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Biodefense Research: A 'Boondoggling' of Critical Biomedical Research Funds?

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I agree that biodefense research funding is a 'boondoggle' that is draining resources from critical biomedical research areas, for example cancer, autoimmune diseases, etc. One saw this same argument years ago with cancer funding versus AIDS funding. I have done [and doing] cancer research, AIDS research, and bioterrorism research, but this "boondoggling" of research funds luckily does not have to follow the *Cancer versus AIDS* funding debate. My rationale for this statement is divided into two components, and both entail redundancy [efficiency] issues. The two components are political and scientific-both are valid and applicable in the real world, but neither one is more important than the other one.

First, the political component. Since the anthrax letters, man-made outbreaks have become a public health issue. Therefore, the Centers for Disease Control (CDC) is the government agency that should not only deal with natural and accidental outbreaks (e.g., *Salmonella typhimurium, Listeria monocytogenes, Staphylococcus aureus* [and methicillin-resistant *Staphylococcus aureus*], *Escherichia coli, Streptomyces, Mycobacterium paratuberculosis*), but also man-made ones (those government-listed bioagents, such as *Bacillus anthracis, Burkholderia mallei, Coxiella burnettii, Francisella tularensis*, Venezuelan equine encephalitis virus, viral hemorrhagic fever viruses, and *Yersinia pestis*). Conversely, the National Institutes of Health (NIH) is the government agency that should focus on biomedical research (e.g., cancer, AIDS, neurological and autoimmune diseases). To have NIH conduct biowarfare research is a redundant use of government resources-NIH and the CDC should not do parallel research. A more redundant example of government resources can be found within the military. Walter Reed Army Institute of Research (WRAIR) focuses on biomedical research relevant to military personnel, such as combat-related injuries and microbes military personnel may encounter in the field. A much smaller research facility, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) does not focus on combat-related injuries, but they do focus on microbes military personnel may encounter in the field. In this case, what is the medical difference from a soldier acquiring a microbe naturally in the field or a solider acquiring a microbe caused by a bioterrorist organization? One then could make the argument that WRAIR should then handle all microbial research.

The government and its agencies should not have major redundant programs, as this leads to inefficiencies, and inevitably a reduction in resources-namely funding. This also leads to a reduction in research novelty, as research funds would then focus primarily from the same research groups seeking funding from both agencies. For example, the Congressionally Directed Medical Research Programs (CDMRP) was created because of three major complaints. Those who directed their complaints to Congress [originally related to breast cancer] were frustrated because: (1) NIH was too slow in awarding grants, (2) the grants were being awarded to the same research groups, which is not bad in itself, but (3) not much was being produced to help those with breast cancer. The CDMRP accomplished a rapid turnover in awarding grants [other granting agencies, large and small, followed suit], but the second and third complaints were never fully strengthened. I know this because I was part of the Congressional oversight for the programs. This is not to say that one funding program is better than the other one; on the contrary, both programs serve a good purpose, but both should not be redundant. The point here is that from a government funding viewpoint, there

must be a clear difference [or approach] among government funding agencies with regards to biomedical research and bioterrorism, just as the National Cancer Institute at NIH does not conduct and support research that helps prevent and treat eye diseases and other disorders of vision?that is for the National Eye Institute at NIH. True, cross-scientific fertilization can exist, but it should not be redundant with respect to their "mission statement", reflected upon what they really do. As any political component of any proposal or program is "political", the probability of any change within this component to help reduce funding shifts is near zero. Therefore, changes should then focus within the scientific component to help reduce funding shifts, as they are more realistic and feasible to accomplish than the political component.

The second component to help reduce the process of shifting funds from biomedical research to bioterrorism research is purely scientific. Man-made and natural outbreaks are not mutually exclusive, as the shared common signature profile (i.e., outbreak profile composed of microbial transmission, identifying the microbe[s], hospitalization, deaths, treatment, quarantine, etc.) can be harnessed and applied to any short- or long-term mitigation plan. As such, no man-made outbreak preparedness plan should be classified, evaluated, or executed as separate budgetary incidents or medical issues from natural outbreak preparedness plans. From a practical point of view, because bioterrorism incidents have a common signature profile that is shared with natural outbreaks and vice versa, the difficulties inherent with outbreaks [and their solutions] should be the same. To support this argument, two popular bioterrorism budgeted items follow, the first related to diagnostics, the other related to tracking (e.g., outbreaks, patients, supply).

Medical Microbial Diagnostics

1. Accurate medical diagnostics should apply both to natural [and includes routine hospital testing] and to man-made outbreaks. Consequently, from a purely public health diagnostic viewpoint, the order of importance in evaluating any medical microbial diagnostics process for everyday use, natural outbreaks, and man-made outbreaks is as follows. The order of medical diagnostic importance is that the process must first be equal to or better than PCR in its sensitivity. Second, its specificity must be equal to or better than PCR. To date, PCR is the most sensitive and specific of the diagnostic tests, and therefore is used as the comparative standard for diagnostic test accuracy (i.e., specificity and sensitivity). The public health rationale behind sensitivity having a higher priority than specificity, is that it is better to have false-positive results (treated non-carriers) than false-negative ones (untreated carriers). Third, the diagnostic process must be multiplexible. The fourth order of importance is the speed of the diagnostic process (i.e., preparation and machine time). Diagnostic time is ranked fourth and not first because if the process is not as sensitive and specific as PCR, and not multiplexible [an early diagnostic concern] it is then irrelevant if a test is rapid. One-minute diagnostic tests are also not as effective if they can only detect one microbe. Which one-minute test-of hundreds-would healthcare providers perform first? The fifth order of importance in the public health medical diagnostic process is cost. Solutions will not be widely applied if it is personally unaffordable, or if insurance companies and the government are unwilling to pay for such tests. Cost inefficiencies are major healthcare concerns. The sixth and seventh orders of importance are of ease of use and portability, respectively. Ease of use and portability should never supersede sensitivity and specificity (i.e., test accuracy), "multiplexibility", time, and cost considerations. The implication here is that an accurate, cost-effective, and rapid test is more critical in the medical diagnostic process than push-button technology. Improving medical microbial diagnostics should be natural and man-made inclusive, regardless of what diagnostic path healthcare policy makers may take.

Tracking programs

2. A tracking system should be widely applicable to both everyday use and for biological outbreaks. It should also be automated. For example, current software outbreak tracking programs, such as the Geographic Information System (GIS) or ProMed, have problems. Currently, these types of systems require data to be entered twice-once for the patient's hospital or clinic record, and a second time for the proposed systems. Entering patient data more than once is inefficient use of time for any healthcare provider, and causes an increase to the overall cost of healthcare while trying to satisfy a well-intentioned but disjointed bioterror preparedness planning. Knowing this, ProMed developers sought to market their system by offering Continuing Medical Education credits. Outbreak software programs that are based on plume projections [calculations based on how a microbe would spread in the air similar to calculating the spread of radiation after a nuclear explosion] are also still common. This implies that the developers are not thinking in terms of everyday public health issues, rather more of a military bioterror attack one-again, taking funds away from other biomedical funding projects. Yet, most man-made and natural disease outbreaks are [will] spread

crop-to-crop, animal-to-animal, animal-to-person, or person-to-person, making plume projection software useless. Plume projection-based technologies would have not worked for outbreaks in SARS, HIV, gonorrhea, Mad Cow, microbial-contaminated salad bars, flu, and other microbial outbreaks.

So then, what solution would apply from everyday use, to an outbreak scenario that is not redundant? On solution is to have an automated outbreak tracking system (OTS) that integrates into any electronic patient database format. While the healthcare providers enter patient data multiple times in other systems, this one-step data entry system would not only provide for the patient's record, but also would automatically code the patients name and "filter" relevant patient data from the hospital's [or clinic] main disease tracking system prior to sending it to authorized public health official's system. The system, being "filtered" and name-coded would comply with the Health Insurance Portability and Accountability Act [HIPAA-compliant]. The proposed teledata diagnostic system is automated such that the threshold outbreak numbers for each microbe, which are predetermined, and warnings or alerts are made automatically. In these scenarios, OTS creates an inverse outbreak detection pyramid profile. What this means is that while the threshold outbreak number for one hospital may be too low to issue an early warning, combining [automatically] the data from surrounding hospitals makes it possible for the local health department to issue an alert regarding any given potential outbreak very early in the outbreak. This would also apply to at the state, regional, and national levels. The proposed system parallels two systems, the current Nuclear Regulatory Commission's integrated early warning system established after the Three Mile Island disaster, and the automated floodgate system at a major shipping lane in Rotterdam, Netherlands. The proposed automated OTS software also would track medication usage, exposure rates, patient demographics, locations of exposures, and any other relevant information needed by healthcare providers and public health officials to curb [and prevent] disease outbreaks. This even includes for routine hospital and clinic patient visits. The automated teledata diagnostic system is a low-cost solution to a major problem, as it is software-driven and can be created using open-source software. The same system can be applied to clinical trials and post-marketing surveillance. Here, current biomedical research efforts and biowarfare research technologies are integrated that can result in expanded uses, and on the same budget line item. The shared result is a reduction in having to shift biomedical funds to fund bioterror preparedness projects.

Much of the funding that has been diverted to bioterrorism research has been siphoned off in the form of fiscal juggling from institutes that award research funds to study disorders and diseases. I am not minimizing the need to fund biodefense research; however, one must determine the comparative risks and allocate the appropriate amount of funding to such endeavors. For example, it makes not sense to have two separate funding programs for biowarfare medical diagnostics and tracking, as there is no such thing as "separate but equal programs". It is often cited that two [of many] contributing factors in the rising cost of healthcare are waste and inefficiency-this is also true with bioterrorism research. Why the redundancy [analogous to repeating medical tests because the original results were misplaced] when it is not necessary, as you do not have to trade quality for cost. Biological risk management rationale in integrating natural and outbreak preparedness plans will diminish the shifting of biomedical funds to bioterrorism projects, but only if all microbial concerns are thought of as a unified public health issue.

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