ABOUT THE MANUSCRIPT
- Working Title: Pandemics, Pills and Politics: Encapsulating Security in the 21st Century

- Which one of the following most closely describes your manuscript?
  ___X__ scholarly monograph;
  _____ a book that will be assigned to students in courses;
  ____ a reference book;
  ___X__ a book for a broad audience?

- Please provide a table of contents with one-paragraph descriptions of each chapter.

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1. Medical Countermeasures: How to Secure Populations Pharmaceutically – This chapter introduces the subject matter by outlining the growing role that governments are according to pharmaceutical defences in the formulation of their security policies. It begins with an overview of three major health-based threats driving this trend – pandemics, bioterrorism, and the spectre of an accidental laboratory release. The chapter goes on to trace the gradual but explicit incorporation of such ‘health security’ threats into the national security strategies of several governments around the world, including Europe, North America and Australia. The chapter shows that this concern with health-based threats has led to a concomitant turn in security policy towards the active development of new pharmaceutical defences for populations – a trend best captured in the rise of the notion of ‘medical countermeasures’. The chapter goes on to trace the evolution of this term, its growing significance in security policy, as well as the new initiatives, forms of funding and institutional formations that have arisen around the active development, acquisition, and stockpiling of new medical countermeasures. It also shows how what is happening through this medical countermeasures enterprise is distinct both from more routine public health activities traditionally carried out by
the state, as well as from older practices such as vaccination in terms of: 1) the
levels of scientific sophistication involved, 2) the much wider array of products
being developed, and (3) the shift from an underlying logic of prevention towards
one of preparedness. In the last section, the chapter shows that this
‘pharmaceuticalization’ of security, which has not been studied so far, raises a
number of vexing questions for governments, pharmaceutical companies, and
citizens alike. The chapter concludes by making the case that recent experience with
the antiviral medication Tamiflu represent a fascinating case study through which to
explore the complex politics and tensions around the pharmaceutical turn in
security policy. The chapter also sets out a new ‘life-cycle’ methodology for
beginning to analyse and explore these issues. This life-cycle method helps capture:
1) the distinctive phases in the development, acquisition, stockpiling, and use of
medical countermeasures; 2) the unique set of policy challenges and tensions that
emerge during each of these phases; and 3) the complex independencies that also
exist between these phases and that can effect the ultimate success of a new medical
countermeasure.

2. **Flu Fighting: Discovering a Virus’s Molecular Achilles Heel** – This chapter sets
out the nature and threat posed by pandemic flu in particular. It provides an
accessible overview of the differences between seasonal and pandemic flu, and why
the latter has once again become a matter of particular concern. The chapter recalls
the historical experiences of pandemics in the 20th century, and the likely impact of
a future pandemic in terms of loss of life, economic impact, and social disruption –
giving pandemic flu a critical security dimension. The chapter also illustrates how
flu viruses are constantly ‘moving targets’ and how this makes them a particularly
serious challenge to grapple with pharmaceutically. The chapter next turns to
explore the commercial opportunities inherent in developing medicines against
these different forms of influenza, and also introduces the reader to the scientific
advances in modern virology that made experts believe that a new class of
pharmaceutical defences against the influenza threat could be commercially
developed. The chapter concludes by identifying the business motivations and
economics underpinning new drug discovery, and what this implies for government
strategies seeking to incentivise the future commercial development of new medical
countermeasures.

3. **Why The Pill Always Wins: Gilead Sciences and the Birth of Tamiflu** – This
chapter looks at the first phase of Tamiflu’s life cycle by tracing its discovery and
early development by a small start-up biotechnology company called Gilead
Sciences in Foster City, California. Based on an extensive interview with the founder
of the company, Michael Riordan, the chapter traces the initial creation of the
company, and explores the drivers behind their decision to commercially invest in
the development of a new influenza antiviral. The chapter describes how the board
of the company included a number of politically influential individuals – such as
Donald Rumsfeld, who would later go on to become Secretary of Defense. The
chapter goes on to explore why – despite the fact that several different companies
were trying to develop this new class of pharmaceuticals – Gilead believed that they
would succeed where others had failed, and why their decision to focus on an orally
administered drug in the form of a capsule would later have huge commercial ramifications. The last part of the chapter discusses how, once the new chemical compound that would become Tamiflu was discovered, Gilead then still had to enter into complex negotiations with big pharmaceutical companies for the further commercial development of the drug – in this case agreeing a deal with the Swiss pharmaceutical giant Roche. The story of the birth of Tamiflu, the chapter concludes, yields a number of wider lessons for the quest to commercially develop new medical countermeasures in the 21st century, especially in terms of the kinds of government incentives that could work.

4. What a Difference a Day Makes: A Difficult Margin Call for Regulators – This chapter traces the course of Tamiflu (and its competitor product Relenza) through the next phase of its life cycle – the process of obtaining regulatory approval. Based on in-depth interviews carried out with the statistical reviewer of Tamiflu and Relenza at the Food and Drug Administration (FDA), the chapter shows the difficulties and tensions that can emerge when trying to secure regulatory approval for new medical countermeasures. The chapter discusses issues around the quality and interpretation of data about efficacy and safety, the relationship between major drug regulators around the world (USA, Canada, Europe, and Japan), and briefly reviews the regulatory approval processes for Tamiflu in those countries. The chapter goes on to expose the huge internal discontent at FDA around the approval of these two drugs, and reveals some of the detailed interactions between drug manufacturers and the regulatory agencies. The chapter also shows how Tamiflu received a pretty bumpy rise with European regulators – with reviewers not being impressed by the quality of the data. In so doing, the chapter shows that consideration of these regulatory issues is a critical aspect of any attempt to develop new medical countermeasures, and that there are also unique challenges when it comes to securing regulatory approval for new medical countermeasures.

5. Playing the Pandemic Card: Big Pharma as Partner and Lobbyist? This chapter begins to look at the complex political economy of drug development, focusing on the ways in which large pharmaceutical companies seek to influence decision-making at key regulatory bodies, such as the Food and Drug Administration (FDA). Based on interviews with former FDA officials, the chapter discusses some of the political pressures the agency faces. It then goes on to show how – specifically in the area of medical countermeasures – the pharmaceutical industry can also invoke global health security considerations as a way of making the case for approving particular drugs. The chapter is thus able to show how government regulators are placed in a particularly difficult situation in the area of health security – having to weigh up a complex set of commercial and political considerations. Indeed, when it comes to the quest to develop new medical countermeasures, governments have to balance their duty to hold industry to account in terms of producing effective and safe medicines, whilst at the same time also having to partner with industry in order to develop such new medical countermeasures.

6. On the Tightrope: Scrambling for a Viable Commercial Market – This chapter turns to the next stage of the pharmaceutical cycle after regulatory approval –
marketing. Specifically, the chapter explores the difficulties that companies can encounter when trying to find or develop wider commercial markets for new medical countermeasures. By tracing the path of Tamiflu after its regulatory approval, the chapter shows that there are several ways in which commercial sales of new medicines are controlled. In most countries, for example, there is a ban on direct-to-consumer marketing of medicines. Second, there is a growing international tendency to subject medicines to cost-benefit analysis. In the case of Tamiflu and Relenza, this led to recommendations by new organizations such as NICE in the UK against the more widespread use of the medications. Finally, the chapter also turns towards considering the unpredictable ways in which governments respond to risk, and how for many years they refused to stockpile such drugs. Here too the chapter begins to explore the power relations and strategies that characterise these interactions between government and industry, and the way the later seeks to work around some of these constraints on commercial sales. By this stage, the chapter concludes, Tamiflu looked like it was going to be a commercial failure.

7. **Stockpiling: Bird Flu (H5N1) and the Pandemic of Preparedness Planning** -
This chapter traces the transition of Tamiflu from a drug principally used for seasonal flu to a pandemic preparedness drug. The chapter describes the H5N1 ('bird flu') outbreaks of 1997 and 2003 that would prove transformative in terms of raising concerns about the spectre of a new flu pandemic based on the highly pathogenic H5N1 bird flu virus. The chapter goes on to trace how these events changed the political calculus around Tamiflu and led to the rapid rise of government stockpiling of Tamiflu. It reviews how governments approached meeting the cost of these stockpiles, and also which non-financial considerations played a role – such as the location of production facilities, how such products would be packaged, and so forth. Here the chapter also presents detailed information about the different sizes that governments chose for their stockpiles. The chapter then goes on to also describe the emergence of other forms of (non-government) stockpiling – such as corporate stockpiling for business continuity purposes, and also personal stockpiling via the Internet. The chapter concludes that experiences with Tamiflu suggest that the current strategy of going for a broad market strategy in the development of new medical countermeasures has severe limitations.

8. **Generic Antiflu: Roche, Developing Countries and the Perfect Patent Storm** -
This chapter looks at the question of how to make new medical countermeasures available for low- and middle-income countries, focusing in particular on the issue of patents and international patent protection. It shows how many governments, fearful of an immanent pandemic and unable to get access to Tamiflu, threatened the manufacturers with overriding their patents by issuing compulsory licences. The chapter also analyses the ways in which producers in middle-income countries tried to produce generic versions of Tamiflu to help those countries that could not get access to drugs, or that could not otherwise afford them. The chapter further explores the strategies that Roche and Gilead Sciences used to ensure that the patents were not breached, whilst at the same time trying to ensure wider access to Tamiflu. Finally, the chapter also looks at the role of international organizations
such as the World Health Organization in creating a global stockpile of last resort for low- and middle-income countries. These considerations point both to underlying technical issues of scaling up production in the context of a perceived imminent global health security threat; but they also point to wider international issues of justice and equitable access to medical countermeasures.

9. Ode to Tamiflu: Of Side Effects, Teenage Suicides and Corporate Liabilities – This chapter focuses on the complicated issue of drug side effects – which can emerge during the mass administration of a new drug. The chapter explores the serious concerns about Tamiflu side effects that emerged in Japan, where most of the world’s consumption of Tamiflu occurred. Public anxiety around the drug arose in Japan following a number of tragic deaths of children and teenagers who had taken Tamiflu, leading to fears about possible neuro-psychological side effects. The chapter reviews the emergence of these concerns, recounts some of the human tragedies involved, and also looks at how both government regulators and the manufacturer Roche tried to manage these issues. The chapter concludes by looking at some of the wider issues this also raises about the legal liabilities for companies involved in developing new medical countermeasures, and also how governments are trying to change this exposure to liabilities so as not to deter companies from becoming more closely involved in the development of new medical countermeasures.

10. The Data Access Backlash: Tamiflu, Complications and Hospitalizations – This chapter looks at the issue of access to the clinical trial data about new medical countermeasures. In the case of Tamiflu, a heated controversy emerged about the data underpinning the claims that it would actually be useful in a pandemic. The chapter thus looks initially at the way in which the manufacturers sought to position Tamiflu as a pandemic preparedness drug. It then traces how the data for such claims was generated, and why the data provoked so much controversy. It also recounts the story of how the internationally respected Cochrane Collaboration then began to challenge Roche to make all of the clinical trial data on Tamiflu public, and reviews the detailed ways in which public research sought to force both companies and regulators to make the data openly accessible. The chapter then goes on to look at the reactive strategies that companies and regulators have adopted in order to manage this issue about access to clinical trial data, as well as the commercial knowledge management strategies adopted to rebuild trust in Tamiflu as a medical countermeasure for pandemic preparedness purposes. These experiences point to wider issues of who can have access to critical information about the safety and efficacy of medical countermeasures.

11. Trusting Tamiflu: Scientists, Conflicts of Interest and Conspiracies – This chapter discusses the difficult issue of conflicts of interests and the role of scientists as intermediaries between public organizations and private companies. The chapter begins by looking more generally at the issue of conflicts of interest. It goes on to review how different public health organizations handle the issues of conflicts of interested differently, especially in terms of where the threshold for the existence of a conflict is set. The chapter further discusses the difficult balances that organization
need to strike between protecting themselves against conflicts of interest, whilst at the same time ensuring they have access to the best expertise. Many of these issues are then explore in more detail through looking at Tamiflu, and how the issues of conflicts of interest played out in that case. A particular focus is on the World Health Organization, where that has been controversy around the influence of industry-funded scientists on the development of advice. The chapter concludes by looking at the issue of trust more generally in the development of new medical countermeasures.

12. **Conclusion**: This chapter recounts the main themes to emerge from the Tamiflu story, locates these within the wider ‘pharmaceuticalization’ of security policy, and identifies key lessons for the future development of medical countermeasures.

**Detailed Description**

- In 200–300 words, describe the content of your manuscript, indicating its thesis, methodology, original contribution to the field, conclusions or findings, and intended audience. (This description will be read by the members of our Faculty Editorial Board, should your work be presented to them for consideration. If your work is accepted for publication, it may serve as the basis for catalogue and other advertising copy.) Please limit the description in this questionnaire to the length indicated. If your prospectus includes a longer description please attach and it will also be considered.

Can a pill strengthen national security? The suggestion may seem odd, but many states around the world have come to believe precisely that. Confronted with an array of health-based threats like pandemics, bioterrorism and emerging infectious diseases, governments are transforming their security policies to include the proactive development, acquisition, stockpiling and mass distribution of new pharmaceutical defences for their populations. What happens – politically, economically and socially – when governments try to secure their populations with pharmaceuticals? How do competing interests between states, pharmaceutical companies, regulators, and scientists play out in the quest to develop new ‘medical countermeasures’? And do citizens around the world ultimately stand to gain or lose from this pharmaceuticalization of security policy?

In *Pandemics, Pills and Politics* Stefan Elbe explores these questions through the first in-depth study of the world’s most prominent medical countermeasure: Tamiflu. Consumed by millions of people around the planet in the fight against pandemic flu, the antiviral medication has attracted scientific controversy about its effectiveness for pandemic preparedness; it has also provoked deep suspicions around undue commercial influence in government decision-making about creating national stockpiles; and it has even found itself at the centre of a protracted political standoff about who should have access to the data about the safety and effectiveness of medicines. Yet, in carefully tracing its fascinating twists and turns via a new ‘life-cycle’ methodology, Elbe shows that the story of Tamiflu also harbours much deeper lessons about the vexing international political, economic, legal, social and regulatory tensions that emerge as governments try to practice security pharmaceutically in the 21st century.