Review of International Studies (2014), 40, 919–938
doi:10.1017/S0260210514000151

The pharmaceuticalisation of security: Molecular biomedicine, antiviral stockpiles, and global health security

STEFAN ELBE*

Abstract. Pharmaceuticals are now critical to the security of populations. Antivirals, antibiotics, next-generation vaccines, and antitoxins are just some of the new 'medical countermeasures' that governments are stockpiling in order to defend their populations against the threat of pandemics and bioterrorism. How has security policy come to be so deeply imbricated with pharmaceutical logics and solutions? This article captures, maps, and analyses the 'pharmaceuticalisation' of security. Through an in-depth analysis of the prominent antiviral medication Tamiflu, it shows that this pharmaceutical turn in security policy is intimately bound up with the rise of a molecular vision of life promulgated by the biomedical sciences. Caught in the crosshairs of powerful commercial, political, and regulatory pressures, governments are embracing a molecular biomedicine promising to secure populations pharmaceutically in the twenty-first century. If that is true, then the established disciplinary view of health as a pre-

security encompasses 'the activities required, both proactive and reactive, to minimize vulnerability to acute public health events that endanger the collective health of populations living across geographical regions and international boundaries'.[2] Such policies are necessary, according to WHO, because a new pandemic infecting roughly 25 per cent 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.[3] The threat of bioterrorism – exemplified by the anthrax letters mailed in the United States in the autumn of 2001 – similarly demands ongoing government efforts to prepare for the deliberate release of a biological agent. The twin spectres of naturally-occurring and intentionally-released infectious disease threats have thus provoked a deep sense of microbial unease at the outset of the twenty-first century.

Security agendas have evolved to reflect this mood shift, and now routinely incorporate health-based threats. In the United States, the 2002 National Security Strategy made direct reference to infectious diseases, pledging that the US government will 'continue to lead the world in efforts to reduce the terrible toll of HIV/AIDS and other infectious diseases'.[4] The 2006 US National Security Strategy again pointed to the threat posed by 'public health challenges like pandemics (HIV/AIDS, avian influenza) that recognise no borders'.[5] When the United Kingdom developed its first official national security strategy in 2008, it too began to highlight pandemic threats – both because of their ability to affect the country, and because they could potentially undermine international stability.[6] Pandemic threats also continue to reside at the apex of the UK's national risk register, and are identified as a Tier 1 (top) threat in the latest National Security Strategy.[7] Those UK efforts, in turn, unfolded against the backdrop of wider European Union initiatives to also develop a European health security strategy.[8] In a way that would have been unimaginable only a decade ago, potentially catastrophic infectious disease threats have become the unlikely bedfellows of more established security threats like terrorism, nuclear proliferation, rogue states, and so forth.[9]

The emergence of those global health security concerns creates new challenges and opportunities for International Relations scholarship. First, global health security marks another significant expansion of the international security agenda. At a time

Commission, 'Commission Staff Working Document on Health Security in the European Union and Internationally' (Brussels: Commission of the European Communities, 23 November 2009); Stefan Elbe, Virus Alert: Security, Governmentality and the AIDS Pandemic (New York: Columbia University Press, 2009); Stefan Elbe, Security and Global Health: Towards the Medicalization of Insecurity (Cambridge: Polity, 2010).

[2] WHO, 'A Safer Future', p. ix.

[3] Ibid., p. 47.

[4] (Cam-

when a number of infectious diseases have become the subject of high-level, sustained and even acrimonious international diplomacy, scholars of International Relations are challenged to rectify their neglect of the international politics of health. Second, global health security also opens up new opportunities for investigating the intricate dynamics of securitisation in world politics.[10] Amidst the pantheon of recent securitisation processes, global health security stands out because it begins to transform the inner biological workings of our bodies into additional sites of security concern.[11] Here the rise of global health security is engendering a range of new practices that can be fruitfully explored with a view to deepening our understanding of contemporary securitisation processes. For those two reasons alone, a burgeoning International Relations literature has already turned its analytical sites on global health security.[12]

Yet there is also a third – and altogether different – reason why the rise of global health security marks such a significant development in world politics. All the high-level concern around global health security dramatically elevat

All of this implies that the conventional disciplinary view of health as a predominantly secondary matter of 'low' international politics is incorrect. On the contrary, this article points to social forces of health and biomedicine that are sufficiently powerful to shape the core practices of international politics – even those of security. Look-

All of that is no doubt making a lot of demands of a singular conceptan–i4-879.er,

of development.[20] Those contracts have led to federal acquisitions totalling tens of

repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration and airway maintenance supplies, and medical/surgical items'.[24] Those stockpiled medical countermeasures are now stored in a large number of pre-packed 'push' pallets, so that they can be delivered anywhere in the United States at short notice. By 2006, such SNS packages reportedly filled 124 cargo containers, weighing 94,424 pounds and taking up 5,000 square feet of floor space.[25] Two years later, by 2008, the total inventory of the stockpile was valued at US $3.5 billion.[26]

The precise geographic location and detailed composition of this stockpile remains classified in order to prevent a run on the supplies during an emergency. However, the US government has disclosed that the stockpile was first deployed on 11 September 2001. Of the four airplanes reportedly cleared to fly in American airspace that night, one was Air Force One – with the remaining three supporting the SNS deployment.[27] The decision to create, and deploy, such dedicated pharmaceutical stockpiles shows that governments are doing more than simply investing in the development of novel medical countermeasures; they are also adapting their security practices to deliver those pharmaceuticals to the population much more rapidly during an emergency.

Perhaps, then, this move towards pharmaceutical stockpiling in security policy is just a peculiarly American phenomenon? The United States, after all, is home to the world's largest pharmaceutical market. It is also one of the few countries in the world where pharmaceuticals can be directly advertised to consumers. And it is a country where the pharmaceutical lobby yields substantial political influence.

There is no doubt that the United States has been at the international forefront of pharmaceutical stockpiling for security purposes; but it would be erroneous to simply dismiss the rise of pharmaceutical stockpiling as a US phenomenon. In fact, the practice of pharmaceutical stockpiling has also been adopted by many other countries around the world. More recently, the European Union established a new legal basis for the voluntary joint procurement of medical countermeasures by member states, especially for influenza vaccines.[28] The Australian government also created a National Medical Stockpile (NMS) with a strategic reserve of essential vaccines, antibiotics, antiviral drugs, as well as chemical and radiological antidotes.[29] The Canadian government similarly maintains a National Emergency Stockpile System,[30] whilst the Uni

part of its pandemic preparedness planning, UK authorities created one of the world's largest stockpiles of antiviral medications in 2005. Amidst fears that H5N1 ('bird') flu could mutate into a form that would cause a devastating human pandemic, the UK government identified the antiviral medication oseltamivir (brand name: Tamiflu) as the 'first line of defence'. The UK subsequently expended considerable public resources to create a new national stockpile of the drug sufficiently large to cover half of its population. Later, the UK government increased the size of

which has played a key role in the rise of pharmaceutical stockpiling, was already in the process of negotiating the donation of three million treatment courses from Roche for the creation of a new international stockpile. In January 2006, this international stockpile was increased by a further two million donated courses earmarked for developing countries.[36] The stockpile was physically co-located in the United States and Switzerland – from where it could be quickly flown to a major airport anywhere in the world.[37]

It was a risky strategy. Could a pandemic really be stopped in its tracks? What if some of the assumptions in the theoretical modelling were mistaken, or if the virus did not behave according to those assumptions? Moreover, the size of the stockpile was clearly still very modest, especially when compared to the billions of people living in low-income countries. Again, however, what is more significant than the overall size of the stockpile, is the fact that this new international stockpile now extended the geographic 'blanket' of antiviral protection to also cover those countries unable to afford their own pharmaceutical supplies. With the creation of the international WHO stockpile, pharmaceutical stockpiling effectively became a global phenomenon.

And still a crucial gap in global health security remained. As public health planners were quick to point out, the mere procurement of new pharmaceutical stockpiles alone would not guarantee security in the event of an outbreak. In fact, those stockpiles would be fairly useless if they were not accompanied by efficient mechanisms for rapidly distributing those medicines to large numbers of people. Relevant government departments would therefore also need to urgently develop new systems of mass pharmaceutical administration. One of the most innovative and prominent examples of such a new logistical system was the launch of the National Pandemic Flu Service (NPFS) in the United Kingdom during the 2009 influenza A (H1N1) 'swine flu' pandemic. Faced with an unexpected surge in human H1N1 infections, which was by that time also beginning to place a heavy burden on the National Health Service (NHS), the authorities in England decided to launch a new telephone and internet-based pharmaceutical distribution system that could deliver the antiviral medications directly to members of the population. It was, in the words of one report, the 'first mass application of non-clinical based triage'.[38]

Once the new pharmaceutical distribution system went live, and after sorting out some of the initial teething issues caused by overwhelming volumes of Internet traffic, obtaining Tamiflu became quite straightforward for citizens. It was simply a matter of picking up the phone or going online, connecting to the new website, and ticking a few boxes related to a set of common flu symptoms. If the symptoms criteria were met, citizens were asked to note down a unique reference number to obtain Tamiflu from the nearest official collection point – preferably through the use of what British authorities affectionately referred to as their 'flu buddies'. Not surprisingly, the system was easily open to abuse from those who wanted to create personal stockpiles of the drug. As one manager of a general medical practice noted with exasperation at the

[36] Samii and Wassenhove, Fighting the Flu, p. 5.
[37] Ibid.
[38] Maureen Baker, 'Quality Assuring the NPFS ... and Further RCGP Reflections on Pandemic H1N1 (2009)', A Report on the NPFS and the H1N1 Swine Flu Outbreak for the Chief Medical Officer (Personal Correspondence, 2010), p. 7.

mechanisms among molecular entities that can be identified, isolated, manipulated, mobilized, recombined, in new practices of intervention, which are no longer constrained by the apparent normativity of a natural vital order'.[42] This molecular vision of life is closely – and in fact doubly – implicated in the pharmaceuticalisation of security.

First, the reimagination of life as constituted by the complex interplay of molecular structures and processes is stimulating an array of profound new anxieties about the microbiological vulnerabilities underlying our existence. That is certainly true in the case of bioterrorism, where the growing ability to purposefully manipulate life at the molecular level gives rise to new fears about how microorganisms could be deliberately reengineered or synthesised to cause immense harm to populations.[43] Similarly, our detailed scientific knowledge of the molecular processes unfolding in nature makes us realise that viruses and bacteria are continuously mutating with the potential to give rise to threatening new pandemics in future. As Angus Nicoll, head of the influenza programme at the European Centre for Disease Prevention and Contr2.9ro

our scienti“c understanding of the molecular processes surrounding in”uenza virus replication … especially following successful isolation of the “rst human in”uenza virus in 1933. Scientists now know that viruses, including in”uenza viruses, cannot replicate on their own; to do that they need to insert themselves into existing cells, and then use the cell to make more copies of themselves. The new virus particles subsequently leave the cell again, destroying the host cell in the process, before going on to infect further cells … repeating this cycle again and again.

Yet the accumulated knowledge about those intricate molecular processes involved in viral replication also exposed a crucial •catch• in the process. As the viruses leave the host cell, they become attached to a coating of (sialic) acid found on the surface of the host cell. To leave the cell and infect neighbouring ones, viruses “rst require the work of a crucial enzyme called neuraminidase … which helps to dissolve this •sticky• acid and free the viruses.[47] Metaphorically, one can think of neuraminidase as the •scissors• that cut newly formed virus particles free from their host cell. This neuraminidase enzyme is widely identi“ed by the •N• designation in the international virus classi“cations frequently reported in the media (for example, H5N1, H1N1, H7N9, etc.).

What would happen to in”uenza viruses in the absence of this enzyme? Without the proper functioning of the neuraminidase, new virus particles would remain •stuck• on the surface of the host cell with nowhere to go, and would therefore not be able to circulate and penetrate other cells … as would be necessary for causing a wider bodily infection. If there could be a way to selectively disrupt, or inhibit, the workings of this crucial neuraminidase enzyme, it could thus mark an entry point for a new type of antiviral medication. Tami”u … and a closely related predecessor drug named Relenza … are two attempts to intelligently and arti“cially design new molecules that would do precisely that. Together they therefore form part of a new class of antiviral therapies called neuraminidase inhibitors.

Yet the deliberate and rational design of such novel molecular therapies … principally by organic chemists … only became possible after Australian researchers had “rst decoded the molecular structure of neuraminidase. Three key developments facilitated that crucial molecular decoding: (1) the deepening of knowledge about the detailed molecular processes involved in virus replication; (2) the emergence of new scienti“c technologies like x-ray crystallography capable of unravelling complex molecular structures; and (3) advances in computer modelling and chemical pharmacology used for the rational design and synthesis of new molecules. Armed with these new knowledges and technologies, scientists were eventually able to deliberately design an •arti“cial• new molecule that could bind to a key site in the neuraminidase enzyme, and that could carry out precisely this desired function of inhibiting the enzyme•s key role in the process of viral replication. And so one of the world•s most prominent medical countermeasures was born. More than any other medical countermeasure, perhaps, the case of Tami”u shows how the molecular vision of life is not just inducing an array of new insecurities; it is also enabling the scienti“c development of innovative pharmaceutical interventions designed at the level of the molecular. As a necessary epistemic precondition for the technical and material

[47] Reto Schneider, •Das Rennen um GS4104: Wie ein Medikament entwickelt, getestet und vermarktet wird•, NZZ Folio: Die Zeitschrift der Neuen Zuercher Zeitung (April 2001), available at: {http://www.nzzfolio.ch/www/d80bd71b-b264-4db4-afd0-277884b93470/showarticle/81bb3c96-9216-4eb5-b602-7e0937369c79.aspx} accessed 1 March 2012.

creation of such novel medical countermeasures, the molecular vision of life promulgated by the life sciences lies at the heart of the pharmaceuticalisation of security.

IV. Biocapital: Business interests and pharmaceutical companies

If molecular knowledge is a necessary precondition for the pharmaceutical turn in security policy, it is not a sufficient one. For the generation of such biomedical knowledge, and its translation into new pharmaceutical treatments, is a capital-intensive activity. Developing new medical countermeasures requires financial investments frequently running into the tens and even hundreds of millions of dollars. Understanding the ways in which capital coalesces around those new molecular knowledges for the purposes of commercial exploitation is therefore another significant driver of the pharmaceuticalisation of security policy.

Kaushik Rajan points to the emergence of biocapital in the 1990s as 'a particular form of capitalism made specific because of emergent technologies and epistemologies of the life sciences'.[48] Such biocapital has been decisive for the development of new medical countermeasures like Tamiflu in at least two ways. First, speculative venture capital frequently plays a pivotal role in the early stages of drug discovery. The new molecule that would eventually become Tamiflu was initially developed at Gilead Sciences in the mid-1990s. Gilead has since risen to become one of the world's most successful biotechnology companies. At the time it was developing Tamiflu, however, Gilead was still only a small start-up company in Silicon Valley, California. During that time it was kept afloat with millions of dollars in private venture capital. Without the willingness of venture capitalists to take considerable financial risks on a new biotechnology business that – at the time – was not yet operating at a profit, and which still had an unproven business model, Tamiflu is unlikely to have ever been commercially developed. There is some evidence that the volume of such venture

Investigative journalists have exposed how – in the case of neuraminidase inhibitors for influenza – pharmaceutical companies like Roche were able to rapidly raise awareness about their new drugs amongst international health organisations – even before the companies had secured regulatory approval.[50] That was achieved by working closely with scientists, who are often also invited by international health organisations to share their expertise. For example, in 1999 – the same year in which Roche was seeking regulatory approval for Tamiflu in the United States – the World Health Organization began to raise concern about pandemic influenza and drafted a document entitled Influenza Pandemic Plan: The Role of WHO and Guidelines for National and Regional Planning.[51] The controversial document, which bears the WHO logo and has been repeatedly cited by the industry, warns of serious consequences of a pandemic and highlights the importance of antiviral medications. Referring mostly to the older generation of antivirals – amantadine and rimantadine – the report also pointed to the development of two new compounds – zanamivir and oseltamivir – that would subsequently become marketed as Relenza and Tamiflu respectively. The report noted: 'if approved, and found to have a good safety profile, either drug would offer the advantage, during inter-pandemic situations, of being useful regardless of the virus type'.[52]

A subsequent investigation published in BMJ (formerly the British Medical Journal) further revealed that the document was compiled by WHO in collaboration with the European Scientific Working Group on Influenza (ESWI) – which was industry-funded by Roche and other influenza drug manufacturers.[53] The BMJ investigation also exposed that several of the experts present at this meeting had earlier been participating in Roche-sponsored events.[54] Such episodes show that one of the ways that commercial backers of innovative molecular therapies may seek to maximise the return on their investment is by seeking to influence governments to procure sizeable quantities of their new products in the name of strengthening health security.[55] The

(and nonhuman) affairs.[56] He has traced how such knowledge is giving rise to complex new forms of association, activism, and exchange, which he was witnessing around access to antiretroviral therapy for people living with HIV/AIDS. Although Nguyen•s notion of therapeutic citizenship is wide-ranging and complex, it is also underpinned by a strong expectation by citizens and patients that they should have rapid and affordable access to the latest pharmaceutical treatments.

Even beyond the contested politics of HIV/AIDS,[57] there are signs that citizens are becoming much more proactive in seeking out the latest pharmaceutical regimens … often facilitated by recourse to the Internet.[58] In the case of Tami"u, direct-to-consumer advertising of the drug was not permitted in Europe due to legal constraints, but extensive media coverage of the pandemic threat certainly made citizens aware of the existence of this new drug. Bolstered by this awareness, citizens could actively seek out the information about this therapy on their own accord. The extent to which citizens were trying to obtain information about Tami"u, and perhaps even trying to

displayed in the Search Volume Index. Although this only provides a rough approximation due to the use of data sampling methods and multiple approximations, it clearly shows the enormously increased Internet activity surrounding Tamiflu during recent pandemic scares. In the graph below, the number 100 represents the peak search interest.

The Search Volume Index for 'Tamiflu' indicates two distinct spikes: one during the international fears of an imminent H5N1 pandemic in 2005, and one during the H1N1 pandemic that begun to spread in the April of 2009. Those peaks coincide with periods of intense media reporting.[59]

not just by commercial pressures, but also by rising popular expectations to ensure widespread access to the latest pharmaceutical treatments.

medical countermeasures.[67] Those novel pathways mean that, in the United States, some medical countermeasures can now be approved on the basis of animal efficacy studies rather than human clinical trials – thus easing the threshold for regulatory approval. New procedures were also introduced authorising the US government – in an emergency situation – to use a drug that had not yet secured regulatory approval, or the use of the drug for purposes other than those for which it was initially licenced.

In Europe, furthermore, the European Medicines Agency initiated three separate procedures for speeding up the availability of influenza vaccines during a pandemic. Those include: (1) a 'mock-up procedure' whereby a vaccine can be authorised in advance of a pandemic on the basis of a strain that could potentially cause a pandemic; (2) an 'emergency procedure', which reduces the authorisation procedure from 210 to seventy days; and (3) a 'modification' procedure whereby a 'seasonal' flu vaccine might be altered to afford protection against a pandemic strain.[68] Without such enhanced regulatory flexibility, it would be more difficult for many medical countermeasures to gain the necessary regulatory approval, and companies would face greater disincentives for investing in the costly development of novel medical countermeasures. The willingness of governments to make their regulatory approaches for approving medical countermeasures more flexible is thus a crucial, final factor in 'unlocking' the pharmaceutical turn in security policy.

Conclusion

Pharmaceuticals have become a much more prominent feature in the twenty-first-century landscape of security policy. Governments with the requisite resources now actively incentivise the commercial development of new medical countermeasures – through the design of novel programmes, through the use of public funds, through the creation of new institutions, and through the introduction of greater regulatory flexibilities. Governments are also building extensive pharmaceutical stockpiles that require continuous maintenance and replenishment, and are even standing up elaborate new logistical systems for distributing those medical countermeasures en masse to their populations outside of clinical settings. Indicators abound, then, that pharmaceuticals are becoming more vital to the task of securing populations.

At the core of that pharmaceutical turn in security policy lies the rise of a molecular vision of life promulgated by the biomedical sciences. Reimagining life as the complex interplay of molecular processes is provoking profound new fears about our collective vulnerability to underlying microbiological processes – be it in the form of pandemics or bioterrorism – that are finding their contemporary political expression in the rise of global health security concerns. At the same time, and as the detailed examination of Tamiflu showed, this molecular vision of life is simultaneously engendering new strategies for intervening upon life processes – principally

designed at the level of the molecular. How we understand life does not just shape what makes us feel insecure, but also influences how we in turn seek to secure life.

That it should be possible for security policy to undergo such a process of pharmaceuticalisation reaffirms the essentially malleable and socially constructed view of

And it can be seen in the ways that biomedicine is beginning to influence how states understand security, how they practice it, and indeed what it means for citizens to feel insecure. Far from merely being matters of 'low' politics, the social forces of health and biomedicine are powerful enough to influence the core practices of international politics – even those of security. For a discipline long accustomed to studying macrolevel processes and systemic structures, international relations are – in the end – also engendered and constituted by our knowledge of the minute morass of molecules.