons. First, transmissibility of an agent via aerosol or water is essential for the agent to enter the target population in sufficient numbers to generate concern. Second, transmissibility of the agent between persons is important since easy spread of the agent from an infected individual to an uninfected person is necessary to instill panic in the target population. The availability of effective treatment is important in regard to the ability to contain the spread of the agent once it is within the population. Tiers should therefore be based on these three properties of an agent: 1) the efficiency of its spread by aerosol and/or water, 2) the person-to-person transmissibility of an agent, and 3) the availability of effective treatments.

My following comments are restricted to the inclusion of monkey B virus (*Macacine herpesvirus* 1, ex-*Cercopithecine herpesvirus* 1, BV) on the select agent list since I have worked with this virus for over 30 years and am familiar with its biological properties.

BV is a herpesvirus that is very similar to the human herpesviruses HSV1 and HSV2. BV is naturally transmitted by direct contact, exactly the same way HSV1 and HSV2 are transmitted among humans. BV (and HSV) can be experimentally transmitted by aerosol, but this is a very inefficient and highly artificial method. The inefficiency is in part due to the instability of herpesviruses - like HSV, BV is readily inactivated by drying. Also like HSV, BV would not be easily transmitted via other likely bioterrorism delivery routes such as drinking water. Furthermore, BV is not readily transmissible once within the human population. To date there has been only one such case reported, and this involved repeated contact between spouses. Due to its environmental instability and the need for direct contact for infection, it is unlikely that BV will ever be attractive as a bioterrorism agent. The absence of BV from the NIH's list of Category A, B & C Agents reflects this (as does the public publication in 1960 by the US Army of a study on aerosol transmission of BV).

I assume that BV was only included on the select agent list only because having been previously classified as a BSL4 agent it would appear silly if it wasn't. The fact that BV was not included on the first original list and was only later added would seem to support this. The classification of BV as a BSL4 agent arose because it appeared that whenever the virus was transmitted to humans it produced lethal disease in ~80% of cases. Of the approximately 60 known human BV cases, only 1 (possibly as many as 2) occurred as a result of a laboratory accident that did not involve work with an infected monkey - all others involved transmission of the virus from an infected monkey. Over the past 80 years since the first human BV case was reported, there have been fewer than 60 documented cases worldwide. While BV is probably more a BSL3 agent than BSL4, even as a BSL4 agent I do not feel it should be retained on the select agent list due to the extremely low probability of its use as a bioterrorism agent and the inefficient transmission of the virus between persons.

A few of the contradictory things about having BV on the select agent list include:

HIV (not a select agent) is much more lethal and easily transmitted between persons than BV is.

There are more cases of lethal HSV1 encephalitis every year in the US than there have been lethal BV cases in the entire world over all of known history.

BV-positive macaques are raised in private and federal facilities that lack "select agent grade" security and are not ABSL3.

Known BV-positive (naturally infected) macaques can be worked with under ABSL2 containment and are not subject to select agent restrictions even though they could shed infectious BV at any time.

A monkey naturally infected with BV can be worked with under ABSL2 while a monkey experimentally infected with BV can only be worked with under ABSL4.