



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

RE: Comments on changes to the list of select agents and toxins

I am writing in response to the request for comments on changes to the list of select agents and toxins as announced in the Federal Register/Vol. 75, No. 139/42363. Specifically, I am recommending that *Rickettsia rickettsii*, the etiologic agent of Rocky Mountain spotted fever, be removed from the list of Select Agents.

My background is as a Ph.D. microbiologist with almost 25 years experience working with biosafety level 3, select agent pathogens including *Coxiella burnetii* and *Rickettsia rickettsii* and *R. prowazekii*. I recently stepped down after 10 years service as chair of the NIH Rocky Mountain Laboratories Institutional Biosafety Committee and Institutional Biosafety Officer. I have been the Responsible Facility Official for the Select Agent program from the implementation of that program until 2005. I have been a contributing editor to the CDC/NIH manual for Biosafety in Microbiological and Biomedical Laboratories (Rickettsial Diseases) for the past three editions. As an active researcher as well as biosafety specialist, I have had unique opportunities to observe and participate in the implementation of Select Agent regulations.

As a working research scientist, I am very much aware of the constraints placed upon laboratory research on these organisms. I am also cognizant of the necessity to restrict unauthorized access to those agents with great potential to cause disruption due to illicit release. My opinion, however, is that relatively few biological agents are capable of great disruption of society and that resources would be best expended monitoring only those agents likely to cause harm.

There are several reasons why *R. rickettsii* should not have been included among Select Agents and should be removed at this time.

i.) Rickettsiae are obligate intracellular bacteria. They cannot be grown outside of living cells, thus can only be propagated in tissue culture or embryonated eggs. Generation of even moderate amounts of infectious material is thus exceedingly difficult even under the best of laboratory conditions and requires specialized equipment such as CO<sub>2</sub> incubators or egg incubators as well as expensive reagents including tissue culture media and fetal bovine serum. Growth of these

organisms thus requires a clean, well-equipped laboratory and is therefore unlikely to be accomplished surreptitiously. Furthermore, the yields of infectious organisms are relatively small. Certainly there would be better choices if a deranged individual were to set out to develop a biological weapon.

ii.) Rickettsiae are vector-borne diseases that are spread by the bite of infected arthropods, such as ticks or lice. They are not spread directly from person-to-person thus would not be readily spread from an initial infection. Generation and dissemination of large populations of infected ticks would be practically impossible.

iii.) Rickettsiae, particularly spotted fever group rickettsiae, are extremely unstable in the environment and would not survive if dispersed into the environment.

iv.) Rickettsiae are susceptible to a number of readily available antibiotics. Preferred treatments include tetracycline or doxycycline. Fluoroquinolones have also been used successfully as has chloramphenicol in specific situations.

v.) Finally, rickettsiae are maintained in nature through hereditary (transovarial) transmission in ticks or via infection of small and large mammals. There is no possibility of eliminating their presence in the environment.

In summary, for the reasons listed above, I feel that *R. rickettsii* poses little to no threat to public health and safety and should be removed from the list of Select Agents. In my opinion, the benefits of lessening restriction on research involving rickettsiae far outweigh any risk associated with their elimination from the Select Agent list. Potential benefits include improved diagnostic capabilities for these bacteria that cannot be cultured on standard bacteriological media and a better potential for vaccine development.

It is an unfortunate fact of today's world that biosecurity has become an overriding concern when working with potentially hazardous microbes. My fear is that increased regulatory oversight will have a negative effect on research. My hope is that a rational evaluation of the true threat posed by these agents could lead to an improved research environment that encourages responsible research without stifling creativity.

In regard to the question of stratification of Select Agents by risk. The entire list should be reexamined from the point of view of which agents could actually disrupt society through accidental or deliberate release. There is no question that those capable of rapid dissemination and high morbidity, such as smallpox, should be maintained at the highest level of containment (as it already is) since even accidental escape could have global consequences. Those agents capable of readily being weaponized, *Bacillus anthracis* might be an example, should also rate a higher level of concern. Other agents on the list may not necessitate such high levels of security. Justification for handling at a lesser degree of security, or removal from the Select Agent list, might include: low transmissibility from person-to-person, low morbidity, difficulty in propagation, poor environmental stability, or susceptibility to readily available antibiotics.

My hope is that by carefully considering the impact of additional regulations on research, we can focus on those security items that are readily achievable to promote a safe yet open and interactive research community that will continue to attract the best and brightest young scientists to maintain the leadership of the United States in biomedical research.

Thank you for your consideration.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ted Hackstadt". The signature is fluid and cursive, with a large initial "T" and a long, sweeping underline.

Ted Hackstadt, Ph.D.