Before the Next Outbreak: Prepare for Everything Together

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Pandemic diseases are one of the top security threats to the U.S. Naturally, the prospect of a highly contagious disease incapacitating and/or killing large numbers of U.S. citizens is a vitally important concern to policymakers. Therefore, in keeping with the broadest principles of the National Security Strategy, the U.S. operates globally to identify and prevent disease epidemics whenever possible. To this end, both the Department of Defense (DoD) and the Department of Health and Human Services (DHHS) are tasked with protecting the health of U.S. citizens. Overall, the DoD can best support DHHS before the next big outbreak by broadening its research portfolio and amplifying its medical outreach programs.

While the DoD focuses on medical concerns related to fighting wars and deploying its service members, it invariably utilizes the same medicines as the rest of the civilian population. Therefore, subcomponents of DoD and DHHS that work on drug development are inextricably linked. This important and often efficient relationship in developing therapeutics and vaccines, commonly referred to as medical countermeasures (MCMs), should serve as a model for interagency coordination, particularly in terms of preparing for the next disruptive global outbreak. Specifically, during the response to the 2014 Ebola crisis in Western Africa, DoD and DHHS coordinated significantly to develop and deliver MCMs to the affected region. This proactive relationship should continue in the absence of a sustained crisis to solidify the hopes of a more rapid and improved response to the
next untreatable deadly disease ravaging another part of the world.

**Background**

The 2014 Ebola crisis was a watershed moment that highlighted the importance of DoD medical research in support of DHHS. However, before discussing some salient learning points from the outbreak response, it is important to understand the organizational approaches of DoD and DHHS with respect to preparing for and responding to infectious diseases.

DoD and DHHS have distinct but interrelated infectious disease missions. Both departments have centralized funding agencies to coordinate and manage specific research portfolios. Within DoD, the Defense Threat Reduction Agency (DTRA) assumes this biodefense-specific capability because biological weapons fall under the broader mantle of weapons of mass destruction (WMD). Within DHHS, the National Institutes of Health (NIH) broadly assumes funding duties for basic and applied research phases, which culminate in experimental MCMs that are poised for human clinical trials and refined manufacturing capabilities. For advanced research and development (R&D), which is designed to secure Food and Drug Administration (FDA) approval and to optimize manufacturing abilities for experimental MCMs, the lead DoD and DHHS agencies are the Joint Project Management Office for Medical Countermeasures Systems (JPM-MCS) and the Biomedical Advanced Research and Development Authority (BARDA), respectively.

With respect to infectious diseases, the departments share the same overall outlook, which is to produce MCMs to prevent and/or treat these infections. The major mission differences between DoD and DHHS MCM development relate to the likelihood, severity, and nature of the threats. The DoD is more concerned with combatting biological weapons in their traditional battlefield context and biological threats to service members in all types of hospitals, as well as current or future operational environments. Meanwhile, the DHHS is more broadly concerned with protecting the American public from hospital-acquired infections, pandemic diseases, and bioterrorism.

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It should come as no surprise that DoD and DHHS often develop MCMs against the same pathogens with the same goals of producing FDA-approved medications. For example, the official mission of JPM-MCS is to “provide U.S. military forces and the nation safe, effective, and innovative medical solutions to counter CBRN threats.” In no uncertain terms, the DoD defends both its military forces and the American public. Military forces are a small subset of the American public, and all Americans are restricted to using only FDA-approved medications. Therefore, this specific subset of research within DTRA and within JPM-MCS complements the corresponding research within the NIH and BARDA. These agencies need not rely upon each other in order to execute their mandates. However, in the event of a domestic or international emergency, DHHS is the lead responding U.S. agency. Therefore, in terms of preparation, DoD absolutely supports DHHS in this respect. While the notion of the DoD supporting another department might be difficult for some to handle, DHHS has the overarching authority to protect U.S. health interests. Perhaps the simplest way to convey this, with respect to drug development, is that all medications, regardless of whether they are designed primarily for military forces or for the American public, must pass the rigors of the FDA, a DHHS agency.
Fortunately, the U.S. government recognizes these fundamentally overlapping mission sets and has devised multiple coordinating bodies. As will be discussed later, Global Health Initiatives establish DHHS as the lead agency for promoting public health abroad. Likewise, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) coordinates U.S. government efforts with respect to MCMs against emerging infectious diseases. The DHHS Office of the Assistant Secretary for Preparedness and Response is in charge of PHEMCE, and certain DoD components are some of many supporting agencies. Under the auspices of the PHEMCE, as well as through continuing personal communications, meetings, and joint attendance at various medical and scientific conferences, drug developers from the DoD and the DHHS routinely share and coordinate their respective R&D portfolios, thereby highlighting this particular form of interagency interoperability.

In response to the Ebola epidemic in Western Africa in 2014–2015, the accelerated development of MCMs for the treatment of Ebola virus disease (EVD) particularly highlighted this efficient relationship between DoD and DHHS. For the purposes of discussing preparation for a future outbreak, this discussion will be limited in scope to therapeutics and vaccines against EVD. However, it is important to note that the DoD developed and distributed highly effective diagnostic testing capabilities to multiple agencies and countries during the Ebola response. While detection alone cannot treat or prevent an infectious disease, it is a critical first step for rapidly and accurately applying medical treatment.

Understandably, EVD was not considered to be a significant threat to U.S. public health prior to the summer of 2014. Rather, it was limited to a DoD concern as both a potential bioweapon and a potential medical threat to military forces deployed to Africa, as well as a DHHS bioterrorism concern. However, as the EVD outbreak morphed into an official epidemic that spanned multiple West African nations, DoD and DHHS rapidly coordinated their efforts in developing MCMs against EVD. Following multiple meetings with other stakeholders, such as Doctors without Borders and the World Health Organization (WHO), the U.S. government, led by the PHEMCE, selected three lead candidate therapeutics and vaccines for accelerated R&D toward FDA approval using emergency Congressional funding.

While an ample stock of therapeutic medications could possibly stem the tide of an epidemic, public health measures spearheaded by mass vaccination are the most effective way to prevent future epidemics. Throughout the Ebola response, the U.S. government was involved in pushing multiple vaccine candidates from experimental animal testing to human clinical studies in both the U.S. and in Western Africa. Importantly, the original developing agency behind the respective candidates, be it a part of DoD or DHHS, was immaterial relative to the potential life-saving benefits of the vaccines in stemming the Ebola epidemic. Policymakers in both DoD and DHHS should remember this credit-agnostic approach in the future in order to avoid classical interagency bickering that might prevent future success.

Similarly, both DoD and DHHS played significant roles in the accelerated R&D of therapeutic candidates. Whereas vaccines are a delayed response to stemming an epidemic, immediate concerns focus on treating the sick. Thus, therapeutic medications were arguably the more urgent, potentially life-saving...
consideration in the summer of 2014. All three of the U.S. government-designated EVD therapeutic candidates were developed by both DoD and DHHS. For example, TKM-Ebola was in advanced development within DoD, funded by JPM-MCS. Also, ZMapp, the so-called “miracle drug” that was often mentioned in the news in the late summer and early fall of 2014, was originally funded by DTRA and developed and tested at the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID); the NIH was also involved in its early development. In response to the epidemic, DoD and DHHS worked together to transition ZMapp from its applied research stages under DTRA into advanced R&D stages managed by BARDA. In what must be hailed as exemplary interagency coordination, BARDA primarily funded ZMapp’s manufacturability and clinical trials with continued guidance from DTRA.

In addition to continued portfolio coordination through the PHEMCE and the coordination during the Ebola response that was geared toward accelerating EVD R&D, DoD and DHHS also collaborated on funding additional EVD MCM development during the outbreak. From their centralized managerial and funding roles within their respective departments, NIH/BARDA and DTRA/JPM-MCS oversaw various R&D efforts executed by laboratories in the U.S. government, universities, companies, and even foreign governments. As part of their coordinated efforts to respond to the Ebola crisis, DoD and DHHS coordinated their requests for proposals and broad agency announcements to identify near-term solutions. Both departments continued to leverage their respective capabilities within their distinct yet overlapping mission sets in order to facilitate the larger U.S. government response to aiding in West Africa and preparing the nation for its own potential EVD outbreak.

Recommendations

Clearly, DoD and DHHS are broadly aligned toward a common goal of FDA-approved medications for both service members and the public at large. The 2014 Ebola response strengthened this existing relationship and also highlighted the importance of solidifying it in preparation for future epidemics. Although the DoD ultimately appears to have prevailed as a strong partner in providing possible MCM solutions to assist with the Ebola response in 2014, DoD’s most appropriate and effective role in future outbreaks requires further discussion.

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One upfront policy concern for DoD infectious disease R&D pertains to the nature of the research itself. With well-defined and lasting budgetary constraints, the DoD can only invest limited funding toward developing MCMs against bio-threat agents and various emerging infectious diseases. Broadly speaking, the DoD has separated these types of pathogens based on their Centers for Disease Control and Prevention (CDC) classification. DTRA funds bio-threat research at service laboratories such as USAMRIID, and the U.S. Army Medical Research and Material Command funds the remaining infectious disease research at laboratories such as the Walter Reed Army Institute of Research (WRAIR). Within each subcategory of research, the DoD focuses on certain pathogens against which to defend service members and the nation. For example, USAMRIID historically researches and develops MCMs against the causative agents of anthrax, plague, Western encephalitic virus, and of course EVD.

While the DoD has accumulated extensive and in-depth knowledge of these limited pathogens, the DoD should diversify its R&D
in coordination with DHHS to provide minimal anticipatory coverage against numerous potential threats. Clearly, there would be drawbacks to the DoD broadening its research against infectious diseases. For one, there is a fundamental danger in spreading resources too thin. It would be more difficult to quantifiably evaluate measures of success without sufficient funding to develop MCMs to a significant degree. Similarly, expanding the DoD’s research portfolio would require either additional manpower or existing researchers to diversify their duties. The result could be a shift from world-class expertise to a shallower knowledge base. Finally, should the DoD invest in MCM R&D against a much broader range of pathogens, it would be far costlier and slower to develop products from basic research through FDA approval for human use.

The inherent benefits of diversification include increased versatility, flexibility, and responsiveness. Both aforementioned drawbacks of spreading resources too thin and potentially losing subject-matter expertise would be mitigated by the extensive collaboration of DoD with the DHHS. Furthermore, while it might appear more difficult for the DoD to fully develop its products through full approval by opening its aperture to address countless more potential pathogenic threats, this does not account for industry involvement. Critical to the FDA approval process, a government agency, such as DTRA, the NIH, or WRAIR, is not supposed to submit a product on its own. As the usual owners and distributers of all government-funded medical products, private companies should be involved in the process. Commercialization strategies are important when recruiting the private sector to work toward the U.S. government’s objectives. Ultimately, FDA approval is hardly the DoD’s burden alone to bear. DoD-funded products should belong at least equally to non-governmental entities; be they companies or universities. Therefore, diversification and a concomitant divestment from acquiring FDA-approved products would free the DoD from excessive investments in products in which industry is historically uninterested. While resources might be spread thin, proverbial eggs would not be placed in the wrong baskets.

Diversification would help to enhance the probability of success in the following response scenario. When surveillance suggests an imminent epidemic, both departments will better be able to accelerate their relevant R&D efforts because they will have coordinated more broadly from the earliest possible stages. In essence, the DoD and DHHS will thereby have a wider range of options from which to choose in the event of an emergency. In 2014, it was a coincidence that the U.S. government was prepared to assist with the Ebola outbreak response in terms of ...
its MCMs against EVD. In the future, the U.S. government might not be as fortunate. The next outbreak could result from a disease against which the DoD is entirely unprepared because of its relatively limited focus on specific pathogens. Broadening this pool will heighten the DoD’s overall readiness and preparedness in advance of the next great outbreak.

One possible way to enact this shifted relationship for infectious disease R&D collaboration between DoD and DHHS could involve leveraging specific expertise from each department. The DoD is highly attuned to developing products for FDA approval via the animal rule, under which “products can be considered for FDA licensing using data from animal studies when it’s too dangerous or simply not possible to conduct clinical trials in people.” Briefly, the FDA will approve an MCM for human use to treat or prevent a rare disease if the developer demonstrates that the product is safe for human use and sufficiently effective in an accepted large-animal model for the disease. MCMs to treat anthrax and plague have recently been approved for human use in this way, with funding by both the DoD and DHHS. Concurrently, the DHHS has much more extensive expertise working with industry due to clearer commercial indications, higher budgets, and the absence of any stigma associated with military research. Therefore, in response to a future outbreak, the DoD could best support the DHHS’s efforts in accelerating development of medications through its vast expertise in animal modeling and animal efficacy studies.

One final way for the DoD and DHHS to successfully solidify their current partnership in preparation for an uncertain future is to retain flexibility when transitioning MCMs from applied to advanced research. The example of DTRA transitioning ZMapp to BARDA in order to rapidly advance the therapeutic toward FDA approval and availability to the public serves as a reminder that both departments succeed when they work closely together. In the same way, the NIH could transition a product from its basic research to JPM-MCS for its advanced R&D.

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In addition to the strategic-level question of which pathogens the DoD should focus upon, the DoD must decide how to present its medical R&D to the public during the next outbreak response. Within the holistic U.S. government approach to defending against both pandemics and bioterrorism, DoD and DHHS have specific missions that generally address strategic-level health threats, whether they are related to bioweapons, bioterrorism, or pandemic disease. The DHHS is the designated lead government component in response to a health crisis. Namely, the CDC took charge during the Ebola response. Working within its customary operational approaches, the DoD contributed to the overall U.S. government response by deploying forces to Liberia in a humanitarian, medical support role. While it took several months for the U.S. government to adequately engage in West Africa, the American public and the world in general accepted the DoD’s decision to deploy forces and medical equipment.

On the other hand, the DoD faced a much more difficult decision for how to respond with respect to its drug development efforts. The American public generally accepts that the U.S. government funds important medical R&D, typically through the NIH. In addition, Americans generally have little concerns that one of the two main functions of the FDA, other than food safety, is to assure that medical interventions are effective and safe. However, the American public might have a harder
time accepting that the DoD also develops medications, often available for everybody to use.

Should the DoD actively promote its medical R&D options when the next outbreak arises? One challenge in promoting DoD’s medical R&D is the fact that the public is largely unaware of this DoD mission; they may fear the resulting medications. After all, products designed for public use are typically more palatable than products designed for “military purposes.” More importantly, divulging the DoD’s defensive research efforts alerts our adversaries to our concerns and enables them to potentially circumvent our known defenses.

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While the DoD normally encourages its funded scientists in the service laboratories such as USAMRIID and elsewhere to publish in scientific journals and share their research at open-source conferences and conventions, these technical and relatively low-impact public maneuvers pale in comparison to a concerted effort from the Pentagon to broadly advertise its central R&D strategies. Clearly, this is the central argument for why the DoD should remain relatively silent about its R&D portfolios before and even during the next outbreak response.

That being said, there are several potentially positive outcomes should the DoD proactively advertise its R&D in responding to a future infectious disease crisis. The DoD and DHHS both strive to defend the American public. Above all else, the DoD, in particular, is charged with defending the nation, which includes providing MCMs to the American public when needed. Clearly, this would be accepted as an effective victory for the U.S. military against an insidious adversary—deadly pathogens, in this case.

The much more uncertain question relates to whether the U.S. military should provide its experimental MCMs to a foreign nation. This was a major policy and ethical dilemma during the 2014 Ebola response, specifically with respect to the development of ZMapp. As it turned out, the DoD did not own the rights to ZMapp based on the terms of its developmental funding, and Mapp Pharmaceuticals nonetheless ran out of its drug supplies relatively quickly due to ZMapp’s manufacturing limitations. In other words, the DoD dodged this question at the time. However, should it arise again in the future, one must circle back to the purpose of the DoD. The U.S. government prefers to defend against potential threats as far forward as possible. Just as the U.S. has not fought wars on its home soil in quite some time, the U.S. prefers to wage its wars against potential homeland epidemics on foreign soils whenever possible. This forward-postured defense should include full transparency on MCM options. While the DoD did not truly possess therapeutics or vaccines to rapidly and effectively save countless lives of West Africans and humanitarian responders, this is not to say that the DoD will not be able to do so in responding to a different disease outbreak in the future.

Developing MCMs is ultimately only one part of preparedness, and it could be ineffective without an efficient means for providing the MCMs in the course of providing all facets of healthcare. To this end, the U.S. government engages in global health in a number of ways. For example, the U.S. contributes financially through the President’s Emergency Plan for Aids Relief and the President’s Malaria Initiative, as well as through contributions to international organizations such as the United Nations, among others. Moreover, the U.S. is committed to developing health-enabling systems, such as frameworks for food safety, detecting and
reporting disease outbreaks, and responding to epidemics. These commitments aim to improve the ability of developing countries to provide for their citizens and improve the health of their people, while also contributing to broader U.S. global development goals and national security concerns.

Naturally, one specific aim of U.S. government global health efforts is to protect its citizens from global health threats, such as virulent infectious diseases that threaten national security by way of globalization and epidemics. A forward, proactive posture is certainly not limited to conventional military forces and their attendant supporting networks. The U.S. ultimately improves global health and protects its citizens from deadly disease and epidemics through a synchronized whole-of-government approach.

Synchronizing U.S. government agencies to achieve national security goals in global health is a daunting feat. Therefore, in 2010, President Obama issued a Global Health Initiative directive for coordinating interagency efforts related to global health. The initiative abides by seven guiding principles (women, girls, and gender equality; country ownership; health systems strengthening; partnerships; integration; research and innovation; monitoring and evaluation) drawn from the Paris Declaration on Aid Effectiveness. Similar to the PHEMCE, DHHS leads the nation’s Global Health Initiative, and other departments support the effort.

DoD’s civilian leaders directed its Global Health Engagement program to focus on strengthening health systems. However, other global health aspects are included in the program, such as monitoring and evaluation, research and innovation, integration, and partnerships to foster strengthening health systems. The DoD Global Health Working Group seeks to balance its global health efforts for its military purpose and support to global health development organizations, similar to how drug development efforts invariably support military and public interests.

MCMs and other technologies for combating disease are more effective and easily sustained in the presence of high-performing health systems. Therefore, one proven way to improve global health, protect national interests, and heighten preparedness before the next great outbreak is through development aimed at strengthening health systems in regions where the military and other U.S. government agencies currently operate or could likely operate in the future.

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The DoD executes its Global Health Engagement program by providing direct patient care and indirect military support to government and international organizations and states. Military medical personnel deliver varying degrees of direct patient care aimed at achieving military objectives, such as limiting human suffering during a disaster response or gaining access and influence through medical action programs. Indirect engagement by way of support is often through other agencies, including DHHS and host nation organizations. For example, USAID led the whole-of-government response to 2014 West Africa Ebola outbreak. Through orders from the President and with support from Congress, USAID leveraged the unique capabilities of the DoD and DHHS to subdue the epidemic and help prevent a
pandemic. In Operation United Assistance, the DoD unquestionably supported USAID and DHHS by deploying service members to West Africa. This response was, therefore, a further example of DoD and DHHS coordination, specifically following a disaster and leveraging Global Health Engagement.

With these lessons in mind, the DoD should continue to optimize its Global Health Engagement missions as a means to distribute its MCMs and support DHHS during global epidemic responses. The military strengthened relationships with the affected countries, fostering the development of regional health systems. Further, the research and innovation opportunities afforded to the military through cooperation with DHHS were instrumental in developing new health technologies and refining current research initiatives beyond MCMs, to include patient care, equipment, and medical techniques.

DoD’s Global Health Engagement should aim to strengthen allied and developing-partner state preparedness to respond to internal public health threats. Operation United Assistance and the humanitarian response to the outbreak deployed thousands of American citizens to an environment that placed them at risk to a particularly horrific disease without an approved treatment or vaccine. It is without question that the state of the health care systems in the affected countries contributed to the epidemic. In the spirit of global health, the aim is to prevent illness in order to foster health and inevitably save lives. Collaboration between agencies in developing MCMs for infectious diseases through the U.S. Global Health Initiative improves global preparedness to contain outbreaks and prevent pandemics.

There should be a distinct boundary to the DoD’s forward posture in best preparing for the next big outbreak. Specifically, the DoD should not be directly involved with clinical trials in foreign countries, particularly those involving rare and deadly infectious diseases. In contrast to offering its experimental MCMs to the DHHS for use on the American public, or even for possible foreign use by international bodies such as the WHO, the DoD would stand to lose far more than it might gain from human experimentation overseas. Regardless, overseas clinical trials are more effective and more beneficial for the DHHS. The DoD should only minimally support such efforts and should refrain from ever becoming the face of such a U.S. initiative.

Unfortunately, Western clinical trials in foreign countries, especially Africa, have a history of ethical conflict. Large pharmaceutical companies have been prosecuted for conducting clinical trials with unethical experimentation, with forced medical procedures, and without proper informed consent. For example, in the 1990s, Pfizer conducted a clinical trial for its antibiotic, Trovan, in Kano, Nigeria. Tragically, eleven children died in the trial, five after taking Trovan and six after taking a different antibiotic. Other children suffered blindness, deafness, and brain damage. Although these disabilities are relatively common outcomes of the bacterial infections themselves, a panel of medical experts later implicated Pfizer in the incident, concluding that the drugs had been administered as part of an illegal clinical trial without authorization from the Nigerian government or proper parental consent. The Nigerian government later filed a lawsuit against Pfizer.

The U.S. was directly involved in another incident of questionable ethics in clinical trials in Africa. The CDC and NIH, along with the WHO, funded clinical trials for the antiviral drug Zidovudine in Zimbabwe in 1994. Greater than...
17,000 women participated in the study, which was touted for testing a medication that prevents mother-to-child HIV/AIDS transmission. Later, it was determined that the study participants did not fully understand the testing methods, the effectiveness of the medication, the possible dangers, or the nature of placebos. Half of the women in the study received a placebo that was known to have no effect, thereby increasing the likelihood of HIV/AIDS transmission. As a result, an estimated 1,000 babies contracted HIV/AIDS even though a proven life-saving regimen already existed. The CDC ended the testing in 1998 after it announced it had enough information from another clinical trial conducted in Thailand.\(^\text{13}\)

These two example studies, as well as many other cases of unethical medical experimentation, significantly contribute to the documented fear and mistrust of doctors and Western medicine in Africa. In general, this fear has had detrimental effects on health in Africa. The incidence of polio infection has increased in Nigeria, Chad, and Burkina Faso because many people avoid vaccinations due to fears the vaccines may be contaminated with HIV or sterilization agents.\(^\text{14}\) Furthermore, many African nations cannot afford to offer medicine for their citizens without subsidies from multinational pharmaceutical corporations. To court these pharmaceutical corporations, some African nations minimize legal regulations on the conduct of medical research, which prevents potential legal battles from arising. This forces some Africans to make a Hobson’s choice—“experimental medicine or no medicine at all.” People living in the rural or slum areas are also more vulnerable to experimentation because they are more likely to be illiterate and to misunderstand the effects of the experimentation.

When viewed collectively, these events and engrained perceptions based on several, historically-difficult situations should caution the DoD. While there might be scenarios where the CDC or other DHHS elements manage clinical trials in foreign countries, there is no discernible reason for the DoD to be actively involved, especially in Africa. Rather, it is highly likely that actively participating in such trials would taint the DoD’s image. Africans in particular do not generally trust pharmaceutical companies. Providing Africans another reason to mistrust the U.S. would impede its military efforts and negatively impact regional security interests.

**Conclusion**

The 2014 Ebola epidemic in West Africa highlighted the importance of continued close interactions between DoD and DHHS with respect to MCM development. While it was fortunate that DoD’s R&D was somewhat prepared to address an Ebola epidemic, the DoD should broaden its R&D efforts in coordination with DHHS in order to prepare for the next great epidemic. Both departments must maintain as broad a readiness as possible, with the DoD clearly supporting the DHHS in this particular mission area. Furthermore, the DoD must continue to engage overseas with foreign healthcare systems in order to optimize its ability to respond to another outbreak. However, the DoD must restrict its overall positioning to R&D and engagements, refraining from actively participating in clinical trials in foreign countries. **IAJ**
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4 Pellerin.


7 “Medical Research Institute Has Years of Ebola Drug Expertise,” Targeted News Service, October 30, 2014.


