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# The race for Ebola drugs: pharmaceuticals, security and global health governance

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## ABSTRACT

The international Ebola response mirrors two broader trends in global health governance: (1) the framing of infectious disease outbreaks as a security threat; and (2) a tendency to respond by providing medicines and vaccines. This article identifies three mechanisms that interlink these trends. First, securitisation encourages technological policy responses. Second, it creates an exceptional political space in which pharmaceutical development can be freed from constraints. Third, it creates an institutional architecture that facilitates pharmaceutical policy responses. The ways in which the securitisation of health reinforces pharmaceutical policy strategies must, the article concludes, be included in ongoing efforts to evaluate them normatively and politically.

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## Introduction

Reflecting on the past two decades of global health governance, scholars highlight two major trends – especially in relation to lethal infectious disease outbreaks. First, there is a growing political tendency to frame such outbreaks as security threats. Driven by concerns about emerging and re-emerging infectious diseases, drug-resistant strains of known diseases and the proliferation of biological weapons, health threats are argued to have an impact on national and international security. The stated reasons for this include the fact that high levels of morbidity and mortality can affect the operations of the state, disturb the global economy by interrupting travel and trade, and threaten military operations. Beginning in the 1980s in the USA, the discourse on ‘health security’ was soon picked up by other governments, notably in Australia, Canada and Western Europe, as well as by international organisations, including the World Health Organization (WHO). In response to these events the framing of health as a security issue has become an important field of study, with scholars analysing the processes through which health issues are ‘securitised’, the extent to which this trend is normatively and politically desirable and – more recently – the complex interplay between dynamics of securitisation and de-securitisation in global health policy.

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That notable trend towards securitisation in global health governance has also been accompanied by a second one – a growing recourse by policy makers to pharmaceutical responses and solutions in managing such global health issues. This second trend largely centres on the provision of medicines and vaccines as a key instrument of global health governance. Thus increasing the availability of – and international access to – pharmaceuticals is now a core mandate of many of the global health institutions that have emerged in the past 25 years. These include the US president's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, Tuberculosis and Malaria, GAVI, more than two dozen product development partnerships, the WHO Prequalification Programme, and the WHO Global Pandemic Influenza Action Plan.

At the national level, furthermore, the USA has taken the lead by creating the so-called Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which promotes the development and national procurement of medicines and vaccines against health-based threats.<sup>1</sup> Other governments, notably from Australia, Canada, various European countries and Japan, have followed suit and created their own policy frameworks on health security, which include measures to facilitate the use of medicines and vaccines to counter global health security threats. This growing emphasis on pharmaceutical response strategies means that global health policy is today not just a site of securitisation alone, but simultaneously a site of 'pharmaceuticalisation' as well.

The twin trends towards securitisation and pharmaceuticalisation in global health governance are now becoming increasingly well understood in their own terms, with separate groups of scholars exploring each trend respectively. What has so far escaped scholarly attention, however, is how these two pivotal dynamics are also profoundly interlinked in practice, and indeed tend to reinforce one another. This lacuna is the result, in part, of the fact that the scholarship on securitisation and pharmaceuticalisation has different disciplinary origins and roots, with scholars in both fields tending to work independently of one another. At the risk of oversimplifying, scholars of securitisation have simply not paid much attention to the growing role pharmaceuticals now play in global health policy, while scholars of pharmaceuticalisation in turn have not focused on recent developments in security policy and the rise of health security. Against that backdrop, this article undertakes the first analysis of how the dual processes of securitisation and pharmaceuticalisation are linked in contemporary global health governance. In particular, the article examines whether the securitisation of health issues promotes or facilitates pharmaceutical responses to infectious disease outbreaks, and – if so – how.

The international response to the recent Ebola outbreak in West Africa emerges as a critical site for carrying out such an analysis. As the article will show at the outset, the dynamics of both securitisation and pharmaceuticalisation have been pervasive in the international response to the recent Ebola outbreak. Efforts to respond to the outbreak mobilised a number of securitisation strategies, while at the same time also being an important site for the development of new pharmaceutical strategies for responding to the Ebola outbreak. Based on a detailed analysis of the international response, the article then goes on to identify three ways in which securitisation processes tend to facilitate pharmaceutical responses to infectious disease outbreaks. First, we argue, securitisation encourages technological policy responses, which in the field of global health policy tend to give pharmaceutical strategies greater salience. Second, securitisation also creates an exceptional political space in which the development, approval and administration of new pharmaceutical interventions can

be freed from many constraints. Third, the framing of health as a security issue over the past two decades has created a set of policies and legal institutions that facilitate the use of pharmaceuticals as a key instrument of global health policy. These ways in which the securitisation of infectious diseases reinforces pharmaceutical policy responses in global health governance must, the article concludes, be included in the ongoing process of their normative and political evaluation.

### Déjà Vu: Ebola as the latest securitisation of infectious disease

On 8 August 2014 WHO declared the Ebola outbreak a Public Health Emergency of International Concern. The Emergency Committee convened by WHO under the International Health Regulations (2005) advised that heads of states with Ebola transmission 'should declare a national emergency,'<sup>2</sup> something several countries in West Africa did in the following weeks, including the worst affected countries – Sierra Leone, Liberia and Guinea – but also Nigeria, where only 19 people would become infected overall. Liberia and Sierra Leone also used military units to enforce quarantines and suppress riots.

The language of security was also employed by political leaders outside the immediately affected region. On 7 September US President Obama called the outbreak a 'national security priority';<sup>3</sup> shortly afterwards he announced plans to send 3000 military personnel into the region. In the following weeks China, France and the UK similarly announced the deployment of military personnel and equipment to West Africa. Even NGOs such as Médecins Sans Frontières and Oxfam, usually critical of military intervention, could see no other way forward than calling for the deployment of military medical capability. Importantly the United Nations Security Council declared on 18 September 2014 that the Ebola outbreak constituted 'a threat to international peace and security.'<sup>4</sup>

The securitisation of the international Ebola response is consistent with a much longer trend in global health governance. In fact, the rapid expansion of security agendas to incorporate health-based threats has received extensive scholarly attention.<sup>5</sup> The framing of global health as an issue of security has mostly been analysed through the lens of securitisation theory,<sup>6</sup> which uses the insights of speech act theory to analyse security issues.<sup>7</sup> Specifically securitisation theory analyses what effects it has when an issue is framed as a security threat. The theory emphasises that 'language can [...] do much more than just convey information' and 'constitute a form of action or social activity.'<sup>8</sup> Securitising an issue, in other words, means more than saying something, it *does* something.

Existing scholarly literature on securitisation in the field of global health has highlighted some of the political effects of securitisation processes on policy priorities, policy procedures and even the institutional structure of global health governance.<sup>9</sup> Furthermore, that scholarship has explored the extent to which the securitisation of infectious diseases is politically desirable, ie whether the trend towards securitisation should be encouraged.<sup>10</sup> More recently it has also begun to analyse the interplay between dynamics of securitisation and de-securitisation in the area of global health policy.<sup>11</sup> Viewed against the background of this growing body of scholarship, the international response to Ebola emerges as the most recent manifestation of the securitisation of global health, and as one consistent with a longer history of securitising infectious diseases already seen in the cases of HIV/AIDS, SARS and pandemic flu. In the case of Ebola, however, that is only part of the story.

## Where are the drugs and vaccines? The pharmaceutical response to Ebola

The international response to Ebola is also consistent with a second major trend in global health governance – the growing recourse to pharmaceutical logics and responses in global health policy. Thus, and in parallel to framing the Ebola outbreak as a security issue, an international pharmaceutical response also began to unfold rapidly. On 11 August, only three days after WHO had declared a Public Health Emergency of International Concern, the Organisation convened a meeting to decide whether it would be ethical to treat Ebola patients with experimental drug compounds that had never been tested in humans. Given the disease's high mortality rate, the meeting concluded that it was.<sup>12</sup> Now the race was on among governments, companies and nongovernmental organisations to find a pharmaceutical solution to the Ebola outbreak.

A further WHO meeting held in early September then agreed on a list of experimental drugs and vaccines whose development should be prioritised.<sup>13</sup> Funding for taking things forward was provided by a range of organisations – including national governments, research councils, philanthropic organisations and partnerships for financing health development.<sup>14</sup> To plan and coordinate clinical trials in Africa, Europe and the USA, new public–private partnerships, spanning organisations from several countries, were created.<sup>15</sup> Yet further efforts went into creating the regulatory pathways necessary for the accelerated development of new drugs and vaccines. Rules and standards were discussed for how to run clinical trials in emergency situations and how to harmonise regulation for the approval of clinical trials and end products internationally to enable simultaneous development and distribution of new drugs and vaccines.

In some respects this intense focus on a pharmaceutical response is puzzling, because it seemed highly unlikely that any of these drugs and vaccines could actually be used in the outbreak.<sup>16</sup> All of them were in the very early stages of development, and even the most optimistic forecasts did not envisage that they would become available for widespread use during the outbreak. Moreover, many public health experts pointed out that contact tracing and isolation had been the key methods of success in the containment of previous outbreaks – leading to the question of why – largely unavailable – drugs and vaccines attracted so much attention in the latest Ebola outbreak.

This intense focus on pharmaceutical strategies means that the international response to Ebola has not just been a site of securitisation, but also one of pharmaceuticalisation. The international Ebola response, in other words, shows evidence not just of a proliferation of security logics, but also points towards an intensification – and indeed international expansion – of pharmaceutical logics, rationalities and interventions in global health policy. The pharmaceuticalisation in global health governance has not received nearly as much attention in the scholarly literature as the securitisation phenomenon. However, an emerging literature is now beginning to capture and analyse this phenomenon. For example, Elbe et al show that the securitisation of health has 'intensified government interest in acquiring pharmaceutical defenses for their populations'.<sup>17</sup> The key role pharmaceuticals have come to play as a policy instrument in global health security<sup>18</sup> – and in global health governance more widely<sup>19</sup> – has been explored mainly through the conceptual lens of 'pharmaceuticalisation'.

This concept was first developed by scholars from sociology and anthropology, who observed an increase in recourse to pharmaceutical products in various areas of social life and who analyse these dynamics and their drivers and implications.<sup>20</sup> The literature has

postulated a number of potential drivers of pharmaceuticalisation. For example, scientific and technological advances in biomedicine are identified as an important factor, because they enable novel pharmaceutical products to be developed.<sup>21</sup> The sheer possibility that exists today of addressing health problems through pharmaceutical products that were not available previously has helped propel drugs and vaccines to the top of the health policy agenda. Second, Peter Conrad also argues that a broader 'medicalization of existence' is a relevant driver of pharmaceuticalisation because it encourages a tendency to address complex issues through recourse to pharmaceutical therapies.<sup>22</sup> Finally, several studies have emphasised that marketing and direct-to-consumer advertising by pharmaceutical companies can increase the societal penetration of pharmaceutical products.<sup>23</sup>

Some of this scholarship on pharmaceuticalisation even looks directly at how various *political* factors can contribute to pharmaceuticalisation processes. Williams et al and Abraham highlight the role of expedited approaches to the approval of pharmaceuticals pursued by some government regulatory agencies, and how this is making more pharmaceuticals available.<sup>24</sup> Elbe et al also show how national governments, international organisations, philanthropic organisations and cross-sectoral partnerships have facilitated the use of pharmaceuticals in global health policy by providing financial and regulatory incentives to encourage pharmaceutical companies to invest in the development of pharmaceuticals for which limited commercial opportunities exist.<sup>25</sup> In a different article Elbe and his colleagues looked beyond specific policy and regulatory incentives to analyse the underlying rationalities of political rule within which pharmaceuticals have emerged as such attractive policy instruments. Drawing on Michel Foucault's notion of a 'crisis of circulation', they argue that pharmaceuticals are such an attractive policy option because they allow for the rapid interception of 'bad' and, in this case, pathogenic systems of circulation without disrupting the 'good' circulatory systems that are deemed critical for maintaining population welfare, such as mobility, commerce and trade.<sup>26</sup>

Notwithstanding this interest in the political drivers of pharmaceuticalisation, however, neither scholars of securitisation nor those of pharmaceuticalisation have so far been able to capture and analyse how these two parallel dynamics are interlinked in practice. Do securitisation processes tend to favour pharmaceutical responses to infectious diseases outbreaks? If so, what are the principal mechanisms or trajectories along which they do this? Focusing specifically on the analysis of the international Ebola response, we identify three such underlying mechanisms linking the framing of health as a security problem with a policy response focused on pharmaceuticals: (1) provoking a greater impetus for technological policy solutions; (2) creating an exceptional political space where the processes of pharmaceutical development, approval and administration can be freed from many constraints; and (3) creating a lasting institutional architecture that facilitates the recourse to pharmaceuticals as a key instrument of global health policy.

### Searching for a quick fix: the race for technological solutions

In the first instance securitisation processes tend to encourage 'quick-fix' and therefore often technologically driven responses. As has been widely noted by securitisation theorists, processes of securitisation invoke a sense of imminent danger. Buzan and Waever point out more generally that 'a security issue is posited (by a securitising actor) as a threat to the survival of some referent object (national, state, the liberal economic order, the rain forests), which

is claimed to have a right to survive...a question of survival necessarily involves a point of no return at which it will be too late to act'.<sup>27</sup> In other words, the process of securitisation promotes the perception of an immediate, potentially irreversible danger that creates a perceived need for rapid response. In a situation perceived as an emergency alternative policy options, such as a long-term engagement with complex socioeconomic issues and political negotiations, for instance, appear less suitable. Demand increases for a quick fix to avert the imminent danger.

That securitisation processes privilege certain policy pathways over others has already been noted in the literature. Nunes argues that 'framing issues as threats to security entails the establishment of a political modality for dealing with them'.<sup>28</sup> Craig Calhoun highlights the rise of emergency as a mode of justification for urgent global intervention.<sup>29</sup> Such emergency interventions, he argues, are short-term and focus on mitigating a temporally circumscribed event. Although the field of health was not one of the initial sectors studied by early securitisation theorists, there is evidence that this effect takes place in global health policy as well. There, too, securitisation processes have promoted such an emergency mode of governance or, as Weir and Mykhalovskiy put it, a 'World on Alert'.<sup>30</sup> Indeed, Stephen Collier and Andrew Lakoff argue that the securitisation of health has fostered an 'emergency modality of intervention'.<sup>31</sup> In addition to creating a sense of urgency and emergency, they also show that the securitisation of global health has promoted interventionist policy responses. More specifically it has promoted interventions that can be launched rapidly and are applicable in different contexts by using standardised protocols and technologies. In that sense, the field of global health remains consistent with the broader findings of securitisation theory.

The need, then, to rapidly intervene and urgently stop the threat is one way in which securitisation processes tend to emphasise technological responses in the area of global health – rather than encouraging longer-term strategies of dealing with underlying socioeconomic and political drivers. It is, however, not the only the reason. For, in the field of global health policy, such interventionist policies are particularly difficult to implement because the source of the threat is often located in other countries. As McInnes points out, the link between health and security has been 'generally cast in terms of a response to exogenous developments, that new risks have emerged and have acquired added salience in the context of accelerated globalization'.<sup>32</sup> Increasing economic interconnectedness, the accelerated mobility of people and goods, and international military operations have played a crucial role in the construction of health as a security issue.<sup>33</sup> Indeed, even the first international conferences linking health and security were driven by states' concerns about cross-border disease spread that was caused by and would create problems for the growing international traffic of goods and persons.<sup>34</sup> Given that the problem of health security is perceived as 'global', an effective response has to be global too.

Yet the problem with implementing interventionist policies on a global scale is that they create particular political sensitivities with regard to national sovereignty. In the field of global health security this has been observed in particular with regard to developing countries. Several studies have pointed out that the security interests behind the securitisation of global health are mainly those of governments in North America and Western Europe, while the origin of the problem is considered to reside largely in the developing world.<sup>35</sup> When an infectious disease becomes securitised, there is thus a tension between the perceived need for rapid intervention across countries, on the one hand, and a legal-political world order that is still largely based on the principle of national sovereignty, on the other.

Technological solutions become particularly attractive in this context not only because they are hoped to work rapidly, but because they may appear politically more neutral, minimising the risk of difficult political confrontations. In this political context there is a turn towards technological measures, such as 'medical response, standardized protocols for managing global health crises, surveillance and reporting systems, or simple technological fixes like mosquito nets or drugs'.<sup>36</sup> Even a cursory glance at the global health governance architecture that has emerged in the past 20 years reveals a plethora of institutions providing technological health interventions. In the field of global health this impetus for technological solutions is certainly not confined to pharmaceuticals. Surveillance systems, for example, are another prominent technological response. Such disease surveillance systems have been established and expanded at both at the national level and international levels.<sup>37</sup>

However, if pharmaceuticals are clearly not the only technological response, they remain a highly significant one. Indeed, policies and institutions to promote the international provision of pharmaceuticals have proliferated in the past 15 years. Prominent examples include the Global Fund to Fight AIDS, Tuberculosis and Malaria, GAVI, the WHO Prequalification Programme (to serve as an international reference point for good-quality medicines and vaccines), the WHO Global Pandemic Influenza Action Plan (to increase the supply of vaccines), the Directly Observed Treatment, Short-Course (DOTS) programme at the heart of WHO's Stop TB Strategy, and a range of cross-sectoral partnerships for the development of new pharmaceuticals, such as Aeras, DNDi, the Medicines for Malaria Venture, PATH and the TB Alliance, to name but a few.

Technological interventions are an attractive policy instrument not only because they promise a quick-fix and a politically more neutral solution but also because such interventions can immensely reduce 'the scale of intervention, from global political economy to laboratory investigation and information management'.<sup>38</sup> For governments in North America and Western Europe, in particular, it is much easier to mobilise resources and domestic political support for interventions that seemingly focus on a precise target in a circumscribed event with direct security relevance for domestic populations, rather than for long-term engagement with complex socioeconomic problems whose domestic relevance is uncertain.

Such a process was also evident in the international response to the Ebola outbreak in West Africa. The portrayal of the epidemic as a security threat invoked the sense of imminent danger and perceived need for rapid action that Buzan and Weaver have pointed out. Specifically the securitisation of the outbreak created a focus on containment and control strategies, which privileged a policy pathway based on rapid, largely technological interventions to enhance surveillance, diagnosis and treatment.<sup>39</sup> Technologies provided by the international community included laboratories and treatment centres, infection and prevention control capacity, personal protective equipment, and diagnostics. Furthermore, governments – especially those in the USA and Europe – WHO and several NGOs emphasised the development of new medicines and vaccines as an important element of outbreak containment and control. It was suggested that 'the window of opportunity for containing the epidemic, using "classical" control tools was closing',<sup>40</sup> and that new medicines and vaccines would both 'dramatically strengthen the ability to counter the disease' and 'act as an insurance policy against future outbreaks'.<sup>41</sup> As described elsewhere in this article, measures to accelerate the development of new pharmaceuticals were among the first steps taken after the Ebola outbreak had been declared a Public Health Emergency of International Concern, and several hundred million US dollars were mobilised in the following months.



The Ebola outbreak in West Africa illustrates once more how the securitisation of a health issue can contribute to a pathway of policies that focus on technological – and often pharmaceutical – fixes, rather than encouraging a more long-term approach that deals with the socioeconomic and political determinants of the problem. The Ebola crisis emerged in the context of stark inequalities – both local and global – and has been interpreted as a manifestation of ‘structural violence’.<sup>42</sup> The international community has accepted that structural factors such as weak national health systems have contributed to the crisis, and committed to strengthening health systems in developing countries. Yet this commitment has so far focused on technical capacity building, while neglecting the political and socioeconomic context that has brought about those weaknesses. Almost two years after the beginning of the outbreak, long-term approaches to ‘fixing’ some of the structural conditions in which the crisis emerged are yet to take a prominent place in the international Ebola response.

### Exceptions: extraordinary measures for pharmaceutical innovation

Securitisation processes create space ‘to use extraordinary means or break normal rules for reasons of security’.<sup>43</sup> The use of extraordinary measures in the context of health security has already received much attention in the literature. Some scholars have noted that the securitisation of health has contributed to the extraordinary mobilisation of money, resources and political commitment.<sup>44</sup> Nevertheless, the space created for extraordinary measures can also be used to weaken civil liberties, human rights and democratic procedures.<sup>45</sup> In the Ebola outbreak three such exceptional measures have been critical for the pharmaceutical response: extraordinary amounts of funding were mobilised to promote the development of Ebola drugs and vaccines, experimental medicines that had never been tested in humans were given to Ebola patients, and candidate drugs and vaccines were rushed into clinical trials.

First, in recognition of the threat that some infectious diseases also pose to security, governments have mobilised enormous financial resources for the development of medicines and vaccines. In the first six months of the international Ebola response, the USA alone authorised more than \$500 million to support accelerated development and manufacture, ‘in keeping with the President’s charge that we tackle Ebola as a national security priority’.<sup>46</sup> The largest UK medical science funding organisation, the Wellcome Trust, provided £3.2 million to fund a clinical trial consortium to tackle ‘one of the most virulent infectious agents known to man, [which] has been declared a threat to international peace and security’.<sup>47</sup> The EU Innovative Medicines Initiative provided €215 million to fund eight vaccine development projects for the Ebola ‘emergency’;<sup>48</sup> and GAVI pledged to provide \$300 million to purchase up to an estimated 12 million doses of a vaccine once it was ready and recommended by WHO.<sup>49</sup>

Moreover, most of the drugs and vaccines that were rushed into clinical development had already benefitted from health security funding released in the aftermath of the terrorist attacks in the USA in 2001. The pharmaceutical response to the Ebola outbreak, therefore, came against the background of governments mobilising much larger sums of funding over the past 15 years to encourage the development of new medicines and vaccines against a range of health security threats. For example, the US government had provided \$5.6 billion for the purchase and stockpiling of medicines and vaccines against diseases considered a health security threat through the Project Bioshield Act in 2004.<sup>50</sup> Before that the US Congress had already increased the bio-defence budget of the US National Institutes of Health (NIH) from \$53 million in 2001 to \$1.7 billion in 2005, although NIH funding essentially flat between

2004 and 2014.<sup>51</sup> PEPFAR has been provided with some \$60 billion since 2003,<sup>52</sup> while \$7.5 billion was pledged to GAVI in 2015.<sup>53</sup> In the name of security, therefore, governments have increasingly intervened in the play of normal market forces – which control the development of routine medicines and vaccines – and have channelled public funds into programmes for the development and procurement of pharmaceuticals against perceived health security threats.

Second, the sense of urgency created by framing the Ebola outbreak as a security threat created exceptional policy space to facilitate the use of drugs that had never been tested in humans. At a very early stage in the international Ebola response, at the 11 August WHO meeting, a consensus was ‘reached... that it is ethical to offer unproven interventions with as yet unknown efficacy and adverse effects, as potential treatment or prevention.’<sup>54</sup> Moreover, WHO, the US government, researchers and funding bodies urged national regulators to consider new regulation on how to approve experimental drugs and vaccines.<sup>55</sup> Regulation on the use of experimental drugs beyond the area of research exists only in a few countries, such as in Europe and the USA, which allow for the use of unapproved pharmaceuticals in emergency situations. Under normal circumstances the rules governing the use of new drugs and vaccines require their extensive testing in humans in lengthy clinical trials. There are several reasons for this. Only about 10% of drugs and vaccines that show promising results in the laboratory and animal studies are found to be safe and effective in humans.<sup>56</sup> Giving experimental drugs and vaccines to patients may therefore cause severe health damage. Furthermore, doing so can be a waste of resources if it deflects attention from other, potentially more effective interventions. Finally, giving experimental drugs to patients outside clinical trials can compromise the systematic collection of data about their effects. Yet, in the weeks following the WHO meeting, several patients received experimental treatments in Europe, Liberia and the USA. Most patients received one or more experimental drug – including brincidofovir, convalescent blood and plasma, favipiravir, TKM-Ebola and ZMapp.<sup>57</sup> That use of experimental treatments in Ebola patients led to both extensive public attention being paid to the new ‘miracle drugs’ and to considerable controversy about the use of experimental drugs for Ebola.<sup>58</sup>

Third, the emergency environment around Ebola created exceptional possibilities for exploring how the development and distribution of medicines and vaccines could be accelerated – even before their efficacy and safety was fully understood. A series of meetings and teleconferences was held at WHO on how to speed up clinical development, including unblocking some of the ethical, financial and regulatory issues involved.<sup>59</sup> According to WHO, the discussions were characterised by ‘a high sense of urgency.’<sup>60</sup> Indeed, almost all available meeting documents make reference to the emergency nature of the situation, to the fact that it was ‘unprecedented in scale and geographical distribution,’<sup>61</sup> to the ‘escalating scale and mortality of the outbreak,’<sup>62</sup> and to the need for ‘immediate action.’<sup>63</sup>

The key question was how to accelerate to only a few months a process that would usually take several years. One idea was that, rather than running the different stages of drug development – such as designing clinical studies, applying for ethical and regulatory review, conducting the studies, licensure and distribution – sequentially, they had to be done largely in parallel.<sup>64</sup> This required the rapid mobilisation of resources, mentioned above, and an unprecedented level of coordination between industry, regulators, scientists and funders, which was achieved through the rapid formation of large consortia of organisations from different sectors and countries.

Accelerating clinical development and approval also required greater international harmonisation of regulation. In November the African Vaccine Regulators Forum agreed to conduct joint ethical and regulatory reviews of clinical trials in Africa.<sup>65</sup> This was put into practice one month later by the national ethics and regulatory authorities in Cameroon, Ghana, Mali, Nigeria and Senegal, which held a joint review for the approval of an advanced vaccine trial. Meanwhile, WHO began work on an emergency regulatory pathway for Ebola vaccines,<sup>66</sup> but specific requirements had not been announced by the time of writing.

Finally, accelerating the development and approval of medicines and vaccines also required an acceptance by all parties that decisions had to be made in situations of considerable uncertainty with regard to the reliability of the data that could be collected from clinical trials and, ultimately, the safety of the products. The need 'to balance the imperative for immediate action to control the outbreaks with ensuring that measures employed were appropriate, safe, and effective'<sup>67</sup> was recognised in several discussions. All groups emphasised that patient safety, good science and reliable data were paramount.<sup>68</sup> Yet, at the end of the day, it was also recognised that compromises would have to be made with regard to trial design and regulatory approval, for instance to be able to speed up development and, moreover, to do this in a situation of an acute outbreak with extremely high mortality rates.<sup>69</sup>

The extraordinary measures implemented to both facilitate the use of experimental drugs and accelerate the clinical development of drugs and vaccines thus employed risk calculations that differed from the respective procedures used under non-emergency conditions. The assessment of the risks weighed against the potential benefits of these measures had changed. In a situation of a perceived 'emergency' and 'threat to security', it seems easier to justify risks as acceptable. This observation has also been made by others studying the implementation of new technologies in the context of health security interventions. In a study on the Smallpox Vaccination Programme in the USA, Dale Rose found that, under the new security rationale, there was a willingness to accept a much higher risk of side-effects of the vaccine than had been acceptable from a public health rationale.<sup>70</sup> A similar logic seems to have been at play when decisions were made to expand the use of pharmaceutical interventions in the international Ebola response.

Not only do securitisation processes encourage technological solutions, then, but the political urgency associated with them facilitates the implantation of extraordinary measures, notably the mobilisation of public funds for pharmaceutical development, the use of drugs that have never been tested in humans and the acceleration of pharmaceutical development. That is a second way in which securitisation processes have encouraged and facilitated pharmaceutical response strategies.

### **Institutionalising pharmaceutical responses to health security threats**

The extraordinary measures taken to facilitate the pharmaceutical response to Ebola did not have to start from 'scratch'. Rather, they could draw on an existing set of policies and legal institutions that had been created in the past two decades to facilitate the use of pharmaceuticals as a key instrument against health security threats. In other words, the securitisation of health has not only created space for extraordinary measures but it has also – over time – created a set of lasting institutions. Some of these have facilitated – indeed made possible – a pharmaceutical response to the Ebola outbreak.

The fact that, when the outbreak occurred, experimental drugs and vaccines against Ebola existed that could be moved into clinical testing, was largely a result of the expansion of bio-defence policies in the USA since the early 2000s. As mentioned above, most of the drugs and vaccines rushed into accelerated clinical trials had initially been developed through NIH bio-defence funding streams. For commercially operating pharmaceutical companies investment in Ebola medicines and vaccines is of little interest because of a lack of commercial opportunities.<sup>71</sup> And, while there were complaints that NIH budget cuts since the mid-2000s had hampered the development of Ebola pharmaceuticals,<sup>72</sup> without public funding for health security hardly any drug or vaccine would have been ready for clinical testing when the outbreak occurred.

In addition to bio-defence funding for pharmaceutical development, three other rules created in the USA to facilitate pharmaceutical responses to health emergencies played a role in the Ebola response: the Emergency Use Authorization (EUA), the Animal Efficacy Rule, and legal liability protection for pharmaceutical companies. The EUA was established as part of the Project Bioshield Act and the Pandemic and All-Hazards Preparedness Reauthorization Act (2013). It can provide authorisation for the use of pharmaceuticals and medical devices that have not yet been fully tested for safety and efficacy.<sup>73</sup> During the Ebola outbreak, several diagnostic tests were authorised under this rule.<sup>74</sup> Before Ebola the EUA was invoked for a drug against anthrax, and for several products during the influenza A (H1N1) pandemic of 2009.<sup>75</sup> Other governments are also looking into introducing similar regulation. In Europe an agreement on strengthening health security reached in 2013 'provides for the possibility that the Commission recognises a situation of public health emergency for the purposes of conditional marketing authorisations for medicinal products.'<sup>76</sup> This would allow accelerated marketing of medicinal products or vaccines in an emergency situation.

Another legal institution that has been referred to in the international Ebola response is the so-called Animal Efficacy Rule introduced in the USA in 2002. The Animal Efficacy Rule responds to the problem that many diseases that are considered health security threats occur only rarely – or not at all – in nature. Medicines and vaccines against such threats can often not be approved on the basis of human clinical trials. The reason for this is that disease outbreaks may be too short or involve too few people for large-scale clinical testing to be organised, and deliberately exposing humans to pathogens merely for the purpose of pharmaceutical development is considered unethical.

Under the Animal Efficacy Rule the US Food and Drug Administration (FDA) can approve pharmaceuticals based on efficacy studies conducted with animal models rather than on human clinical trials. The product's safety, however, has to be demonstrated in human studies. So far the Animal Efficacy Rule has been used for only a small number of products, including one to treat pneumonic plague and another one against anthrax.<sup>77</sup> In Europe the European Medicines Agency (EMA) has initiated procedures for accelerating the availability of vaccines during an influenza pandemic, including a 'mock-up procedure' whereby a vaccine can be authorised on the basis of the virus strain that might cause a pandemic – before the pandemic has actually occurred; of an 'emergency procedure' that reduces the period of approval; and of a 'modification' procedure whereby a vaccine that was approved only for seasonal influenza can be modified and approved for pandemic influenza.<sup>78</sup>

At the time of writing neither the Animal Efficacy Rule nor the EMA initiatives has been used to approve drugs or vaccines against Ebola. Yet the Animal Efficacy Rule is actively being considered to approve some of the drugs and vaccines currently undergoing clinical

trials.<sup>79</sup> Originally it was hoped that at least some of the trials could be completed during the outbreak. Approval could then have been obtained on the basis of the data gathered during these trials. However, infection rates have been decreasing rapidly since the end of 2014, which means that many trials have run out of patients, and those still ongoing may do so in the next few months – before sufficient data are generated. A report by the Center for Infectious Disease Research and Policy (CIDRAP) at the University of Minnesota and the Wellcome Trust therefore suggests that the Global Health Security Agenda, an international health security institution launched in February 2014, ‘could provide an effective mechanism to accelerate regulatory review and deployment of Ebola vaccines in the future.’<sup>80</sup> Specifically the report calls on national regulators to harmonise regulation for pharmaceutical approval internationally, including by adopting measures like the Animal Efficacy Rule and the EUA.

Furthermore, it has been suggested that the WHO Prequalification Programme could be amended to also cover unapproved drugs and vaccines.<sup>81</sup> The WHO Prequalification Programme is a key global health institution in facilitating access to pharmaceuticals because it forms a single point of reference for drug quality. Global health organisations can therefore also purchase easily from low-cost manufacturers in developing countries where regulatory standards are weak. Yet, in its current form, the WHO Prequalification Programme cannot be used for experimental drugs and vaccines.

A third legal institution that has become of critical importance in the pharmaceutical response to the Ebola outbreak is the legal liability of manufacturers. This issue concerns the question of who pays for legal claims against pharmaceutical companies when side-effects or other injuries occur among people participating in accelerated clinical trials or receiving a medicine or vaccine that has been approved on the basis of only limited or no testing in humans. In 2005 the USA introduced protections against liability claims that may be brought against pharmaceutical companies that develop medicines and vaccines required in health emergencies. In the following years the mechanism was invoked in relation to anthrax botulism, to pandemic influenza and to smallpox.<sup>82</sup>

During the international Ebola response pharmaceutical companies, scientists, WHO, and the UK and US governments called for indemnity for the manufacturers involved in the development of Ebola medicines and vaccines.<sup>83</sup> The US government issued a declaration that extended liability protection for two years for three experimental Ebola vaccines and also shielded the manufacturer of an experimental drug from legal liability<sup>84</sup>. However, the US government can provide protection only for claims brought in a US court, not internationally. The US Secretary for Health and Human Services, Sylvia Burwell, therefore called on other governments to enact similar regulation. As Burwell explained, ‘as a global community, we must ensure that legitimate concerns about liability do not hold back the possibility of developing an Ebola vaccine, an essential strategy in our global response to the Ebola epidemic in west Africa.’<sup>85</sup> To address this problem, WHO suggested that a group of donors, in collaboration with the World Bank, could be formed to establish an international liability fund.<sup>86</sup>

The international Ebola response shows, therefore, how policies and legal institutions established in the name of health security can facilitate the recourse to pharmaceutical policy strategies. The international Ebola response has built on existing institutions to pursue a pharmaceutical approach, such as national bio-defence funding and legislation to approve experimental drugs and protect manufacturers from legal liability. Moreover, the move towards greater international harmonisation of clinical trial and approval procedures,

as well as liability protection, has further advanced the process of building institutions that facilitate the use of pharmaceuticals as a key instrument of global health governance.

## Conclusion

This article has highlighted two pivotal dynamics that characterise the international Ebola response and indeed global health governance more broadly: (1) the framing of health as a security issue; and (2) the provision of pharmaceuticals as a key instrument of global health governance. In exploring the ways in which these two processes are linked in practice the article has identified three mechanisms or pathways through which the securitisation of infectious disease subtly, but powerfully, encourages pharmaceutical policy responses.

First, the framing of health as an issue of national and international security invokes a sense of imminent danger that creates a perceived need for immediate intervention and a quick fix. Alternative policy pathways, such as long-term socioeconomic changes, appear much less appropriate in a situation of perceived emergency. Moreover, as international intervention is difficult in a world order still dominated by national sovereignty, it creates a bias for interventions that are perceived as politically neutral. In that context technologies, including pharmaceutical technologies, become politically attractive. Although pharmaceuticals are certainly not the only technological 'solution' that comes into play in this context, they are one of the most important.

Second, the framing of health as a security issue has created an exceptional political space in which extraordinary funding could be mobilised for developing medicines and vaccines, not only against Ebola but against a range of health threats. Moreover, the securitisation of health has also created exceptional political space to break key norms and rules governing the development and approval of drugs and vaccines. Medicines that had never been tested in humans were given to Ebola patients, and procedures put in place to speed up clinical tests in ways that would not normally be possible.

Finally, the securitisation of health has created a lasting institutional architecture for pharmaceutical response strategies that the international Ebola response was able to draw upon, and which it has advanced further. Of particular importance here were national institutions in the USA such as the EUA, Animal Efficacy Rule and liability protection for manufacturers. During the Ebola outbreak this institution-building process has been pushed further ahead by efforts to increase the international harmonisation of regulation of clinical trials and approval procedures, as well as liability protection.

There is, of course, no doubt that improved access to pharmaceuticals enabled by various global health governance institutions in the past two decades has done much to improve people's health and saved countless lives, including through access to anti-retrovirals for HIV and to childhood vaccines. However, by focusing policy attention largely on providing access to drugs, vaccines and other medical technologies, there is also a danger of obscuring the complex socioeconomic and political determinants of health. Indeed, there is a risk of obscuring the fact that pharmaceutical and other technologies work in specific socioeconomic contexts that shape their efficacy.<sup>87</sup> The reason that infectious diseases, such as Ebola, tend to spiral out of control mostly in low-income countries is the result of weak health systems, poverty, legacies of war, and deeply unequal global power relations, to name but a few of the complex issues underlying this catastrophe. Indeed, these issues have been recognised in public and policy debates from the beginning of the outbreak. Moreover, there have always

been significant doubts that the drugs and vaccines rushed into accelerated development would be ready to help the people affected by the Ebola outbreak.

Yet, despite the public acknowledgement of the socioeconomic dimensions of this epidemic, millions have been spent on a pharmaceutical response to the Ebola outbreak – and billions more in the past two decades on a pharmaceutical approach to strengthening global health security. Many scholars have pointed out that the global health security agenda is driven by the national interests of governments in North America and Western Europe, and that the policy focus therefore is on containment rather than the prevention of epidemics. Nevertheless, many public health experts have continued to express doubts that a pharmaceutical response was appropriate to achieve containment. Hence this explanation does not seem entirely satisfactory. To understand the focus on pharmaceuticals as a key instrument of global health policy, we need also to look at how the framing of health as a security threat has established political rationales, practices and institutions of governance. Moreover, the subtle but powerful ways in which the securitisation of infectious diseases reinforces pharmaceutical strategies in global health governance must be included in the ongoing process of their normative and political evaluation.

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## Notes

1. Hoyt, *Long Shot*.
2. WHO, "Statement on the 1st Meeting."
3. Klein, "Ebola is a 'National Security Priority'."
4. United Nations, S/RES/2177, 1.
5. Cooper, *Life as Surplus*; Elbe, *Virus Alert*; Elbe, "Haggling over Viruses"; Enemark, "Is Pandemic Flu?"; Lakoff and Collier, *Biosecurity Interventions*; McInnes and Lee, "Health, Security and Foreign Policy"; and Rushton and Youde, *Routledge Handbook*.
6. Buzan et al., *Security*.
7. Austin, *How to do Things*; and Searle, *Speech Acts*.
8. Elbe, *Security and Global Health*, 11.
9. Aldis, "Health Security"; McInnes, "HIV/AIDS and Security"; Rushton, "Global Health Security"; Weir, "Inventing Global Health Security"; Buzan et al., *Security*; Elbe, *Security and Global Health*; and Hanrieder and Kreuder-Sonnen, "WHO Decides on the Exception?"
10. Elbe, "Should HIV/AIDS be Securitized?"
11. McInnes and Rushton, "HIV/AIDS and Securitization Theory"; and Enemark, "Ebola in West Africa."
12. WHO, *Ethical Considerations*.
13. WHO, "Consultation on Potential Ebola Therapeutics."
14. White House, "Progress in our Ebola Response"; Wellcome Trust, *Ebola Treatment Trials*; Innovative Medicines Initiative, "First Innovative Medicines Initiative"; and WHO, *Second WHO High-level Meeting*.
15. NIH, "Liberia-US Clinical Research Partnership"; Wellcome Trust, "New Trial of TKM-Ebola Treatment"; WHO, "Trial of Vaccine"; Moran, "Chimerix"; NIH, "PREVAIL"; and Wellcome Trust, "Ebola Treatment Trials."
16. When the first candidate treatments and vaccines entered into clinical trials in late 2014, the height of the epidemic had indeed passed and several trials faced difficulty even recruiting sufficient patient numbers. Yet small outbreaks continued to occur in West Africa and in the summer of 2015 one trial indicated that a vaccine (rVSV-ZEBOV) might have been found that was highly efficacious in preventing Ebola. Henao-Restrepo, "Efficacy and Effectiveness of an rVSV-vectored Vaccine."
17. Elbe et al., "Medical Countermeasures," 265.
18. Elbe et al., "Medical Countermeasures"; and Elbe et al., "Securing Circulation."
19. Roemer-Mahler, "The Rise of Companies from Emerging Markets."
20. Abraham, "Pharmaceuticalization of Society"; Clarke et al., *Biomedicalization*; Gabe, *Pharmaceuticalization*; Lakoff, *Pharmaceutical Reason*; Petryna et al., *Global Pharmaceuticals*; and Williams et al., "The Pharmaceuticalisation of Society?"
21. Clarke et al., *Biomedicalization*.
22. Conrad, *The Medicalization of Society*.
23. Healy, *Let Them Eat Prozac*; Dumit, *Drugs for Life*; and Goldacre, *Bad Pharma*.
24. Abraham, "Pharmaceuticalization of Society"; and Williams et al., "Pharmaceuticalisation of Society?"
25. Elbe et al., "Medical Countermeasures"; and Roemer-Mahler, "The Rise of Companies from Emerging Markets."
26. Elbe et al., "Securing Circulation."
27. Buzan and Wæver, *Regions and Powers*, 71.
28. Nunes, "The Politics of Health Security," 64.
29. Calhoun, "The Imperative to Reduce Suffering."
30. Weir and Mykhalovskiy, *Global Public Health Vigilance*.
31. Collier and Lakoff, "The Problem of Securing Health."
32. McInnes, "The Many Meanings," 14.
33. Institute of Medicine, *Emerging Infections*; Brower and Chalk, *The Global Threat*; and WHO, *World Health Report 2007*.
34. Fidler, "The Globalization of Public Health"; and Kamradt-Scott, "Health, Security and Diplomacy."



35. Weir, "Inventing Global Health Security"; Rushton, "Global Health Security"; Aldis, "Health Security as a Public Health Concept"; Elbe, "Should HIV/AIDS be Securitized?"
36. Collier and Lakoff, "The Problem of Securing Health," 17.
37. Fearnley, "Redesigning Syndromic Surveillance"; Weir, "Inventing Global Health Security"; and Davies, "Securitisating Infectious Diseases."
38. King, "The Scale Politics," 67.
39. See, for instance, United Nations, S/RES/2177, 1; WHO, "Statement on the 1st Meeting"; and WHO, "Ebola Response Roadmap."
40. WHO, *Second WHO High-level Meeting*, 6.
41. WHO, *Ethical Considerations*, 6; and WHO, *Second WHO High-Level Meeting*, 3.
42. Leach, "The Ebola Crisis"; and Wilkinson and Leach, "Briefing."
43. Buzan and Wæver, *Regions and Powers*, 6.
44. Singer, "AIDS and International Security"; and McInnes and Rushton, "HIV/AIDS and Securitization Theory."
45. Buzan et al., *Security*; and Elbe, "Should HIV/AIDS be Securitized?"
46. White House, "Progress in our Ebola Response."
47. Wellcome Trust, "Ebola Treatment Trials."
48. Innovative Medicines Initiative, "First Innovative Medicines Initiative"; and Innovative Medicines Initiative, "Innovative Medicines Initiative launches Ebola+."
49. WHO, *Second High-level Meeting*.
50. White House, "President Bush Signs Project Bioshield Act."
51. US Department of Health and Human Services, "Testimony of Anthony S. Fauci."
52. PEPFAR, "PEPFAR Funding."
53. GAVI, "Gavi's Resource Mobilisation Process."
54. WHO, *Ethical Considerations*.
55. Wellcome Trust and CIDRAP, *Recommendations*; and WHO, "Consultation on Potential Ebola Therapeutics."
56. Paul et al., "How to Improve R&D Productivity."
57. WHO, "Compassionate Use of Experimental Treatments."
58. Rid and Emanuel, "Ethical Considerations."
59. WHO, "Ebola Treatment and Interventions."
60. WHO, "High-level Meeting on Ebola Vaccines."
61. WHO, "Consultation on Potential Ebola Therapies."
62. WHO, "Agenda of the Meeting."
63. WHO, "Consultation on Potential Ebola Therapies."
64. Kieny, "Overview of Vaccine Development."
65. WHO, "Fast-tracking the Development"; and WHO, "African Regulators' Meeting."
66. WHO, *Second High-level Meeting*.
67. WHO, "Consultation on Potential Ebola Therapies."
68. WHO, *High-level Meeting*.
69. Ibid.
70. Rose, "How did the Smallpox Vaccination Program?," 103.
71. The number of people contracting Ebola in the past has been very small compared with other diseases. Moreover, Ebola outbreaks occur mostly in poor countries where people are often unable to pay for medicines. Conventional mechanisms for commercial investment in drug development, notably market size and intellectual property protection, are therefore not effective in the case of Ebola.
72. Stein, "Ebola Vaccine."
73. Stroud et al., *Medical Countermeasure Dispensing*, 5.
74. US Food and Drug Administration, "Ebola Virus EUA Information."
75. Stroud et al., *Medical Countermeasure Dispensing*, 25.
76. EU, "Presidency Confirms Agreement."
77. Elbe et al., "Medical Countermeasures."
78. European Medicines Agency, "Authorization Procedures."

79. US Food and Drug Administration, *Vaccines*; Hirschler, "Liberia Ebola Vaccine Trial"; and Burton, "NIH to Start Vaccine Study."
80. Wellcome Trust and CIDRAP, "Accelerating Development," 31.
81. Ibid; and Marinissen et al., "Strengthening Global Health Security."
82. Stroud et al., *Medical Countermeasure Dispensing*, 24.
83. Hirschler and Nebehay, "Drugmakers may need Indemnity"; and Wintour, "David Cameron Presses for Indemnities."
84. US Department of Health and Human Services, "Ebola Virus Disease Vaccines"; and US Department of Health and Human Services, "Ebola Virus Disease Therapeutics."
85. Quoted in McCarthy, "US provides Immunity."
86. WHO, "WHO High-level Meeting."
87. Koch, "Disease as a Security Threat."

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