

Additional Diseases to Consider for Priority Review Vouchers

**FDA Public Hearing
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Qualifications for Priority Review Voucher Eligibility

- Under the Food and Drug Administration Amendments Act of 2007 (Pub. L. No. 110-85), pharmaceuticals that qualify for priority review vouchers (PRVs) must target tropical diseases and:
 - “Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary”
- The PRV is an invaluable incentive for encouraging innovation and investment in neglected tropical diseases that affect millions of individuals throughout the world

Additional Diseases to Consider for Priority Review Vouchers

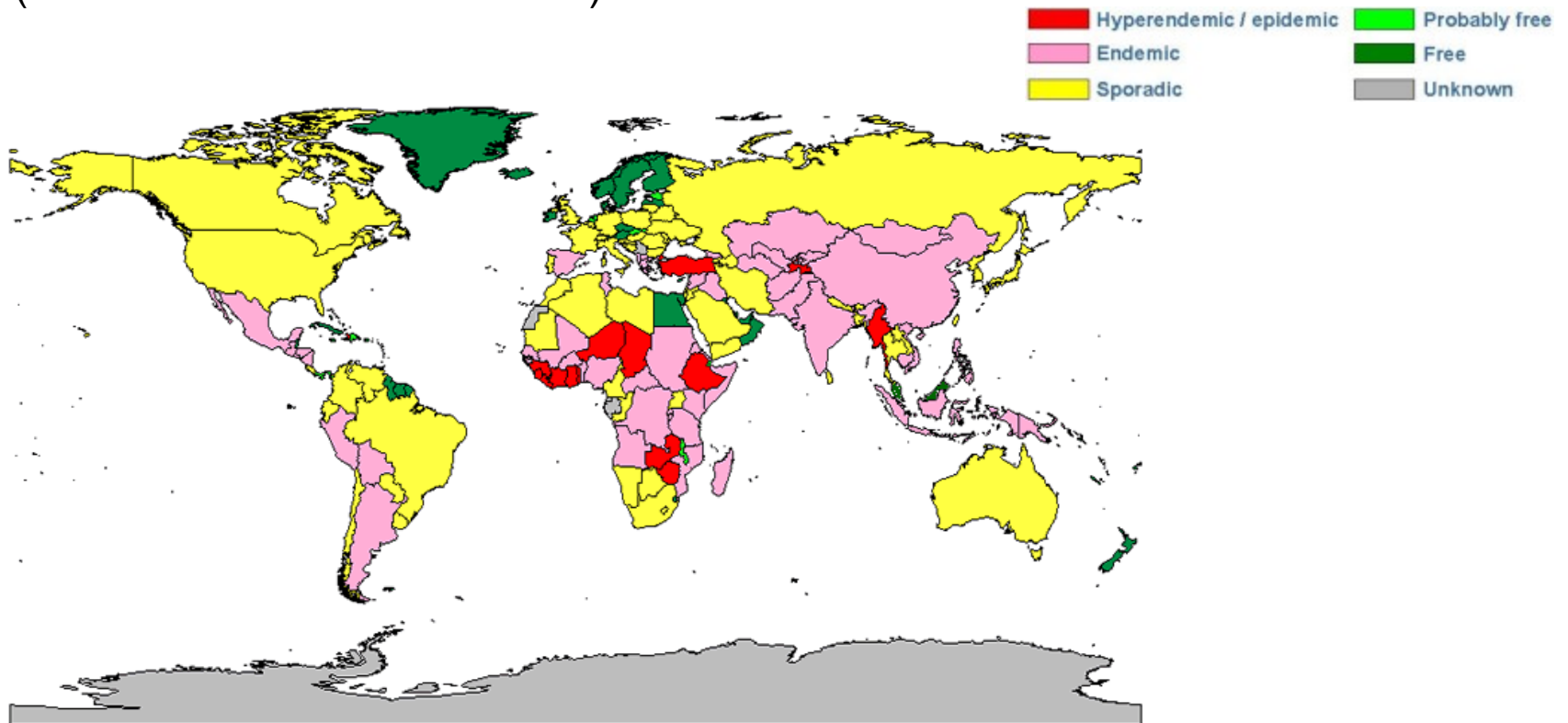
- In addition to the current 16 diseases, the following diseases should be included in the definition of “tropical disease” because they (1) have no significant commercial market in developed nations and (2) disproportionately impact poor and marginalized populations:
 - *Bacillus anthracis* (Anthrax)
 - *Clostridium botulinum* toxin (Botulism)
 - *Francisella tularensis* (Tularemia)
 - *Arenaviruses* (e.g., Junin)
 - *Filoviruses* (e.g., Ebola, Marburg)
 - *Yersinia pestis* (Plague)
 - *Burkholderia mallei* (Glanders)
 - *Burkholderia pseudomallei* (Meliodosis)
 - *Rickettsia prowazekii* (Typhus)

Burden on the Disadvantaged/ Lack of Commercial Market

- For example, it is estimated that over 95% of human cases of anthrax, botulism, filovirus, Junin virus, and plague occur in developing countries
 - The diseases are associated with poor living conditions and/or close proximity to wildlife rarely found in the developed world
- In developed countries, the incidence of these diseases is well under 10,000 human cases per year
- Currently, no new products targeting these diseases have been approved by the FDA, no products are in Phase III trials, and only 1 product is in Phase II trials
- All would likely qualify as “orphan diseases” indicative of no significant commercial market in the U.S. or developed world

Example: Prevalence of *Bacillus anthracis* (anthrax) infections

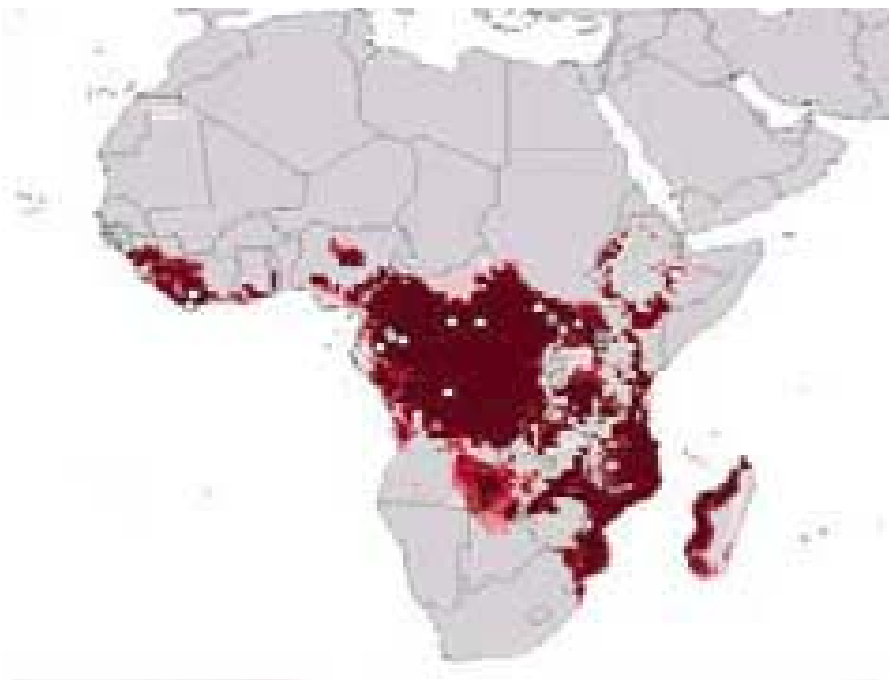
(human and animal infections)



Source: WHO Collaborating Center for Remote Sensing and Geographic Information Systems for Public Health. 2003.

Example: Filoviruses in Africa

Geographic projection of ecologic niche model based on all known filovirus disease occurrences in Africa.



Source: Peterson AT, Bauer JT, Mills JN. Ecologic and geographic distribution of filovirus disease. *Emerg Infect Dis* 2004; 10(1): 40-47. <http://www.cdc.gov/ncidod/EID/vol10no1/pdfs/03-0125.pdf>.

Addition of these Diseases would Improve Public Health and Security

- Benefits of adding these infectious diseases to the list of “tropical diseases” eligible for PRVs include:
 - Providing additional prevention and/or treatment options for poor and marginalized populations that are disproportionately impacted by these potentially debilitating diseases
 - Encouraging innovation and investment in the development of products that have the added benefit of providing protection from biological threat agents that could impact our national security

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QUESTIONS?

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