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Medical countermeasures for national security: A new government role in the pharmaceuticalization of society

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ABSTRACT

How do governments contribute to the pharmaceuticalization of society? Whilst the pivotal role of industry is extensively documented, this article shows that governments too are accelerating, intensifying and opening up new trajectories of pharmaceuticalization in society. Governments are becoming more deeply invested in pharmaceuticals because their national security strategies now aspire to defend populations against health-based threats like bioterrorism and pandemics. To counter those threats, governments are acquiring and stockpiling a panoply of 'medical countermeasures' such as antivirals, next-generation vaccines, antibiotics and anti-toxins. More than that, governments are actively incentivizing the development of many new medical countermeasures – principally by marshaling the state's unique powers to introduce exceptional measures in the name of protecting national security. At least five extraordinary policy interventions have been introduced by governments with the aim of stimulating the commercial development of novel medical countermeasures: (1) allocating earmarked public funds, (2) granting comprehensive legal protections to pharmaceutical companies against injury compensation claims, (3) introducing bespoke pathways for regulatory approval, (4) instantiating extraordinary emergency use procedures allowing for the use of unapproved medicines, and (5) designing innovative logistical distribution systems for mass drug administration outside of clinical settings. Those combined efforts, the article argues, are spawning a new, government-led and quite exceptional medical countermeasure regime operating beyond the conventional boundaries of pharmaceutical development and regulation. In the first comprehensive analysis of the pharmaceuticalization dynamics at play in national security policy, this article unearths the detailed array of policy interventions through which governments too are becoming more deeply imbricated in the pharmaceuticalization of society.

1. Introduction

Recent scholarship identifies multiple drivers for the pharmaceuticalization of society (Abraham, 2010; Gabe, 2014; Williams et al., 2009, 2011). Scientific advances in biomedicine are one significant factor, because such discoveries enable novel pharmaceutical products to be developed (Clarke et al.,, 2010). The broader medicalization of existence too is a relevant driver, as it encourages a social tendency to address complex issues through recourse to pharmaceutical therapies (Conrad, 2007). More aggressive industry promotion and direct-to-consumer advertising can similarly increase the societal penetration of pharmaceutical products, which is why several influential studies have emphasized the influence of pharmaceutical companies (Healy, 1997, 2004; Dumit, 2012; Goldacre, 2012). Governments by contrast have so far only been accorded a much more modest role in the scholarship, which tends to focus on the expedited approaches some state regulatory agencies are taking in the approval of new pharmaceuticals (Abraham, 2010; Williams et al., 2011). This article, however, shows that governments are much more active and complex drivers of pharmaceuticalization than the received picture suggests. Governments too are today accelerating, intensifying and opening up new trajectories of pharmaceuticalization in society; and they are doing so through a much broader array of policy instruments than just their regulatory powers alone.

Key to this renewed political investment in pharmaceuticals is the fact that governments now view the protection of their populations against acute infectious disease threats as a core part of their national security mission. The World Health Organization (WHO) has warned governments that a new pandemic infecting

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roughly 25% of the world population (a figure derived from previous pandemics), would affect more than 1.5 billion people and cause enormous social disruption due to a rapid surge in illnesses and deaths (WHO, 2007: 47). Governments have also been spurned into preparing for the deliberate release of a biological agent through an act of bioterrorism – as exemplified by the anthrax letters mailed in the United States in the autumn of 2001. Acknowledging those microbial vulnerabilities, governments in the United States and Europe have expanded their security agendas to formally incorporate health-based threats (WHO, 2007; EC, 2009). Indeed, the rapid proliferation of the new notion of 'health security' in a plethora of international policy debates and official documents testifies to the growing significance that governments now attach to defending their societies against such infectious disease threats (WHA, 2001; GHSI, 2002; WHO, 2007; European Council, 2008; EC, 2009; Elbe, 2009, 2010b). Security policy, as Melinda Cooper observes, needs 'to arm itself against the generic microbiological threat, from wherever it might emerge' (Cooper, 2008:75).

One of the principal ways governments are trying to counter those threats is by acquiring and stockpiling a panoply of 'medical countermeasures' – like antivirals, next-generation vaccines, antibiotics and anti-toxins. So strong, in fact, is the political interest in obtaining better pharmaceutical defences, that governments are also trying to actively incentivize the commercial development of many *new* medical countermeasures. This article identifies, maps and analyzes the complex array of new policy initiatives governments are introducing to stimulate the development of such novel medical countermeasure. For its source material, the article draws upon semi-structured, background interviews carried out with key informants from government, industry and academia in the United States and Europe, where medical countermeasure are a political priority. Informants were selected on the basis on their detailed knowledge of the government programmes and regulatory procedures surrounding medical countermeasures. Interviews explored the key issues involved in the development, approval, and deployment of medical countermeasures – especially of antivirals and vaccines. Those findings were corroborated through extensive analysis of a wide range of policy papers, background papers, working papers and articles on medical countermeasures produced by governments, think tanks, and newspapers; as well as of scholarly articles and books published on health security.

Analysis of the source material suggests that recent government efforts to stimulate the commercial development of new medical countermeasures principally rely upon the state's unique power to introduce exceptional measures in the name of protecting national security. At least five extraordinary government interventions can be identified: (1) allocating earmarked public funds, (2) granting comprehensive legal protections to pharmaceutical companies against injury compensation claims, (3) introducing bespoke pathways for regulatory approval, (4) instantiating emergency use procedures, and (5) designing innovative logistical distribution systems for mass drug administration beyond clinical settings. Those combined measures are spawning a new, government-led and quite exceptional medical countermeasure regime operating outside of the conventional boundaries of pharmaceutical development and regulation. In the first comprehensive analysis of the pharmaceuticalization dynamics at play in contemporary security policy, this article unearths the array of policy interventions through which governments are becoming more deeply imbricated in the pharmaceuticalization of society.

2. Health security: the microbial turn in security policy

The 'biological' – even 'microbial' – turn in security policy is increasingly well documented (Cooper, 2008; Elbe, 2003, 2009, 2010b; Lakoff and Collier, 2008; McInnes and Lee, 2006; Enemark, 2009; Rushton and Youde, 2014). Scholars in International Relations have advanced detailed explorations of how a number of pressing international health issues have become 'securitized' (Elbe, 2006, 2010a; Davies, 2008; McInnes and Rushton, 2013). Scholars of public health, conversely, have documented how that field is simultaneously becoming more security oriented – reminding readers of the historical legacies of linking public health and security in the context of colonialism (King, 2002, 2003; Brown, 2011; Brown and Bell, 2008; Wright, 2006). Irrespective of whether one starts from the perspective of security or public health, it is evident that the worlds of security and health are beginning to converge ever more closely – conceptually, institutionally, and programmatically.

Two distinct but related infectious disease threats animate this convergence. The first threat – bioterrorism – surfaced in security debates during the 1990s. The subsequent terrorist attacks of 11 September 2001 in the United States, and the mailing of letters laced with Anthrax through the U.S. postal system, would prove decisive in elevating political perceptions about bioterrorism. As David Franz, the former Commander of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), put it in 2002:

> The thought of an outbreak of disease caused by the intentional release of a pathogen or toxin in an American city was alien just 10 years ago. Many people believed that biological warfare was only in the military's imagination, perhaps to be faced by soldiers on a far-away battlefield, if at all. The "anthrax letters" and the resulting deaths from inhalation anthrax have changed that perception. The national, state, and local governments in the United States are preparing for what is now called "not if, but when and how extensive" biological terrorism (Franz and Zajtchuk, 2002).

The threat of a *deliberate* release of a disease-causing agent thus marks one key driver for increased national security concerns about acute infectious diseases.

Slightly different drivers are at play in the case of *naturally* occurring infectious diseases – like pandemic influenza (Dry and Leach, 2010; Dingwall et al., 2013; Figuié, 2013). Many public health experts observe that three such flu pandemics occurred in the twentieth-century alone (Kilbourne, 2006). First came the pandemic of 1918, undoubtedly the worst of the twentieth-century when measured by scale of absolute human mortality. It struck at the end of the First World War, and therefore prior to the widespread availability of antibiotics and respirators – contributing to a severe mortality rate estimated to run into the tens of millions (Johnson and Mueller, 2002). Two further pandemics (in 1957 and 1968) followed in the second half of the twentieth century, albeit with considerably smaller death tolls. The cyclical periodicity of these events has nonetheless generated a perception amongst public health experts that future pandemics are inevitable. As Angus Nicoll, head of the influenza programme at the European Centre for Disease Prevention and Control (ECDC) puts it: 'European policy-makers and politicians are put in a hard place by the prospect of modern influenza pandemics. They don't know when one is going to happen, where it will start or what it will be like. The only certainty is that future influenza pandemics will occur and they will be unpredictable' (Nicoll and Sprenger, 2011).

Both of those 'twin' infectious disease threats have been subject to diverging expert assessments regarding their likelihood and severity. Charles Allen, the Chief Intelligence Officer of the Department of Homeland Security, for example, testified before Congress that 'in general, terrorist capabilities in the area of

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