The number of FDA-approved and licensed drugs and vaccines for category A and B agents is currently limited and not reflective of the pharmacy of today. In an effort to speed the licensure of additional drugs and vaccines for these diseases, the FDA has a rule for the licensure of such countermeasures against agents of bioterrorism when adequate and well-controlled clinical efficacy studies cannot be ethically conducted in humans. This is commonly referred to as the "Animal Rule." Thus, for indications in which field trials of prophylaxis or therapy for a naturally occurring disease are not feasible, the FDA will rely on evidence solely from laboratory animal studies. For this rule to apply, it must be shown that (1) there are reasonably well-understood pathophysiologic mechanisms for the condition and its treatment; (2) the effect of the intervention is independently substantiated in at least two animal species, including species expected to react with a response predictive for humans; (3) the animal study endpoint is clearly related to the desired benefit in humans; and (4) the data in animals allow selection of an effective dose in humans. As noted above, levofloxacin for treatment of plague and raxibacumab for treatment of inhalational anthrax have been licensed via this mechanism.

Finally, the Biomedical Advanced Research and Development Authority (BARDA) was established in 2006 within the U.S. Department of Health and Human Services to provide an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies. As authorized by the All-Hazards Preparedness Reauthorization Act of 2013 in conjunction with the Project Bioshield Act of 2006 and the Pandemic and All Hazards Act of 2006, BARDA manages a series of initiatives designed to facilitate biodefense research within the federal government, create a stable source of funding for the purchase of countermeasures against agents of bioterrorism, and create a category of "emergency use authorization" to allow the FDA to approve the use of unlicensed countermeasures during times of extraordinary unmet needs, as might be present in the context of a bioterrorist attack.

Although the prospect of a deliberate attack on civilians with disease-producing agents may seem to be an act of incomprehensible evil, history shows us that it is something that has been done in the past and will likely be done again in the future. It is the responsibility of health care providers to be aware of this possibility, to be able to recognize early signs of a potential bioterrorist attack and alert the public health system, and to respond quickly to provide care to the individual patient. Among the websites with current information on microbial bioterrorism are *www.bt.cdc.gov*, *www.niaid.nih.gov*, and *www.cidrap.umn.edu*.