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Will the Ebola Epidemic Serve To Make Reform of the Broken Health Research and Development Framework Go Viral?

JEREMY MCDONALD*

ABSTRACT

The recent Ebola outbreak in West Africa has captured the public imagination as few other epidemics have, as its rapid spread and lethal effect demonstrated the devastating toll that infectious diseases can exact from a world unprepared to confront them. In light of the epidemic’s tragic consequences, numerous experts have called for reform of the system of global health governance whose shortfalls allowed the epidemic to assume the horrifying dimensions it did. Among the many inadequacies that the outbreak uncovered is the insufficient amount of research into and development of treatments and vaccines for infectious diseases of poverty, among them the so-called “neglected tropical diseases.” This lack of vital research and development long predated the present Ebola outbreak, and, given how widespread calls of reform have been since the epidemic, it bears assessing whether the crisis will provide the impetus necessary for meaningful change to the calcified research and development framework that has long ignored Ebola and like ailments. Due to a variety of factors that this Note seeks to explain, however, this will likely not be the case.

INTRODUCTION

The West African Ebola epidemic that began in 2013 and ravaged the nations of Sierra Leone, Liberia, and Guinea appears to be on the wane. Although isolated flare-ups of the disease have followed on the

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heels of World Health Organization (WHO) pronouncements of the outbreak’s cessation, Ebola incidence has fallen drastically since its peak period from September 2014 to May 2015, when hundreds of new cases were being reported weekly. Additionally, the clinical trials for three potential Ebola vaccines conducted at record speed amidst the outbreak have had encouraging results: one vaccine candidate, pharmaceutical giant Merck’s rVSV-ZEBOV, prevented infections in 100 percent of the patients to whom it was administered, allowing for hope that any potential for future outbreaks will be severely diminished.

Given that there have been more than twenty Ebola outbreaks before the current one and that the virus was first discovered in 1976, however, it may seem puzzling that these trials were necessary at all, or in other words, that there was no approved treatment or vaccine for Ebola at the time the most recent epidemic began. But in this respect, Ebola is illustrative of a sadly persistent theme in the annals of global health: the general dearth of research into and development of treatments and vaccines for infectious diseases that are largely endemic to impoverished populations in developing states, collectively referred to as “neglected tropical diseases” (NTDs). The term “neglected” is apt:

2. See Ana Maria Henao-Restrepo et al., Efficacy and Effectiveness of an rVSV-Vectored Vaccine Expressing Ebola Surface Glycoprotein: Interim Results from the Guinea Ring Vaccination Cluster-Randomised Trial, 386 LANCET 857, 857 (2015).
5. See Neglected Tropical Diseases, WORLD HEALTH ORG. [WHO], http://www.who.int/neglected_diseases/diseases/en/ (last visited Dec. 10, 2015) [hereinafter NTDs] (providing a detailed summary of each type of NTD). The WHO does not classify Ebola as an NTD. See id. (listing WHO-classified NTDs). However, Ebola shares many similarities with these illnesses, namely its infectious nature, the demographic of its victims, and the locations where it is endemic. As such, the current Ebola outbreak provides a useful case study for the purposes of this Note’s analysis of whether the current R&D paradigm, which has so far largely ignored infectious diseases such as NTDs and Ebola, is likely to change in response to the epidemic. Additionally, NTDs are not an exhaustive list of all infectious diseases that more heavily burden developing nations; others, such as malaria, also claim a vast number of victims and yet are the objects of an insufficient amount of R&D. See REVIEW ON ANTIMICROBIAL RESISTANCE, SECURING NEW DRUGS FOR FUTURE GENERATIONS: THE PIPELINE OF ANTIBIOTICS 1 (2015) (noting the decline in antibiotics available for tuberculosis, malaria, and HIV/AIDS). However, this paper will confine its examination of the R&D prospects for NTDs in the wake of Ebola, given that they are paid an even more marginal amount of attention than malaria and other similar ailments.
although NTDs constitute 12 percent of the global disease burden and afflict over one billion people worldwide, the resources devoted to their mitigation are minimal. Only 1 percent of all global health research and development (R&D) funding is allocated to projects concerning these illnesses, and of the 850 new therapeutic products registered by pharmaceutical companies between 2000 and 2011, one percent were for NTDs.

The danger posed by this lack of attention has been poignantly demonstrated by the latest Ebola epidemic, as its death toll (11,316 people, by the most recent estimates by the WHO) dwarfs by far the death tolls of all previous outbreaks of the disease. In view of the sheer extent of the devastation, numerous experts have voiced the sentiment that the Ebola crisis represents a watershed moment in global health governance that must be met with sweeping changes.

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7. See NTDs, supra note 5.


9. Pedrique et al., supra note 6, at 372 tbl. 1.


is beyond the scope of this Note, however. Instead, it will confine itself to an examination of whether the epidemic will provide the impetus necessary for a shift away from the current health R&D paradigm that has so far largely ignored NTDs—as some have hoped.14

Part I of this Note provides a brief summary of the many factors that contributed to Ebola's rapid spread. Part II then provides a short description of the various proposals that have been offered to stimulate R&D into NTDs, as well as an analysis of why these proposals have had little impact to date. Part III examines the R&D-related reform proposals emerging from the reports issued by a number of expert panels assessing the response to the Ebola crisis. Lastly, Part IV argues that despite the tragic effects of the Ebola epidemic, it will likely not spark any meaningful change to the entrenched health R&D paradigm.

I. THE EBOLA OUTBREAK: ITS ORIGIN AND SPREAD

WHO staff and Guinean health officials have traced the origin of the current epidemic to December 26, 2013, when an 18-month-old boy from Meliandou, Guinea developed an illness resulting in the typical symptoms of Ebola: fever, black stools, and vomiting.15 The boy died two days later, yet his disease did not: several members of the boy's family contracted the Ebola virus, and one of them carried it with him to Conakry,16 Guinea's capital and home to more than a seventh of its population.17 In this dense urban environment, the disease spread rapidly. Yet it remained undetected for months, a consequence of the Guinean government's failure to build its infectious disease surveillance capabilities, despite the legal obligation to do so placed on it by the International Health Regulations (IHR).18 Finally, on March 22, 2014, the Institut Pasteur in Lyon, France confirmed that the viral culprit

14. See Marco Schäferhoff et al., Chatham House, Rethinking the Global Health System 4-5 (2015), https://www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20150923GlobalHealthArchitectureSchaferhoffSuzukiAngelidesHoffman.pdf (arguing that the Ebola outbreak highlights the need for more development of "global public goods," one of which is greater levels of research into and development of treatments for neglected diseases); see generally Manica Balasegaram et al., A Global Biomedical R&D Fund and Mechanism for Innovations of Public Health Importance, 12 PLOS Med., May 2015, at 1, 3 (arguing that "[t]he devastating loss of human life from the Ebola outbreak of 2014 must not be in vain" and calling for the establishment of a fund to subsidize R&D into emerging infectious diseases and neglected diseases).
16. See id.
18. See id.
behind the mounting death toll was Ebola.\textsuperscript{19} Two days later, Ebola was confirmed in Liberia, followed soon after by Sierra Leone in May,\textsuperscript{20} a chain of transmission facilitated by highly mobile populations and porous borders between the three states.\textsuperscript{21}

The weak investment in public health infrastructures by the governments of Guinea, Sierra Leone, and Liberia not only delayed detection of Ebola but also resulted in unsafe methods of treatment inviting further transmission. Health workers toiled without personal protective equipment or sufficient infection controls, and hundreds of them contracted the disease and perished as a result.\textsuperscript{22} Treatment facilities were unsanitary, overcrowded, and understaffed, leading many infected individuals to avoid them and further transmit the disease to their surrounding communities.\textsuperscript{23} The atmosphere of panic led to violence against aid workers and police,\textsuperscript{24} and traditional West African burial rites, many of which called for the ritual touching and bathing of the bodies of the infected deceased, allowed for further opportunities of disease transmission.\textsuperscript{25} Yet for all this, health officials in the affected countries downplayed the extent of the disaster for months, for fear of suffering the economic repercussions that attend the declaration of an epidemic.\textsuperscript{26}

\textsuperscript{19.} See Origins, supra note 15.
\textsuperscript{22.} See Roache et al., supra note 3, at 3.
\textsuperscript{23.} See id.
\textsuperscript{24.} See Empowered WHO, supra note 20.
\textsuperscript{25.} See Roache et al., supra note 3, at 4.
\textsuperscript{26.} See HARVARD-LSHTM REPORT, supra note 13, at 3. The phenomenon of economic loss following epidemic declaration is well documented. For instance, after Mexico alerted the WHO to its H1N1 influenza epidemic in 2009, twenty countries banned the importation of Mexican pork and pork products, despite a statement by the WHO that the disease could not be contracted through the consumption of pork. See Rebecca Katz & Julie Fischer, The Revised International Health Regulations: A Framework for Global Pandemic Response, 3 GLOBAL HEALTH GOVERNANCE, Spring 2010, at 6. Sierra Leone, Guinea, and Liberia suffered similar repercussions after the presence of Ebola became known, as numerous states enacted quarantines and travel restrictions to and from Sierra Leone, Guinea, and Liberia. These restrictions severely harmed the affected countries, as they obstructed trade and the delivery of vital medical services. See Empowered WHO, supra note 20, at 1903. Moreover, as they were not enacted with scientific justification, see id. at 1906, they violated the IHR. See WHO, International Health Regulations, art. 43, para. 2 (2005).
This reluctance to acknowledge the severity of the situation was evident even among the foremost institution charged with global health governance, the WHO. Despite being informed by Médecins Sans Frontières (MSF) aid teams on the ground of the dire threat Ebola posed, the WHO chose to downplay its extent during the early months of the epidemic.\textsuperscript{27} While MSF characterized the Ebola outbreak as "out of control" and stressed the need for additional deployment of resources in late June,\textsuperscript{28} the global community declined to take decisive action until after the medical evacuation of two infected U.S. aid workers from Liberia in late July.\textsuperscript{29} In this vacuum, humanitarian groups such as MSF shouldered the bulk of the burden of caring for the majority of those stricken by Ebola.\textsuperscript{30}

On August 8, 2014, months after the outbreak began, the WHO declared the Ebola outbreak a Public Health Emergency of International Concern (PHEIC) under the IHR,\textsuperscript{31} a designation reserved for "extraordinary event[s] which [are] determined . . . to constitute a public health risk to other States through the international spread of disease and [that] potentially require a coordinated international response."\textsuperscript{32} Subsequent to this declaration, an unprecedented outpouring of aid from the global community ensued. Commitments of financial support and additional health personnel came from the African Union, China, Cuba, the European Union, the United Kingdom, the United States, the International Monetary Fund, the World Bank, United Nations (U.N.) agencies.\textsuperscript{33} On September 16, 2014, U.S. President Obama authorized the deployment of 3,000 U.S. military personnel to affected sites to support logistics and construct treatment centers.\textsuperscript{34} Clinical trials for three potential Ebola vaccines rapidly ensued,\textsuperscript{35} and practices that had previously contributed to the spread of the virus, such as unsafe burials and patient avoidance of treatment

\begin{itemize}
\item \textsuperscript{27} See HARVARD-LSHTM REPORT, supra note 13, at 3.
\item \textsuperscript{28} See id.
\item \textsuperscript{29} See Empowered WHO, supra note 20.
\item \textsuperscript{30} See Roache et al., supra note 3, at 6.
\item \textsuperscript{31} See Empowered WHO, supra note 20.
\item \textsuperscript{32} WHO, International Health Regulations, art. 1 (2005).
\item \textsuperscript{33} See HARVARD-LSHTM REPORT, supra note 13, at 4.
\item \textsuperscript{34} See Empowered WHO, supra note 20.
\item \textsuperscript{35} See Tina Rosenberg, Amid Failure and Chaos, an Ebola Vaccine, N.Y. TIMES (Nov. 24, 2015), \url{http://opinionator.blogs.nytimes.com/2015/11/24/after-the-crisis-tools-for-limiting-ebola/?action=click&contentCollection=Business%20Day&module=RelatedCoverage&region=Marginalia&pgtype=article} (noting that the time between the commencement of clinical trials for the vaccine candidates and their use in treatment, "a process that normally takes years," was "compressed into six months").
\end{itemize}
facilities, began to subside as community outreach and education efforts took hold.\textsuperscript{36}

This immense outpouring of support has helped to contribute to the current state of relative containment of the disease. However, its belated occurrence helped shape the dramatic contours of the trail of death, illness, and financial ruin Ebola left in its wake. As previously mentioned, the epidemic claimed thousands more lives than any previous outbreak of the disease ever had. Survivors of the disease face a difficult road to recovery, as many of them suffer from a variety of ailments, including severe joint pains, vision loss, and mental health issues.\textsuperscript{37} Additionally, the economic harm inflicted by the epidemic has been crippling, as the World Bank has estimated that the total combined losses to gross domestic product (GDP) suffered by Sierra Leone, Liberia, and Guinea (already three of the weakest economies in Africa) to be $2.2 billion.\textsuperscript{38} Taken together, these facts serve as a stark reminder of the grim toll that infectious diseases can exact from regions ill prepared to deal with them.

II. PAST PROPOSALS FOR THE STIMULATION OF NTD R&D AND THEIR EFFECT

The Ebola epidemic dramatically and tragically demonstrated the need for more research into and development of treatments and vaccines for infectious diseases of poverty, including NTDs. But proposals to augment R&D efforts concerning such ailments predate the outbreak. Below I review some of the most common among them and assess their impact to date. Additionally, I offer an analysis of why that impact has remained minimal despite the continuing scourge of NTDs.

A. Past Proposals

The primary factor contributing to the desultory state of NTD R&D is the lack of commercial value that may be derived from any

\textsuperscript{36} See Empowered WHO, supra note 20, at 1903.


\textsuperscript{38} ERROL GRAHAM ET AL., WORLD BANK GROUP, UPDATE ON THE ECONOMIC IMPACT OF THE 2014-2015 EBOLA EPIDEMIC ON LIBERIA, SIERRA LEONE, AND GUINEA 2 (2015), http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2015/06/18/090224b082df93b3/1_0/Rendered/PDF/Update0on0the00ra0Leone00and0Guinea.pdf.
treatments or vaccines developed for them.\textsuperscript{39} Pharmaceutical companies, the most profitable of which are quartered either in the United States or the European Union,\textsuperscript{40} and which possess by far the greatest part of the world's applied R&D capacity,\textsuperscript{41} have little financial incentive to engage in R&D in the NTD context. Drug development is quite costly,\textsuperscript{42} yet those who stand to benefit most from NTD R&D have virtually no purchasing power.\textsuperscript{43} Recognizing this, experts have for some time advanced numerous proposals that attempt to assuage the financial concerns that pharmaceutical companies would otherwise face in allocating R&D resources to NTDs. Most of these call for the implementation of policies that would commit government funds to pharmaceutical companies choosing to undertake NTD R&D. These proposals can largely be grouped into two categories: first, "push mechanisms," those that subsidize research inputs,\textsuperscript{44} and second, "pull mechanisms," those that reward research outputs.\textsuperscript{45}

The theory behind push mechanisms is that providing up-front financial or technical assistance will lower the reluctance pharmaceutical companies would otherwise feel about undertaking NTD R&D. Some of the more common push mechanisms that have been proposed include direct funding of private research, such as through

\textsuperscript{39} See Lawrence O. Gostin & Eric A. Friedman, Towards a Framework Convention on Global Health: A Transformative Agenda for Global Health Justice, 13 YALE J. HEALTH POL'Y L. & ETHICS 1, 28 (2013). The use of the word "primary" is deliberate, as the perceived unlikelihood of NTD treatments being profitable is not the sole factor behind the lack of NTD R&D; others, such as the absence of any mechanism to reliably insure patient access to any resulting treatments, have been posited as well. See PHILIP STEVENS, INT'L POL'Y NETWORK, DISEASES OF POVERTY AND THE 10/90 GAP 7–8 (2004).


\textsuperscript{42} Some estimates place the average cost incurred by a pharmaceutical company in developing a new treatment to be between US $802-1,778 million. Peter Stephens & H.G.M. Leufkens, Research and Development, in THE WORLD MEDICINES SITUATION REPORT 2011, at 1, 2 (3d ed. 2011).

\textsuperscript{43} See David Webber & Michael Kremer, Perspectives on Stimulating Industrial Research and Development for Neglected Infectious Diseases, 79 BULL. OF WORLD HEALTH ORG. 735, 736 (2001).


\textsuperscript{45} Id. at 191.
targeted R&D tax credits;\textsuperscript{46} direct funding of public research, such as through grants to research universities or institutions;\textsuperscript{47} and the use of product development partnerships (PDP).\textsuperscript{48} The typical PDP model consists of a nonprofit organization that partners with a research institute, university, company, or some mixture of the foregoing, develops with them a portfolio of medicines to use in the treatment of NTDs, and provides the partners with funding, technical assistance, and managerial oversight during each stage of the development of the product.\textsuperscript{49}

Pull mechanisms, on the other hand, seek to reward research outputs, thereby coming into play only with successful development of a new treatment or vaccine. Examples of commonly proposed pull mechanisms include priority review vouchers,\textsuperscript{50} advance market commitments (AMC),\textsuperscript{51} and innovation prize schemes.\textsuperscript{52} In essence, pull mechanisms serve as a means of “market shaping”\textsuperscript{53} whereby a downstream source of revenue is guaranteed to the developer of a

\textsuperscript{46} See Webber & Kremer, supra note 44, at 738.
\textsuperscript{49} See id.
\textsuperscript{50} See David B. Ridley et al., Developing Drugs for Developing Countries, 25 HEALTH AFF. 313, 322 (2006). The basic principle is simple: a developer of a drug for an NTD secures a priority review voucher from a drug regulatory body, such as the FDA. Later, it redeems that voucher for expedited review of another one of its drugs with potentially significant commercial value. See Lesley Hamming, The Promise of Priority Review Vouchers as a Legislative Tool to Encourage Drugs for Neglected Diseases, 11 DUKE L. & TECH. REV. 390, 394 (2013).
\textsuperscript{51} With an AMC, a purchaser—commonly envisioned as one or a group of international agencies, foundations, or governments—guarantees a pharmaceutical company that they will purchase at a preset price a given quantity of an NTD treatment that company develops after the guarantee is made. See Adrian Towse & Hannah Kettler, Advance Price or Purchase Commitments to Create Markets for Treatments for Diseases of Poverty: Lessons from Three Policies, 83 BULL. WORLD HEALTH ORG. 301, 301–02 (2005).
\textsuperscript{52} Proposals for use of the prize scheme generally call for the establishment and payout of a lump sum by a prize sponsor to developers of an innovative treatment for an NTD, rather than granting them patent rights for that treatment. See, e.g., James Love & Tim Hubbard, Comment, The Big Idea: Prizes to Stimulate R&D for New Medicines, 82 CHI.-KENT L. REV. 1519, 1520 (2007). Commentators have also proposed an alternative prize scheme in which the payout a developer would receive would be scaled in proportion to the beneficial impact the new drug has. See Shamnad Basheer, Alternative Incentives for Pharmaceutical Innovation, 27 INTELL. PROP. J. 13, 34 (2014).
\textsuperscript{53} See SCHÄFERHOFF ET AL., supra note 14, at 26.
treatment or vaccine for an NTD, revenue that the beneficiaries of these products could not themselves provide.  

Apart from push and pull mechanisms, another, more ambitious proposal has been offered that would rely on the mechanisms of international law: the development and ratification of a binding international agreement on R&D into infectious diseases of poverty. This concept has been percolating within the global health community for some time, and just over a year before the beginning of the Ebola outbreak, the “Consultative Expert Working Group on Research and Development” established by the WHO recommended the adoption of a binding R&D treaty under Article 19 of the WHO Constitution, which grants the World Health Assembly the authority to “adopt conventions or agreements with respect to any matter within the competence of the [WHO].” The proposed agreement would obligate WHO Member States to devote a specific portion of their GDPs to R&D meant to meet the health-related needs of developing countries, either by scaling up domestic R&D expenditures or committing finances to a pooled international fund.

54. In the case of priority review vouchers, the downstream source is speculative rather than certain, as with the case of AMCs and prize schemes. The perceived benefit from priority review vouchers is the increased profits a drug developer may reap from being able market a drug to consumers earlier after redeeming the voucher. Additionally, the sale of a priority review voucher also provides another potential source of revenue; some evidence exists to suggest that such vouchers have significant commercial value. See, e.g., Knight Sells Priority Review Voucher to Gilead, KNIGHT THERAPEUTICS (Nov. 19, 2014), http://www.gud-knight.com/en/knight-sells-priority-review-voucher-to-gilead (sale of the voucher amounting to $125 million).


56. See Love & Hubbard, supra note 53, at 1531 (“On February 24, 2005, 162 leading scientists, academic law professors, economists, NGOs, members of parliaments, government officials and others wore the WHO Executive Board and CIPH to request that they evaluate a proposal for a New Global Medical R&D Treaty.”). Proposals for treaties aiming to meet the health needs of developing countries have been framed more ambitiously, as well. See, e.g., Gostin & Friedman, supra note 40 (proposing a "Framework Convention on Global Health" that would aim to provide, among other things, universal health coverage and increased channeling of financial resources to developing countries for the purposes of sanitation and noncommunicable disease treatments).


58. WHO CONST. art. 19.

59. See CEWG Report, supra note 58, at 17.
B. The Proposals' Upshot: Continued Neglect of NTDs

As the foregoing demonstrates, there is a wealth of scholarship devoted to remedying the scarcity of NTD R&D. Unfortunately, however, there is a comparative dearth of examples of these proposals being implemented, with PDPs being the main exception. They have proliferated since the turn of the century and include such influential global health institutions as the Medicines for Malaria Venture; the Global Alliance for Vaccines and Immunisation; and the Drugs for Neglected Diseases Initiative (DNDi). Of these, DNDi provides perhaps the best example of the potential PDPs can have in developing new treatments for NTDs, as it has helped produce four: one for Chagas disease, two for leishmaniasis, and one for Human African trypanosomiasis. Unfortunately, however, PDPs represent at best a piecemeal solution to the lack of NTD R&D, as they are too few and too underfunded to provide a complete cure for the pharmaceutical industry's inattention to these diseases.

Outside of the successes of PDPs, the picture remains bleak and NTDs still very much neglected. Pull-mechanism proposals have suffered either one of two fates: (1) not being implemented, as has been the case with innovation prize schemes; or (2) being implemented to little effect. The latter has been the fate of priority review vouchers and AMCs. Though a bill authorizing the U.S. Food and Drug Administration to grant priority review vouchers to researchers who developed an NTD treatment was passed into law in 2007, its effect on inducing NTD R&D has been quite modest, with only one voucher being

61. See Mueller-Langer, supra note 45, at 190.
62. See DNDI Treatments, DNDI, http://www.dndi.org/treatments (last visited Apr. 16, 2016). DNDi has also delivered two treatments for malaria, which, though not classified as an NTD, afflicts a similar demographic: 88% of malaria cases and 90% of malaria deaths occur in developing nations in Sub-Saharan Africa, an area to which many NTDs are endemic. See Malaria, WHO, http://www.who.int/mediacentre/factsheets/fs094/en/ (last visited Apr. 16, 2016).
63. See Morgan, supra note 42, at 100.
64. Various attempts have been made to pass "Medical Innovation Prize Fund" Acts into U.S. law, the most recent of which was helmed by U.S. Senator Bernard Sanders, but none of them have been successful. See Basheer, supra note 53, at 31 n.58.
65. See Hamming, supra note 51, at 394. The priority review voucher system for NTDs is currently codified at 21 U.S.C. § 360(n). See id. at 394 & n.25.
granted to a developer of an NTD treatment so far.\textsuperscript{66} As for AMCs, only one, for pneumococcal diseases, has ever been launched,\textsuperscript{67} and it serves as poor evidence for the claim that AMCs will serve as a stimulant: many of the vaccines that the program has delivered were already available or in late stage development at the time of the program's inception.\textsuperscript{68} Finally, reception to the notion of a binding international R&D treaty has been tepid.\textsuperscript{69} Although the World Health Assembly agreed in May 2012 to begin negotiating such a treaty,\textsuperscript{70} no agreement has been forthcoming.

Given the numerous proposals that have been advanced to resolve the issue, this continuing inertia is puzzling. But a measure of clarity may be provided by an examination of the incentives bearing on the actors whose conduct these proposals seek to influence: governments of developed states and pharmaceutical companies.

1. Developed-State Governments

Despite the recent explosion of financial assistance flowing from the developed to the developing world,\textsuperscript{71} which may suggest to some that the global health system is remarkable for its altruistic character, an element of self-interest still pervades the foreign policy choices governments of states make with respect to global health. As David Fidler observes, "states tend to be more interested in problems that directly threaten their interests, require collective action in order to minimize the threat, and involve limited, feasible interventions."\textsuperscript{72}

Such tendencies serve to explain the adoption of the IHR.\textsuperscript{73} As revised in 2005, the IHR require WHO Member States to develop their

\textsuperscript{66} See PRIORITY REVIEW VOUCHER, priorityreviewvoucher.org (last visited Apr. 19, 2016). In fairness, however, it should be noted that vouchers have been granted to developers of treatments for malaria and tuberculosis, diseases that are not classified as NTDs yet are most prevalent in locations and among demographics similar to those affected by NTDs.


\textsuperscript{68} See Basheer, supra note 53, at 53.

\textsuperscript{69} See Balasegaram et al., supra note 14, at 2.


\textsuperscript{71} Development assistance for health has witnessed an almost threefold increase since the beginning of this century, "from $10.9 billion in 2000 to $30.6 billion in 2011." SCHAFERHOFF ET AL., supra note 14, at 16.

\textsuperscript{72} Fidler, supra note 12, at 12.

\textsuperscript{73} See Harley Feldbaum & Joshua Michaud, Health Diplomacy and the Enduring Relevance of Foreign Policy Interests, PLOS MED., Apr. 2010, at 1, 4.
core capacities to detect and monitor diseases and to report outbreaks that constitute public health risks and emergencies due to their potential for cross-border transmission.\textsuperscript{74} This emphasis on the collective responsibilities of states to alert the larger political community to infectious disease threats “establish[ed] health security as a global public good.”\textsuperscript{75} But given that developed countries have generally not been the sources of infectious diseases that the IHR seek to protect against,\textsuperscript{76} and given that the IHR do not obligate developed states to provide any financial assistance to developing states attempting to build their core capacities,\textsuperscript{77} any benefits that the IHR may secure accrue mostly to developed rather than to developing states. As such, some experts have caustically described the IHR as “only an extension of age-old power politics.”\textsuperscript{78}

Similarly, this entrenched practice for states to make foreign policy choices with respect to health that directly advance or protect their interests can be seen in the character of the diseases they typically turn their attentions to. Generally, diseases that have demonstrated pandemic potential such as SARS, MERS, and H1N1 influenza have been subject to greater efforts to combat them.\textsuperscript{79} But perhaps the best example of this tendency lies in the level of attention and resources devoted to HIV/AIDS. The disease has truly a global reach, afflicting approximately 37 million people worldwide.\textsuperscript{80} Consequently, it has attracted the lion’s share of political attention and financial assistance from the developed world: Millennium Development Goal 6, adopted by the U.N. General Assembly in 2000,\textsuperscript{81} expressly made combating

\textsuperscript{74.} See NAM REPORT, supra note 13, at 24.
\textsuperscript{75.} Id.
\textsuperscript{76.} A notable exception is the 2009 H1N1 pandemic, which first arose in Mexico and then quickly spread to the United States and Canada. See Katz & Fischer, supra note 26, at 5–6.
\textsuperscript{77.} See Empowered WHO, supra note 26, at 1906 (noting that all that the IHR contain is “permissive language...requiring 'states to collaborate with each other, to the extent possible'”) (emphasis in original).
\textsuperscript{78.} Feldbaum & Michaud, supra note 74, at 4; see also Katz & Fischer, supra note 26, at 9 (“[T]he underlying global health security paradigm [established by the IHR] can be perceived . . . as an enormous obligation for developing nations assumed primarily to protect the populations of developed nations . . . .”).
HIV/AIDS a priority, and nearly 18 percent of development assistance for health is devoted to efforts toward treating the disease.

Even examples of aid provision by developed states to developing states that appear more evidently altruistic are shaded with a tinge of self-interest. As Harley Feldbaum and Joshua Michaud observe, developed states have in recent years used the provision of health aid as a "soft power" means of advancing foreign policy interests. The U.S. military is a prime example of this phenomenon. For instance, some years ago the U.S. Navy launched the hospital ships *Mercy* and *Comfort* to provide care to medically neglected populations around the world. Similarly, during antiterrorist operations in the Horn of Africa, Afghanistan, and Iraq, U.S. military personnel provided medical aid to local citizens in an attempt to secure their support for the military's efforts.

In short, while the efforts and resources of developed states have undeniably been instrumental in the progress made toward alleviating the burdens of some public health threats to developing states, such as the HIV/AIDS and malaria epidemics and maternal mortality, their efforts have not been made out of purely charitable inclinations. Rather, they serve to advance various interests of these states, including economic stability and security by averting the threat of communicable diseases, and the political legitimacy and influence that comes from providing aid to citizens of developing states.

Given these tendencies, the reasons for continued neglect of R&D into NTDs become apparent. Thus far, NTDs have generally not demonstrated themselves to be potentially as great a threat to the security of developed states as other global pandemics of the twenty-first century such as SARS, HIV/AIDS, or H1N1 influenza. Though many NTDs, such as leishmaniasis, Chagas disease, and onchocerciasis, have been known for years, they have remained largely confined to developing states, despite the ever-increasing mobility of populations.

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83. SCHÄFERHOFF ET AL., supra note 14, at 16 n.viii.
84. See Feldbaum & Michaud, supra note 74, at 2.
85. See id.; see also Fidler, supra note 12, at 6 ("U.S. aid agencies are placing greater emphasis on global health as part of . . . counterinsurgency strategies.").
86. The rates of both have decreased significantly since the adoption of the Millennium Development Goals. See SCHÄFERHOFF ET AL., supra note 14, at 17.
87. Chagas disease, for instance, claims the vast majority of its victims in Central and South America. See *Chagas Disease (American Trypanosomiasis)*, WHO, http://www.who.int/mediacentre/factsheets/fs340/en/ (last visited Apr. 19, 2016). Visceral leishmaniasis is found in a wider range of geographic areas, including South America, Africa, and Southeast Asia, but it is virtually unknown in the United States and Europe.
brought about by globalization. Even dengue, a global epidemic estimated to have infected up to 390 million people worldwide, has been projected by experts to pose virtually no risk of spreading to and reaching epidemic levels in developed states in either the Americas or the European Union. Moreover, on the few occasions that it has spread to such states, supportive treatment has generally sufficed to contain it, obviating the need for the development of any vaccine or therapeutic treatment. Thus, the direct and observable threat to the economic interests or security of developed states that generally spurs them to commit resources to combat public health problems outside their own borders is largely absent in the case of NTDs.

Moreover, while states have recently shown a greater willingness to integrate health aid into their foreign policy choices as a means of "soft power," the foregoing examples of such aid constitute aid of a different kind than investment in R&D. R&D is a costly, lengthy endeavor, with the production of a new treatment or vaccine at the end of a process not guaranteed; by contrast, the "soft power" health interventions discussed here were essentially one-off transactions involving the delivery of preexisting medical tools and services. Additionally, international health aid still generally flows to "high-visibility events . . . such as the


88. Samir Bhatt et al., The Global Distribution and Burden of Dengue, 496 NATURE 504, 504 (2013). This estimate includes patients from the Americas, Africa, Asia, and Oceania, demonstrating the wide reach of the disease. Id. at 505.

89. See id. at 506 fig.2(b).

90. For instance, Hawaii recently suffered a rather minor dengue outbreak (246 cases) that appears to have come under control, with almost all patients being reported as no longer infectious. See Dengue Fever—Hawaii Island Outbreak, HAWAII DEPT HEALTH, http://health.hawaii.gov/docd/dengue-outbreak-2015/ (last visited Feb. 2, 2016). Similarly, Europe has largely been immune. See EUR. CTR. FOR DISEASE PREVENTION & CONTROL, ANNUAL EPIDEMIOLOGICAL REPORT: EMERGING AND VECTOR-BORNE DISEASES 30 (2014), http://ecdc.europa.eu/en/publications/Publications/emerging-vector-borne-diseases_annual-epidemiological-report-2014.pdf [hereinafter DENGUE REPORT]. Though 15 of 31 countries from the European Union and the European Economic Area reported cases of dengue in 2012, the overall incidence in the bloc's population was 0.26 infections for every 100,000 persons. See id.

91. See DENGUE REPORT, supra note 90, at 33 (reporting that in the 2012–2013 dengue outbreak in the Portuguese Madeira Islands, which had over 2,000 reported cases, "[n]o severe clinical form or death was reported.").

92. PHARM. RESEARCH & MFRS. OF AM., DRUG DISCOVERY AND DEVELOPMENT 2 (2007) (stating that the drug development process can take up to fifteen years).
Asian tsunami” and “diseases that capture the public’s imagination.”93 NTDs, however, have largely been pushed out of the public eye by more noticeable health threats, such as HIV/AIDS, malaria, and tuberculosis, the subjects of Millennium Development Goal 6.94 Therefore, NTDs provide little possibility of conferring the positive publicity (and the consequent political legitimacy) on developed states that would make enactment of policies stimulating NTD R&D worthwhile.

Viewed against this backdrop, any significant contribution of resources by developed states to resolving the issue of lack of R&D into NTDs would essentially be charity. In fact, a cursory glance at the source of the financial support for the institutions most involved with what little NTD R&D there is, PDPs,95 confirms this: the majority of funding for PDPs comes from philanthropic institutions such as the Bill and Melinda Gates Foundation96 and the Wellcome Trust.97 But as states typically give with some expectation of receiving some benefit in return, proposals such as AMCs, innovation prize schemes, or a global treaty mandating R&D into infectious diseases of poverty such as NTDs are unlikely to ever gain much traction.98

The literature that grapples with stimulating R&D into NTDs, however, generally does not account for these factors. Instead, it typically advances normative arguments about why such efforts are

93. Gostin, supra note 56, at 225.
94. See Nick Feasey et al., Neglected Tropical Diseases, 93 BRIT. MED. BuLL. 179, 180 (2010).
95. See Towse et al., supra note 49, at 22 (noting that PDPs were involved in 85% of the projects for development of products for neglected diseases).
96. MARY MORAN ET AL., NEGLECTED DISEASE RESEARCH AND DEVELOPMENT: A FIVE YEAR REVIEW 99 (2012), http://www.policycures.org/downloads/GF2012_Report.pdf. It should be noted, however, that this figure includes R&D into HIV/AIDS, malaria, and tuberculosis, diseases which still are neglected relative to the number of individuals they infect but which are not classified as NTDs by the WHO. Thus, even much of the philanthropic funding for infectious disease R&D is not funneled toward NTDs. In fact, the G-Finder Report indicated that HIV/AIDS received 33.8% of all infectious disease R&D funding (whether from the public sector or philanthropic institutions), malaria 18.4%, and tuberculosis 17.3%, with only a pittance left over for NTDs such as trachoma. See id. at 10.
97. See id. at 84 (noting that the Gates Foundation and the Wellcome Trust donated 95.1% of all philanthropic funding for NTD R&D in 2011).
98. See Klock supra note 71, at 842 (“[T]reaties work well when all parties receive some incremental benefit as a result of their legal obligations to each other”, but in the case of an R&D treaty for NTDs, “only [developing countries] receive any benefit . . . [making it] unclear why industrialized countries would voluntarily incur the sovereignty costs involved” with such a treaty). Additionally, such a maneuver would represent a radical departure from the WHO’s traditional reluctance to negotiate legally binding agreements: since its inception in 1948, it has negotiated only three, the Framework Convention on Tobacco Control, the “Nomenclature Regulations,” and the IHR. See id. at 827-829.
needed, emphasizing that it is an affront to justice for a wide swath of humanity to languish in illness simply because they are too poor to pay for necessary treatments.\(^9\) While there is merit to this argument,\(^1^0\) the failure, shared by other proposals of reform of global governance, to provide any persuasive explanation as to why states would adopt these proposals\(^1^1\) risks the perpetuation of the current state of affairs: a suboptimal level of investment by developed states in R&D for NTDs.

2. Pharmaceutical Companies

The reluctance of pharmaceutical companies to undertake NTD R&D in the manner envisioned by proposals may be explained largely as a byproduct of the general disinclination of states to incorporate push and pull mechanisms into their legal regimes. After all, most push and pull mechanisms envision some outlay of government resources, yet governments have exhibited little enthusiasm for this manner of resource allocation. Moreover, given past experience, pharmaceutical companies would have reason to suspect the credibility of any ex ante government agreement to purchase NTD treatments after their development. On one previous occasion, for instance, the U.S. government failed to purchase the promised amount of seasonal flu vaccines it called for from pharmaceutical companies,\(^1^2\) and any number of political circumstances may arise in the interim period between any purchase agreement and a vaccine or treatment’s development that may prevent the necessary funds from materializing.\(^1^3\) When this is added to the fact that access to already developed vaccines and treatments is generally poor in developing

\(^9\) See, e.g., Bryan Mercurio, Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines, 5 NW. J. INT’L HUM. RTS. 1, 38 (arguing that the “developed world has a duty to ... countries suffering public health problems”, such as lack of treatments for NTDs); CEWG REPORT, supra note 58, at 30 (“While we have the technical capacity to provide access to lifesaving medicines, vaccines or other interventions, which are indeed widely available in the developed world, millions of people, including children, suffer and die in developing countries because such means are not available and accessible there. Governments around the world have recognized the force of this moral argument, but there is still a large gap between rhetoric and action.”) (quoting The Global Health Innovation Quotient Prize: A Milestone-Based Prize To Stimulate R&D For Point-Of-Care Fever Diagnostics, BIO VENTURES FOR GLOBAL HEALTH (2011), http://www.who.int/phi/news/cewg_2011/en/index.html)).

\(^1^0\) As Lawrence Gostin and Eric Friedman have written, the present system, in which “the happenstance of one’s birth [is] still the greatest determinant of health” is manifestly unjust. See Gostin & Friedman, supra note 40, at 9.

\(^1^1\) See Fidler, supra note 12, at 17.

\(^1^2\) See DALBERG GLOBAL DEV. ADVISORS, supra note 68, at 68.

\(^1^3\) See id.
countries, thereby making it uncertain that the intended beneficiaries of the products of NTD R&D would be able to secure them, the reasons underpinning the pharmaceutical industry’s continuing inertia in the area of NTD R&D seem clear. Whether Ebola will change this remains to be seen.

III. RESEARCH AND DEVELOPMENT REFORM PROPOSALS THAT EMERGED FROM THE CRISIS

As one group of commentators has written, “[p]erhaps more than any disease outbreak before it, Ebola is being widely used as a starting point for assessing the state of the global health architecture and crafting new proposals.” Below I examine reports issued by three expert panels formed in response to the Ebola crisis: the Ebola Interim Assessment Panel (EIAP), formed at the behest of the WHO; one formed in a joint effort between the Harvard Global Health Institute and the London School of Hygiene and Tropical Medicine (LSHTM); and one commissioned by the U.S. National Academy of Medicine (NAM).

A. EIAP Report

As the EIAP aptly puts it, “the Ebola outbreak demonstrated that research and development for neglected diseases remains inadequate.” However, the EIAP does not provide much further content that would help explain how an adequate level of R&D could be reached. Instead, it issues the rather vague recommendation that a “platform for the development of diagnostics, therapeutics, and vaccines must be put in place and developed to such an extent that, when there is an outbreak, much of the preparatory . . . work will have been completed and it will then be possible to move quickly to production and deployment.” Its emphasis on “outbreak” R&D does not sound a hopeful note for those hoping for increased NTD R&D after Ebola. As mentioned, outbreaks of NTDs have not yet demonstrated much ability to spread to developed states, where the vast majority of R&D capacity is located. Thus, while the EIAP writes that it believed Ebola outbreak

104. Though access is improving, delivery of treatments still remains a pressing issue. For instance, almost 40% of those in Africa infected with HIV are without access to life-saving antiretrovirals, and even simpler health interventions such as insecticide-treated mosquito nets are unavailable to 51% of the African population at risk of contracting malaria. See SCHAFERHOFF ET AL., supra note 14, at 18.
105. Id. at 31.
106. EIAP REPORT, supra note 13, at 21.
107. Id.
was “a defining moment for the health of the global community[,]”108 its report does not provide any concrete proposals on how the health of the “bottom billion”109 of that community could be better secured through R&D in the aftermath of the Ebola crisis.

B. Harvard-LSHTM Report

The Harvard-LSHTM report offers a holistic assessment of the lessons to be learned from the Ebola epidemic, recommending ten measures to take before the next global pandemic arises.110 Of these ten, one in particular is relevant for present purposes: its recommendation to “[e]stablish a global facility to finance, accelerate, and prioritise research and development.”111 According to the report, the “facility would support manufacturing, research, and development for drugs, vaccines, [and] diagnostics . . . where the commercial market does not appropriate incentives[,]”112 and would “offer the advantage of enabling coordination between different research funders through a common framework, strengthening networks between researchers, establishing processes for priority setting, and reducing transaction costs for both grantees and smaller donors.”113

This recommendation echoes prior calls for the establishment of a global health fund administered to finance R&D into infectious diseases of poverty such as NTDs.114 However, like them, it is open to the criticism that it lacks the detail necessary for its implementation.115 For instance, the report does not explicitly state where funding for this facility would come from. However, if it is expected (or hoped) to come from developed states, this recommendation suffers from the same flaws as previous proposals of ways to stimulate R&D into infectious diseases of poverty: it contains no explanation of why Ebola would reverse the

108. Id. at 5.
109. See Feasey et al., supra note 95, at 180.
110. See HARVARD-LSHTM REPORT, supra note 13, at 1–2.
111. Id. at 11.
112. Id.
113. Id.
114. See, e.g., John-Arne Rettingen et al., Securing the Public Good of Health Research and Development for Developing Countries, 90 BULL. WORLD HEALTH ORG. 398, 399 (2012) (advocating for the CEWG’s recommendation of an establishment of a pooled fund for subsidizing NTD R&D); see also Peter J. Hotez et al., A Global Fund to Fight Neglected Tropical Diseases: Is the G8 Hokkaido Toyako 2008 Summit Ready?, 2 PLOS NEGLECTED TROPICAL DISEASES 1 (2008) (“[T]here are several reasons why a Global Fund–type mechanism would satisfy an urgent need to support NTD control and elimination.”).
115. As David Fidler has written, “[b]older plans to craft a new architecture for global health governance tend to lack specifics that would give these concepts concrete form.” Fidler, supra note 12, at 16.
general trend of states offering only pittances to finance such R&D, merely stating that its recommendation is "feasible." Moreover, given the dizzying array of entities already populating the global health landscape, it is questionable whether the facility envisioned by the Harvard-LSHTM panel would be able to provide the coordination necessary for effective R&D into infectious diseases.

Additionally, the report never explains why pharmaceutical companies and other health technology developers would be motivated to compete for whatever resources that the facility may offer them, rather than simply persist in the business practices that have currently made them one of the most profitable industries in the world. Finally, while the report claims that there is a growing consensus that some sort of pooled international funding mechanism is needed, it cites for support proposals cut from the same cloth as those that have failed to be implemented before, undermining the notion that any such consensus truly exists.

C. U.S. NAM Report

Similar to the Harvard-LSHTM report, the NAM report offers a host of recommendations on measures that should be taken so as to strengthen global health governance in the future. In its report, the NAM stresses the need for a "more robust R&D strategy," given the ever-growing (and ominous) specter of infectious disease outbreaks that was demonstrated so painfully by the Ebola crisis. As the centerpiece of its strategy, it recommends that the WHO establish a "Pandemic Product Development Committee" (PPDC). The PPDC, while developed by the WHO, would function independently of it and would operate during both interim periods between outbreaks and the

116. See HARVARD-LSHTM REPORT, supra note 13, at 1.
117. See Fidler, supra note 12, at 15 ("The explosion of actors, institutions, initiatives, and funding has created an environment characterized by political competition, regime fragmentation, lack of evidence-based priority setting, wasted money, ... and normative incoherence.").
118. For instance, the ten largest pharmaceutical companies, all of which are headquartered either in the European Union or United States, can expect annual profit margins of approximately 30%. See Pharmaceutical Industry, supra note 41.
119. See Balasegaram, supra note 14, at 3. See generally REVIEW ON ANTIMICROBIAL RESISTANCE, supra note 5 (proposing a $2 billion "innovation fund" for financing new antibiotics to combat the rise of antimicrobial resistance and a "designated global body" with buy-in from states to purchase sales rights for the new antibiotics).
120. See NAM REPORT, supra note 13, at 69.
121. See id. at 70.
122. See id.
outbreaks themselves. During the interim periods, when no pressing emergency is at hand, the PPDC would coordinate efforts by a variety of global health actors to develop and manufacture treatments and products for diseases with pandemic or epidemic potential.\textsuperscript{123} And during the midst of an outbreak, the PPDC would draft an "emergency preparedness plan" coordinating the efforts of all actors willing to contribute to the mitigation of an outbreak.\textsuperscript{124} To fund its efforts, the NAM proposes that the WHO negotiate a $1 billion annual commitment from global R&D stakeholders by the end of 2016.\textsuperscript{125} Potential sources of funding, the NAM notes, were many and included direct contributions from national governments, from R&D budgets devoted to national security, and from philanthropic institutions concerned with improving global health.\textsuperscript{126}

The NAM's proposal of a facility to finance the development of infectious disease treatments and products roughly mirrors the EIAP and Harvard-LSHTM reports' proposals for a similar platform, and so suffers from some of the same defects. For instance, though it emphasizes the economic sensibility of investing in such a product development facility, noting that the World Bank has estimated that global pandemics in the twenty-first century could cost more than $6 trillion,\textsuperscript{127} it fails to provide any explanation why the Ebola epidemic would spur the global health community to take prophylactic action. Indeed, such a response would be a radical departure from the general trend of health interventions by the global health community. As David Fidler has noted, global health governance responses to public health threats such as HIV/AIDS, SARS, H1N1 influenza, and other infectious diseases have typically been retroactive rather than proactive.\textsuperscript{128} As these diseases, particularly influenza, posed an apparently greater danger to the global community than does Ebola,\textsuperscript{129} Ebola seems unlikely to serve as a catalyst for a R&D reform as revolutionary as that proposed by the NAM.

Moreover, even were the PPDC established, a few elements in its design make it somewhat doubtful that it could be effective as the NAM suggests. For instance, while the NAM proposes that the PPDC operate independently of the WHO, it is not entirely clear how this could be the

\begin{itemize}
  \item \textsuperscript{123} See id.
  \item \textsuperscript{124} See id.
  \item \textsuperscript{125} See id. at 73.
  \item \textsuperscript{126} See id.
  \item \textsuperscript{127} See id. at 18.
  \item \textsuperscript{128} See Fidler, supra note 12, at 15.
\end{itemize}
case, given that NAM envisions the WHO establishing the PPDC. Additionally, the manner in which the PPDC is proposed to be financed would likely not preserve its independent operation, a concern demonstrated by the WHO's own funding experience. The WHO's budget has decreased for years, and the majority of the funding that it does receive from is earmarked for specific purposes, undermining its ability to further what prerogatives it, rather than its donors, deems most necessary. In light of this evidence, it seems questionable whether the PPDC could truly function as an entity not beholden to its donors.

In addition, it is not at all apparent that the WHO could negotiate the funding necessary for the PPDC's establishment, given that its widely criticized performance in the Ebola debacle has brought its credibility to an all-time low. And the vast challenges of coordination that would face the facility proposed by the Harvard-LSHTM panel would also face the PPDC. But more importantly, since NTD R&D has never figured highly in the priorities of developed states, and the PPDC would represent a radical departure from the past pattern of responses to infectious disease pandemics, its establishment is improbable.

IV. MOVING FORWARD: WILL EBOLA SERVE TO MAKE SUPPORT FOR RESEARCH AND DEVELOPMENT REFORM GO VIRAL?

As these reports indicate, the devastation that Ebola caused in West Africa has given rise to the notion that some change must occur, including in the arena of R&D into infectious diseases of poverty, where pharmaceutical companies and states have been virtual noncontestants for years. But due to the particular facts of the Ebola outbreak, such an outcome seems unlikely. As mentioned above, the most recent Ebola outbreak was preceded by more than two dozen others, none of which ever assumed the present's breathtaking scale. Yet there, too, there was no approved treatment or vaccine for Ebola, suggesting that the failures of global health governance that contributed most to the disastrous consequences in Sierra Leone, Guinea, and Liberia had little to do with R&D. This, indeed, is indicated by the assessments of the three panels and other experts evaluating the Ebola crisis. In them, two

130. See SCHÄFERHOFF ET AL., supra note 14, at 23.
132. In fact, the R&D portion of the response to Ebola appears to be one of the few areas in which the response is deemed to have been somewhat successful. See EIAP REPORT, supra note 13, at 21 (commending WHO for its efforts in fast-tracking vaccine candidate trials); see also HARVARD-LSHTM REPORT, supra note 13, at 10 ("In several instances, WHO proved its capacity to lead, convene, coordinate, and establish norms among a broad range of public and private actors on research and development . . . ").
factors explaining the outbreak's extent are repeatedly emphasized: first, the failure of Sierra Leone, Guinea, and Liberia to develop their core capacities as mandated by the IHR, a failure that allowed Ebola to spread undetected and unimpeded; and second, the failure of the global health community to promptly provide support for the three countries once the dire nature of the outbreak became known.

The failure of states to comply with the IHR's demand that states develop their capabilities to detect, control, and report infectious diseases that threaten to spread beyond their borders has been widely documented in the aftermath of the Ebola epidemic. The EIAP report, for instance, lamented the great number of states that had not achieved the core capacities mandated by the IHR, and as Dr. Charles Clift writes, "[t]he failure to detect and report the outbreak in Guinea early enough and the fact that the initial response, once it was reported, was not robust were principal reasons why the outbreak spread to Liberia and Sierra Leone and the capital cities in all three countries." Given this consensus, one may expect any tangible reform to emerge from the Ebola epidemic to be tailored more toward support for capacity-building than infectious disease R&D. Indeed, some evidence already exists that suggests that this may be the case: those concrete financial commitments that have emerged to date (not including those directly focused on containing the outbreak) have focused on capacity-building rather than R&D.

Additionally, the "epidemic of legal non-compliance" with the IHR during the Ebola epidemic included numerous instances of states imposing quarantines and restrictions on the delivery of vital aid (whether that aid took the form of health personnel or medical equipment) to Sierra Leone, Guinea, and Liberia, without scientific justification as required by the Regulations.

133. The EIAP, for instance, devoted wholly a third of its report to detailing the ways in which the IHR were violated and how they should be amended so as to avoid this in the future. See EIAP REPORT, supra note 13, at 10–14.

134. See id. at 5 ("[S]ignificant and unjustifiable delays occurred . . . "); see also HARVARD-LSHTM REPORT, supra note 13, at 4 ("[T]he operational response commenced slowly . . . "); NAM REPORT, supra note 13, at 9 ("[A]fter the outbreak was recognized, the international response was slow and uncoordinated.").

135. By November 2014, 81 states were not in compliance, while 48 did not inform WHO of their compliance status. See EIAP REPORT, supra note 13, at 10.


137. For instance, the United States has pledged $1 billion to support the building of core capacities in 30 developing states, including those most affected by the Ebola outbreak. See HARVARD-LSHTM REPORT, supra note 13, at 5.

138. See International Health Regulations, supra note 26, at art. 43, para. 2.
weak health systems of the affected countries, allowing Ebola to spread mostly unimpeded. Yet had states been more willing to keep their channels of trade open and the global community more willing to intervene sooner, the situation likely would have been far less dire, as Ebola's method of transmission (through direct contact with bodily fluids) makes it easy to contain relative to other infectious diseases even without any therapeutic treatments. Thus, though the lack of an approved treatment or vaccine for Ebola certainly increased the burden the disease imposed, it is difficult to say that this lack was the most noteworthy failure that the epidemic uncovered. As such, the crisis seems unlikely to be a watershed event in global health governance with respect to NTD R&D.

Moreover, though the scale of the Ebola epidemic was devastating, it failed to reach the far more dire dimensions that some experts predicted that it could. Perversely, then, its containment may perhaps be viewed by developed states as confirmation that the current model of "limited, feasible interventions" suffices to address the issue of infectious diseases of poverty. But even if it is not so viewed, the Ebola epidemic's toll pales in comparison to the number of victims claimed yearly by other infectious diseases such as malaria, tuberculosis, and dengue. As none of these diseases have spurred any meaningful change to the current health R&D framework, it seems somewhat doubtful that the Ebola epidemic will have a contrary effect.

Even the manner in which the highly effective vaccine, Merck's rVSV-ZEBOV, came about suggests that no momentum toward increased NTD R&D predated the Ebola outbreak, momentum that the outbreak could have augmented. Instead, rVSV-ZEBOV's development is rather more an example of a fortunate convergence of developed-state research efforts and developing-state need. The discovery of rVSV-ZEBOV's effectiveness against Ebola arose not from concern for the

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139. See HARVARD-LSHTM REPORT, supra note 13, at 4 ("[P]ublic . . . restrictions on trade and travel further harmed an already suffering region and hindered control efforts.").


141. For instance, at one point during the outbreak the U.S. Centers for Disease Control projected that the number of cases could potentially reach 550,000. See Roache et al., supra note 3, at 3.

142. See Fidler, supra note 12, at 12.


safety of the African populations most at risk of contracting the disease, but rather out of a concern by researchers in developed states that the virus could be used as a bioterrorism agent against North American populations.\textsuperscript{145}

Moreover, contemporary global crises and trends in global health make it unlikely that any appreciable increase in NTD R&D will come about as a result of the Ebola outbreak. Years ago, David Fidler predicted that political attention to global health would dwindle due to the rise of other high-profile crises requiring collective action, such as global terrorism and climate change.\textsuperscript{146} With the ever-expanding influence of terrorist groups such as the Islamic State and the recent adoption of the Paris Agreement on climate change,\textsuperscript{147} such an assessment seems to have been accurate. Additionally, the rising incidence of noncommunicable diseases such as cancer and heart disease\textsuperscript{148} provides one more reason to think that the Ebola epidemic will not spark any appreciably greater R&D into NTDs. Pharmaceutical R&D has tracked the rise in noncommunicable diseases,\textsuperscript{149} as has WHO priority-setting.\textsuperscript{150} Greater commitment to NTD R&D, then, would represent a commitment to a problem that some in the global health community view as having been eclipsed in importance by other pressing issues. And while Ebola has brought greater attention to the problem of infectious diseases, it is likely that this attention will diffuse in time, as has been the case with past, more dangerous, pandemics.\textsuperscript{151}

In short, the rapid spread of the Ebola epidemic was more attributable to factors other than a lack of R&D; it was of a relatively small size in comparison to other infectious disease epidemics that have failed to stimulate a greater commitment to NTD R&D; developed states continue to invest in infectious disease R&D only insofar as it protects their security priorities; the rise of high-profile issues such as global terrorism and climate change has commandeered high-level political attention; and the shift in the global disease burden has shifted to

\textsuperscript{145} See Rosenberg, supra note 36.
\textsuperscript{146} See Fidler, supra note 12, at 19.
\textsuperscript{148} See \textsc{Schaferhoff et al.}, supra note 14, at 18.
\textsuperscript{149} See Stephens & Leufkens, supra note 43, at 6 (pointing out that 85% of all medical conditions being investigated by pharmaceutical companies are noncommunicable conditions).
\textsuperscript{150} See Fidler, supra note 130, at 1888 (arguing that the WHO has downgraded the importance of the public health threat posed by infectious diseases and chosen instead to focus its recent efforts on addressing noncommunicable diseases).
\textsuperscript{151} See id. at 1889.
noncommunicable conditions from infectious diseases. For these reasons, R&D into NTDs will likely continue to progress at minimal levels, notwithstanding the awful damage that Ebola demonstrated that such infectious diseases can inflict.

CONCLUSION

David Quammen best summarized the lesson to be drawn from the Ebola outbreak:

[W]hat we should recognize, what we should remember, is that the events in West Africa . . . tell us not just about the ugly facts of Ebola's transmissibility and lethality; they tell us also about the ugly facts of poverty, inadequate health care, political dysfunction . . . and of neglectful disregard of those circumstances over time by the international community.152

They do indeed. Ebola and similar diseases, such as NTDs, have not suddenly ambushed a world previously unaware of their existence. They have remained neglected for years because they afflict remote and impoverished populations in locations far afield from where the bulk of the world's R&D capacity resides. Because there is little political incentive for developed states to make up for this shortfall, they continue to exact a heavy human toll. The current spread of the Zika virus through the Caribbean and Central and South America is simply the most recent example of this phenomenon, as the virus was first identified in Uganda in 1947, yet its true effects remain largely a mystery to scientists.153

Ebola was a disaster that demonstrated the many weaknesses of global health governance: the WHO's abdication of its role as the guardian of global health, the failure of the community of states to fulfill its obligations under international health law, and the persistent neglect of diseases that disproportionately affect impoverished

152. See QUAMMEN, supra note 4, at 110.
153. See Donald G. McNeil et al., Short Answers to Hard Questions About Zika Virus, N.Y. TIMES, http://www.nytimes.com/interactive/2016/health/what-is-zika-virus.html (last updated Feb. 24, 2016). Due to the virus' relatively mild symptoms and the fact that its role, if any, in causing microcephaly (abnormally small heads and brain damage) in the infants of infected pregnant women is unclear, the lack of focus on Zika may be more understandable than the lack of attention to NTDs. See id. However, perhaps so as to avoid a repeat of the Ebola debacle, the WHO has declared the Zika outbreak a public health emergency of international concern. See id.
populations. But as this Note has attempted to show, this last phenomenon is unlikely to change appreciably in response to the Ebola epidemic. Other epidemics, some more deadly than Ebola, have come and gone without inducing a greater level of NTD R&D, and due to the particular circumstances of the Ebola epidemic, there is little reason to believe that it will provoke a different response.

Nonetheless, the sheer amount of attention that Ebola has received, evident in the number of panels formed to consider it and the immense outpouring of resources from the global community to contain the disease, allows for some measure of hope. Financial commitments to aid in the development of core capacities required by the IHR have quickly materialized in the wake of the epidemic. With external support, developing states may be able to construct public health systems better capable of responding to infectious disease threats such as Ebola and NTDs like it, hopefully protecting against “the creation of a permanent global health underclass of poor and marginalized people.”¹⁵⁴ But as with the accuracy of this Note’s prediction on the future of infectious disease R&D, this remains to be seen.

¹⁵⁴ See Gostin & Friedman, supra note 40, at 19.